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SaeboGlove therapy for Upper limb disability and Severe Hand Impairment after stroke

A thesis by

Jen Alexander, BSc (Hons), MSc (distinction)

Submitted in fulfilment of the requirements for the Degree of Doctor of Philosophy (PhD)

To

The University of Glasgow

From

The Academic Section of Geriatric Medicine in

Institute of Cardiovascular and Medical Sciences,

Faculty of Medicine

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Abstract

Background:

Upper limb movement impairment affects around 80% of people experiencing a stroke acutely. Severe movement impairment including impaired active digital extension are particularly common, seriously hinder access to meaningful, self-directed, functional, guideline-based rehabilitation and predict poor recovery.

Upper limb movement impairment involves severe chronic disability and reduced quality of life for the majority affected and an evidence-based intervention to improve function when active digital extension is lacking has yet to be identified.

Non-robotic Dynamic Hand Orthoses (DHOs) are novel rehabilitation aids intended to assist digital extension and access to functional rehabilitation, yet little is known about their use or effectiveness in stroke rehabilitation.

The work in this thesis is informed by two intervention development activities conducted by the author preceding it. The activities include the design, delivery, and successful piloting of a complex intervention involving a dynamic hand orthosis (SaeboGlove) (The EMPOWER Help for Hands Programme) and a subsequent related patient and public involvement activity.

Methods & results:

The thesis followed the Medical Research Council framework for the development and evaluation of complex interventions and aimed to appraise and progress the existing evidence base on the use of DHOs to improve upper limb recovery after stroke.

Reviews to appraise the existing evidence: The research commenced with two literature reviews on the use of non-robotic DHOs in stroke rehabilitation; a scoping review to map existing research (Objective 1a) and a systematic review with meta-analysis of the randomised controlled trials (RCTs) identified in the scoping review to synthesise evidence on the effects of DHOs on upper limb

recovery (Objective 1b). Risk of bias in the systematic review was determined using The Cochrane risk of bias tool 1.0.

The scoping review identified 23 studies (n=229) in adult stroke survivors, all considered to have moderate to severe upper limb functional capacity. The evidence base on the use of non-robotic DHOs in stroke was lacking. There was (1) an absence of any systematic reviews, (2) a shortage of RCTs (only four small RCTs found) and (3) limited research in general with (i) adequate reporting of key information (participants, interventions, outcomes, and stakeholder involvement of any kind), (ii) high quality designs (e.g. multiple recruitment sites, adequate power to establish effectiveness, long term follow-up) and (iii) stroke survivors in the acute/subacute phase of recovery.

The systematic review and meta-analysis included the four RCTs (n=48) identified in the scoping review. The research gaps identified were consistent with those in the scoping review. No safety concerns were reported. Heterogeneity was low and a positive effect in favour of the use of non-robotic DHOs after stroke was observed in comparison to usual care, and usual care plus placebo regarding upper limb function and dexterity (primary outcomes) but not impairment (secondary outcome). However, a high risk of bias due, largely, to poor methodological reporting and a lack of high quality RCTs (e.g. with multiple recruitment sites, adequate power to establish effectiveness, long term follow-up) meant that there was uncertainty around the positive effects observed.

Evaluation to progress the existing evidence: The previously piloted EMPOWER intervention and study design underwent minor refinement and subsequent evaluation using learning gained from the development activities preceding this doctorate and the reviews conducted in it. The evaluation aimed to address identified gaps/limitations thereby progressing the existing evidence.

An outcome evaluation evaluated effects of the EMPOWER intervention on upper limb function using a pragmatic, multisite, parallel group RCT with blinded outcome assessment, adequate statistical power and long term follow up (Objective 2a). Adult stroke survivors from two Scottish Health Boards with upper limb disability and severe hand impairment including reduced or absent active digital extension, 7-60 days post stroke, were randomly assigned (1:1) via

a central online service to receive six weeks of (1) usual care plus the EMPOWER intervention (individualised self-directed, repetitive, functional-based practice involving a SaeboGlove) **(SaeboGlove group)**, or (2) usual care alone **(Usual Care group)**.

The primary outcome was upper limb function measured by the Action Research Arm Test (ARAT) 6 weeks post randomisation. Secondary outcomes were the ARAT at 14 weeks and upper extremity impairment (Fugl Meyer Upper Extremity Score – Motor Total and Hand subscore, Sensory Total), self-perceived habitual functional upper limb use (Motor Activity Log), upper limb pain intensity (Visual Analogue Scale), degree of new disability (modified Rankin Scale (mRS), self-reported performance in activities of daily living (Barthel Index) and self-reported quality of life / health status (Stroke Impact Scale (Total plus Hand subscore) and EuroQol (EQ-5D-5L)) at 6 and 14 weeks. Linear regression analyses were performed on an intention to treat basis, adjusting for baseline value of the outcome, study site, time since stroke (≤1 month, >1 month) and severity of upper limb function (ARAT 0-10, 11-28, 29-46). Results are reported as adjusted mean between group differences with 95% confidence intervals and p-values.

78 participants were randomised (39 per group) between November 2019 and October 2022 from six study sites in Scotland. At randomisation 63.0 (80.8%) suffered ischaemic stroke, 28 (35.9%) were female, mean (SD) for age was 63.3 years (13.2), time from stroke was 28.6 days (15.1), and ARAT Total score was 13.3 (11.8).

Although the Usual Care group reported spending more upper limb therapy time with a therapist over the intervention period (weeks 1-6), they reported spending much less time on upper limb therapy overall (with and without a therapist) during weeks 1-6 (*mean* and *median* of 8.7 hours and 12.0 hours less respectively) and 1-14 (*mean* and *median* total of 6.8 hours and 18.9 hours less).

Outcome completion was good at the 6 (91.0%) and 14 week (82.1%) visits. The EMPOWER intervention led to a significant improvement in the primary outcome of upper limb function (ARAT Total) at 6 weeks (15.8 versus 23.8 points respectively, adjusted between group difference 7.1 points, 95% CI 0.22 to 14,

p=0.047). ARAT Grasp, Pinch, and Grip subscores were also significantly improved at 6 weeks while the Gross subscore was not.

The change in the FMUE Motor Hand and Total scores were also both statistically significantly improved in the SaeboGlove compared to the Usual Care group at the 6 week visit. However, no other secondary outcome measures were statistically significant at any point in time. No safety concerns were identified for either intervention.

A qualitative process evaluation embedded within the RCT explored factors relating to support that moderate implementation of/engagement with the EMPOWER intervention using semi-structured interviews with a purposive sample of stroke survivor receiving it (n=7), their carers (n=5), and therapists (n=6). Thematic analysis and a generic inductive approach were used to identify frequent and noteworthy themes to inform future implementation/engagement (Objective 2b).

Four main themes influencing therapy implementation/engagement were identified: (1) Rehabilitation is hard work, (2) Stroke severity heightens the rehabilitation challenge and support required, (3) More meaningful upper limb therapy is needed/wanted, and (4) The EMPOWER intervention is acceptable and HELPs support engagement. Recommendations to optimise successful implementation/engagement therefore include: (1) adhering to the intended intervention implementation/engagement, (2) prior to therapy commencing ensuring that (i) staff have sufficient clinical expertise to establish realistic expectations in stroke survivors on what therapy engagement/recovery will involve and (ii) the work of rehabilitation is managed with tailored support based on individual needs/preferences, particularly when stroke symptoms are more severe, (3) utilising meaningful upper limb therapy tasks and objects, ideally before imminent discharge home, (4) continuing the EMPOWER programme without a dynamic hand orthosis when the six week intervention period ends to optimise continuity if functional upper limb rehabilitation goals are ongoing, and (5) on occasion, if clinically justified, extending the intervention by a couple of weeks.

Conclusions:

The existing research on non-robotic DHOs in stroke, with no systematic review and only four small RCTs, was limited and involved poor reporting and research designs. The SUSHI trial responded to these limitations and increases confidence in the systematic review findings. Individualised self-directed, repetitive, functional-based practice involving a SaeboGlove, started between 7 and 60 days after stroke in people with severe hand impairment including reduced/absent active digital extension led to significant improvements in ARAT score at 6 weeks after randomisation. The EMPOWER intervention was felt to improve the physical and emotional support to engage in upper limb therapy compared to usual care therapy. Stroke survivors receiving the EMPOWER intervention also recorded higher upper limb therapy engagement despite receiving less therapist input. Thus, the EMPOWER Help for Hands programme appears to be a more efficient intervention in terms of recovery time, therapist time (therapy input) and outcome. The improved rehabilitation support provided likely explains the increased upper limb therapy engagement and outcomes observed, novel findings in this challenging, hard to reach group.

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Acknowledgement

I would like to thank my supervisory team Professor Jesse Dawson, Professor Peter Langhorne, and Professor Frederike van Wijck for all their expertise, support, and encouragement. I also wish to thank Professor Lisa Kidd and Professor Alex McConnachie for their specialist input and oversight on qualitative and mixed methods research and statistical analysis.

I thank Chest Heart and Stroke Scotland and the Chief Scientist Office for funding this work and members of the Stroke Research Team in the Queen Elizabeth University Hospital in NHS Greater Glasgow & Clyde for their help with data entry/management (Ozzy Dincarslan) and baseline and outcome assessments (Elizabeth Colquhoun, and Wendy Jackson).

I would like to acknowledge the Chief Investigator (Professor Jesse Dawson, NHS Greater Glasgow & Clyde, Queen Elizabeth University Hospital), Principal Investigators at recruiting sites (NHS Greater Glasgow & Clyde: Professor Peter Langhorne / Dr Terry Quinn (Glasgow Royal Infirmary), Dr Christine McAlpine (Stobhill Hospital), Dr Felicity Boyce (Royal Alexandra Hospital); NHS Lanarkshire: Dr Mark Barber (University Hospitals Monklands, Hairmyres and Wishaw)), members of The Trial Steering Committee (my supervisory team, Dr Terry Quinn, Dr Niall Hughes and Dr Else Charlotte Sandset) and The Patient and Carer Research Advisory Group (Steven and Angela Griffin, Pauline and Charlie Ferguson) for their support and help with managing the study.

I would like to thank Professor Helen Rodgers for advising me to remember to enjoy the process at the outset. This helped so much (a lot of the time).

Special thanks go to the clinical teams and Stroke Research Network within participating sites for joining me on this journey with continued enthusiasm. Your help with recruitment, recording usual care therapy and supporting the therapy during a pandemic was amazing. This study simply could not have taken place without you.

The biggest thanks go to my fantastic husband Martijn who supported me throughout, kept me sane and encouraged me to notice and celebrate every

small achievement along the way, often with a glass of prosecco. You are one of a kind.

Lastly, I would like to acknowledge all the patients, carers and therapists who participated and every stroke patient I have had the pleasure to work with, learn from and be part of your recovery journey. You inspired this project, fueled this mission and it is you that this thesis is dedicated to.

Author's Declaration

The research reported in this thesis was performed in the academic section of Geriatric Medicine in the Institute of Cardiovascular & Medical Sciences, University of Glasgow based at the Queen Elizabeth University Hospital when I was a postgraduate research fellow with Chest Heart and Stroke Scotland.

I declare that the ideas underpinning the work in this thesis are mine. The design of the protocols described, coordination of research activities, delivery of the EMPOWER intervention and write up were conducted by me with guidance from my supervisory team, principally Professor Jesse Dawson from the University of Glasgow. Additionally, guidance on the literature search strategies in Chapter 2, statistical analysis plan in Chapter 4 and implementation science and qualitative research in Chapter 5 were provided by Catriona Denoon (NHS Greater Glasgow and Clyde), Professor Alex McConnachie (University of Glasgow) and Professor Lisa Kidd (Glasgow Caledonian University) respectively.

Professor Jesse Dawson and Professor Peter Langhorne were co-reviewers in the systematic review and meta-analysis in Chapter 2.

For the RCT in Chapter 4 potential participants were identified to me by clinical teams in recruiting sites along with Ruth Graham and Derek Esson (SRN research nurses at Glasgow royal Infirmary and University Hospital Monklands respectively), screening of participants was performed by me with the help from Elizabeth Colquhoun (research nurse) and Wendy Jackson (research support worker) at the coordinating site (Queen Elizabeth University Hospital), outcomes were scored by Elizabeth Colquhoun and Wendy Jackson and data entry and management was performed by Ozlem Dincarslan (study administrator, Queen Elizabeth University Hospital). The Clinical Trials Unit in the University of Glasgow (Robertson Centre for Biostatistics) developed and maintained the central online randomisation service and analysed this data.

For the qualitative study in Chapter 5 participants were sampled by Professor Jesse Dawson and recruitment, interviews, transcription, and co-analysis of the first 10 of the 18 interviews was performed by Chin Soong (medical student).

Professor Lisa Kidd, Professor Jesse Dawson, and Chin Soong were co-reviewers of the data and the final themes/subthemes and findings.

All other work was completed by me.

The original research completed for this thesis was performed in line with the Declaration of Helsinki and regulatory guidance from The Medicines and Healthcare products Regulatory Agency (MHRA) for CE marked medical devices. Consent for the RCT in Chapter 4 and the implementation science and qualitative research in Chapter 5 were gained according to the requirements of the West of Scotland Research Ethics Committee. All data were managed in compliance with the Data Protections Act and the General Data Protection Regulation.

Abbreviations

ADL	Activities of daily living
ADE	Adverse Device Event
ARAT	Action Research Arm Test
BBT	Box and Block Test
BI	Barthel Index
CIMT	Constraint Induced Movement Therapy
CONSORT	Consolidated Standards of Reporting Trials
COREQ	Consolidated criteria for reporting qualitative research interviews and focus groups
DHO	Dynamic Hand Orthosis
DHOs	Dynamic Hand Orthoses
EQ-5D-5L	EuroQol with 5 Dimensions and 5 Levels
FMUE	Fugl-Meyer Upper Extremity score
GP	General Practitioner
GRASP	Graded Repetitive Arm Supplementary Programme
ICF	International Classification of Functioning, Disability, and Health
MAL	Motor Activity Log
MAS	Modified Ashworth Scale
MCID	Minimum Clinically Important Difference
MHRA	The Medicines and Healthcare products Regulatory Agency
MMSE	Mini Mental State Examination
MRC	Medical Research Council
mRS	modified Rankin Scale
PIS	Patient Information Sheet
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analysis
PRISMA-ScR	Preferred Reporting Items for Systematic reviews and Meta-Analysis for Scoping Reviews
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SADE	Serious Adverse Device Event
SIS	Stroke Impact Scale
SRN	Stroke Research Network
SUSHI	SaeboGlove therapy for Upper limb disability and Severe Hand Impairment after stroke
TIDieR	Template for Intervention Description and Replication
T-SET	The SaeboGlove Evaluation Trial
USADE	Unexpected Serious Adverse Device Event
VAS	Visual Analogue Scale
WHO	World Health Organization

List of publications

Chapter 2

Alexander, J., Dawson, J. and Langhorne, P. (2021a) 'Dynamic hand orthoses for the recovery of hand and arm function in adults after stroke: A systematic review and meta-analysis of randomised controlled trials', *Top Stroke Rehabil*, 2021/02/02, 1-11, available: http://dx.doi.org/10.1080/10749357.2021.1878669.

Chapter 4

Alexander, J., Langhorne, P., Kidd, L., Wu, O., McConnachie, A., van Wijck, F. and Dawson, J. (2021b) 'SaeboGlove therapy for upper limb disability and severe hand impairment after stroke (SUSHI): Study protocol for a randomised controlled trial', *European stroke journal*, 23969873211036586, available: http://dx.doi.org/10.1177/23969873211036586.

List of presentations

Chapters 1 and 3

Alexander, J. (2020) ‘Rationale and design of the SUSHI trial’, Oral presentation online to the Scottish Stroke Care Audit Group meeting.

Alexander, J. (2020) ‘Rationale and design of the SUSHI trial’, Oral presentation online to the Living with Stroke and other Long Term Neurological Conditions research group from the Nursing, Midwifery and Allied Health Professions Research Unit.

Chapters 1, 4 and 5

Alexander, J. (2021) ‘SUSHI Site Initiation Visit - Overview (Part 1)’, Video presentation recorded on Zoom.

Chapter 4

Alexander, J. (2021) ‘SUSHI Site Initiation Visit - Screening (Part 2)’, Video presentation recorded on Zoom.

Alexander, J. (2021) ‘SUSHI Site Initiation Visit - Assessments (Part 3)’, Video presentation recorded on Zoom.

Alexander, J. (2021) ‘SUSHI Site Initiation Visit - SaeboGlove Therapy (Part 4)’, Video presentation recorded on Zoom.

Alexander, J. (2021) ‘Three scoring training examples for SUSHI outcome assessments: the ARAT, FMUE, mRS, Barthel, EQ5D5L, MAL and VAS’, Video presentation recorded on Zoom.

Chapter 1

Introduction

1 Chapter 1 Introduction

This thesis will focus on aspects of upper limb recovery following stroke.

This introductory chapter will provide a narrative review that highlights the scale and nature of stroke, and key mechanisms contributing to stroke recovery. With this initial context, the magnitude and gravity of post stroke upper limb problems will then be reviewed along with key challenges currently encompassing upper limb recovery, including a physical, or motor, perspective. Particular attention will be placed on challenges encountered by those who experience severe upper limb motor impairment.

A programme of original research that aims to address some of these challenges will then be proposed. The aims and objectives of this programme and an explanation of how each chapter will fulfil them will then be provided.

1.1 Stroke statistics

1.1.1 Definition

The World Health Organization (WHO) defines stroke as:

> "rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin" (Hatano 1976, p.541).

1.1.2 Types

Commonly two major stroke categories are described depending on the nature of the vascular event taking place, ischaemic or haemorrhagic (Stroke Association 2018).

Ischaemic strokes are by far the most common, and account for approximately 87% of strokes in the UK (King's College London 2022). They occur when an artery or small blood vessel deep in the brain becomes blocked due to the formation of a blood clot or other matter (e.g. fatty deposit) in the circulatory

system (Feigin *et al*. 2003; Ovbiagele and Nguyen-Huynh 2011; Stroke Association 2018; Intercollegiate Stroke Working Party 2023).

In contrast, haemorrhagic strokes account for only around 13% of UK strokes (King's College London 2022). They occur when a blood vessel bursts either within the brain (intracerebral haemorrhage) or on the surface of the brain (subarachnoid haemorrhage) (Feigin *et al*. 2003; Ovbiagele and Nguyen-Huynh 2011; Stroke Association 2018; Intercollegiate Stroke Working Party 2023).

1.1.3 Aetiology & major risk factors

When an ischaemic or haemorrhagic stroke occurs, the blood supplying the brain is disrupted causing brain cell death and ultimately brain damage (Sekerdag *et al*. 2018). The specific location and volume of brain damage determines the extent and range of the neurological signs, symptoms and disability that consequently ensue (Beloosesky *et al*. 1995; Alexander *et al*. 2012; Vogt *et al*. 2012).

Major risk factors for stroke include personal (increasing age, female sex (incidence: global: 53% female versus 47% male (Feigin *et al*. 2022) which contrasts Scotland: 48% female versus 52% male (Public Health Scotland 2022)), socioeconomic (poverty, health care inequality, education and employment), medical (Ischaemic heart disease, atrial fibrillation, diabetes mellitus, hyperlipidaemia, hypertension and obesity), lifestyle (smoking, a poor diet, lack of physical activity, and alcohol consumption), geographical (residing in Eastern Europe, Asia, Africa and the Caribbean (Feigin *et al*. 2017; Stroke Association 2018; American Heart Association 2019)) and environmental factors (air pollution) factors (O'Donnell *et al*. 2010; Kernan *et al*. 2014; Shah *et al*. 2015; Feigin *et al*. 2017; Bridgwood *et al*. 2018; Stroke Association 2018) .

1.1.4 Health & socioeconomic resource burden – Population

Stroke is a medical condition with a high incidence, the second and third leading cause of death and disability respectively globally, and a considerable socioeconomic burden to public health (Feigin *et al*. 2022).

1.1.4.1 Health burden - Population

Globally 12.2 Million new strokes occur every year (Feigin *et al*. 2022), with corresponding figures in the UK and Scotland exceeding 100,000 (Stroke Association 2018; Royal College of Physicians 2019) and 15,000 (NHS National Services Scotland 2022) respectively. This equates to a lifetime stroke risk globally of around 25% (Feigin *et al*. 2022).

Around 15% of stroke victims die in hospital in the UK (National Institute for Health and Care Excellence 2023) and stroke accounts for 11.2% of deaths globally (World Health Organisation 2018). The majority survive but stroke causes more disabilities than any other condition with around 85% of stoke survivors requiring assistance with everyday activities, such as washing, dressing, cooking and feeding, when they leave hospital (Stroke Association 2018; Royal College of Physicians 2019) and around a third remaining dependent on others for basic activities of daily living (Katan and Luft 2018; Sennfält *et al*. 2019). Thus, increased levels of permanent disability, rather than death, present the greatest stroke health burden (Katan and Luft 2018).

Improvements in medical care in high income countries over the past decade have been accompanied by a considerable decrease in stroke incidence, mortality, and morbidity/disability (Feigin *et al*. 2022). However, the global absolute number of incident and prevalent strokes, related mortality and morbidity continues to rise due to a combination of medical advances, rise in stroke lifestyle risk factors and an ageing and growing population (Feigin *et al*. 2022). In the UK alone, expert projections in 2015 indicate that the incidence and prevalence of first-time stroke in people over the age of 45 years are likely to rise by 59% and 123% respectively by 2035 (Stroke Association 2017). Thus, the need to identify strategies that reduce permanent disability and dependency is greater than ever.

1.1.4.2 Socioeconomic burden - Population

The annual societal cost of stroke in the UK in 2015 was £26 billion, with a cost of approximately £3.4 billion to the NHS, £1.6 billion due to productivity losses and the majority, £21 billion, being attributed to the value of care (formal social care: £5.2 billion, unpaid, informal care: £15.8 billion) (Stroke Association 2017). Due to rising numbers of older people, increasing care costs as a result of inflation and anticipated improvements in stroke survival rates, annual costs are projected to triple over the next 20 years, thereby highlighting the high socioeconomic impact of post stroke disability (Stroke Association 2017).

1.1.5 Health and socioeconomic resource burden – Individual

1.1.5.1 Health burden – Individual

On an individual level, stroke is usually an unexpected and potentially catastrophic life event that can affect every aspect of life. The WHO's International Classification of Functioning, Disability, and Health (ICF) is a biopsychosocial framework for the classification of health and health-related concepts (World Health Organisation 2001) (Figure 1). It recognizes that disease can affect an individual by causing impairment of body functions and structures, restricting a person's ability to perform everyday activities, and limiting their participation in everyday life situations. Additionally, the ICF incorporates personal (e.g. age, coping style, education) and environmental (e.g. physical environment, attitudes, services, technology, support) factors, recognizing the potential influence they can have on an individual's ability to function in society.

Figure 1: International Classification of Functioning, Disability and Health

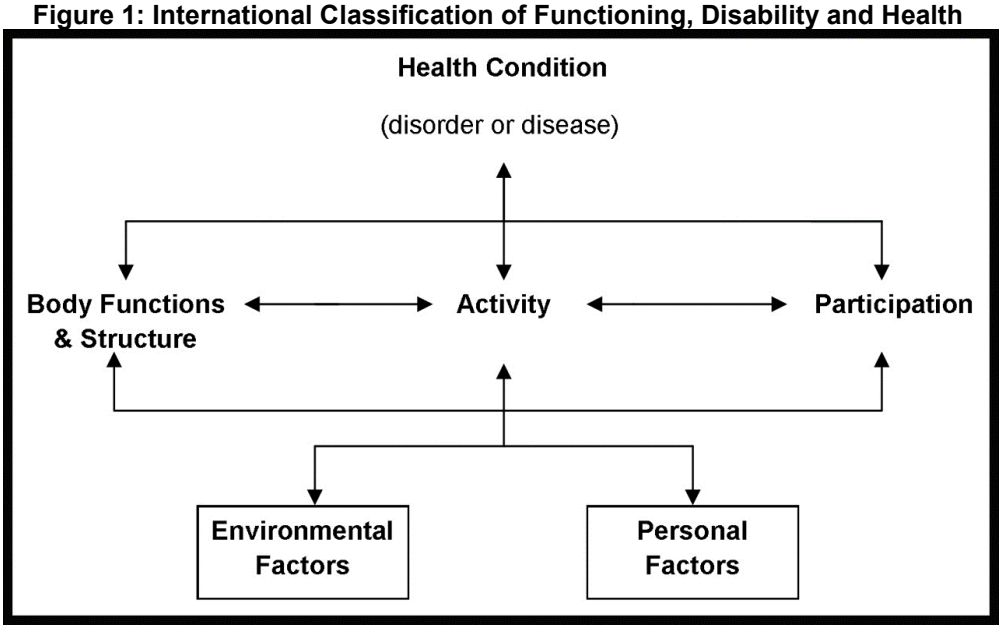


Diagram representing the potential problems encountered, body function and structure, activity, and participation, because of a health condition along with their interaction with each other, and with environmental and personal factors. Taken from World Health Organisation, 2001, available at: International Classification of Functioning, Disability and Health (ICF) (who.int) under a Creative Commons CC BY 3.0. Full Terms at: Creative Commons — Attribution-NonCommercial-ShareAlike 3.0 IGO — CC BY-NC-SA 3.0 IGO

Research by Lawrence et al. (2001) involving a large (n=1259), south London multi-ethnic population of first-ever stroke survivors suggests that most survivors experience a minimum of six to 10 acute impairments after a stroke (Lawrence *et al*. 2001). The post stroke prevalence of acute impairments at the time of

maximum neurological deficit observed in this research ranged in prevalence from 7.23-77.4% and identified upper limb motor impairment to be the most prevalent (Lawrence *et al*. 2001).

Thus, stroke is a heterogeneous condition as impairments experienced typically coexist and are wide-ranging. They also frequently persist and negatively influence functional ability (Kwakkel 2004; Levin *et al*. 2009; Nijland *et al*. 2010b), participation in meaningful life situations and overall health status (Figure 1) (World Health Organisation 2001; McKevitt *et al*. 2011). For example, research suggests that around 20-30% of stroke survivors do not recover walking ability (Dean and Mackey 1992; Warlow *et al*. 2003), 50% have no upper limb function at six months after stroke (Broeks *et al*. 1999) and 50-60% experienced problems managing fatigue (McKevitt *et al*. 2011). Thus, it is unsurprising that 20-75% feel unable to return to work (Treger *et al*. 2007) and 67% report negative changes to the type and frequency of leisure activities and interests they engage in (McKevitt *et al*. 2011).

1.1.5.2 Socioeconomic burden – Individual

The long-term sequelae of stroke often have a considerable personal financial impact on stroke survivors and their carers, contributing to the overall distress experienced. One in three survivors report that the cost of living rises as a consequence of their stroke (Stroke Association 2018) and people of working age are two to three times more likely to be unemployed eight years later (Maaijwee *et al*. 2014). The cost of living varies, rising with stroke severity (Luengo-Fernandez *et al*. 2009). In the UK, the average economic burden borne by a family of a stroke survivor is approximately £22,377 (Stroke Association 2018).

1.2 Stroke recovery & rehabilitation

The overall recovery experienced after stroke is a multidimensional process that depends on the location and volume of the initial brain damage that occurred (Beloosesky *et al*. 1995; Vogt *et al*. 2012) the subsequent post-stroke difficulties encountered (Langhorne), socioeconomic factors (Feigin *et al*. 2022), intervention selection and implementation (Skivington *et al*. 2021) and the extent of the neurological recovery that follows (Cramer 2018).

1.2.1 Overview of neural repair and recovery

1.2.1.1 Neural repair

Neurological recovery is a complex process involving neural repair. Neural repair has been defined by Cramer (2018) as:

> "…restoring the structure or function of the central nervous system after injury…" (Cramer 2018, p.57)

When a stroke occurs, a series of complex growth-related events are triggered to optimise neural repair (Marlier *et al*. 2015). Three main stages of reparation are involved and are shown in Figure 2.

Figure 2: Stages of Neural Repair after stroke

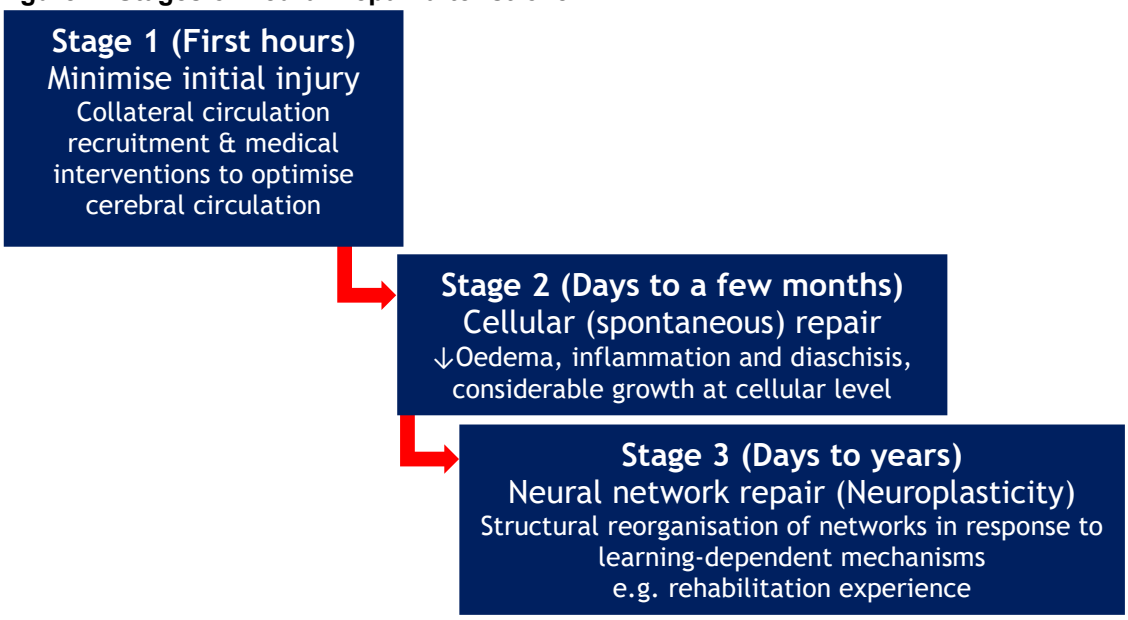


Diagram representing the three main stages of neural repair with approximate timelines after stroke. Adapted from Cramer et al. 2018, available at: Treatments to Promote Neural Repair after Stroke (j-stroke.org) under a Creative Commons CC BY 3.0. Full Terms at: Creative Commons — Attribution-NonCommercial 3.0 Unported — CC BY-NC 3.0

These stages are (1) minimising the initial injury via circulatory optimization within hours of stroke onset (e.g. through collateral circulation recruitment and medical interventions) (Nishijima *et al.* 2015; Cramer 2018), (2) cellular, or spontaneous, repair occurring within days to a few months (e.g. reduced oedema and cellular growth) (Kwakkel *et al.* 2006; Marlier *et al.* 2015) and (3) neuroplasticity, a process where neural networks are repaired over days to years in response to learning-dependent mechanisms (e.g. rehabilitation experience), to optimize *behavioural performance* (e.g. functional recovery) (Figure 3) (Wieloch and Nikolich 2006; Kleim and Jones 2008).

Figure 3: Rehabilitation, neuroplasticity, and recovery

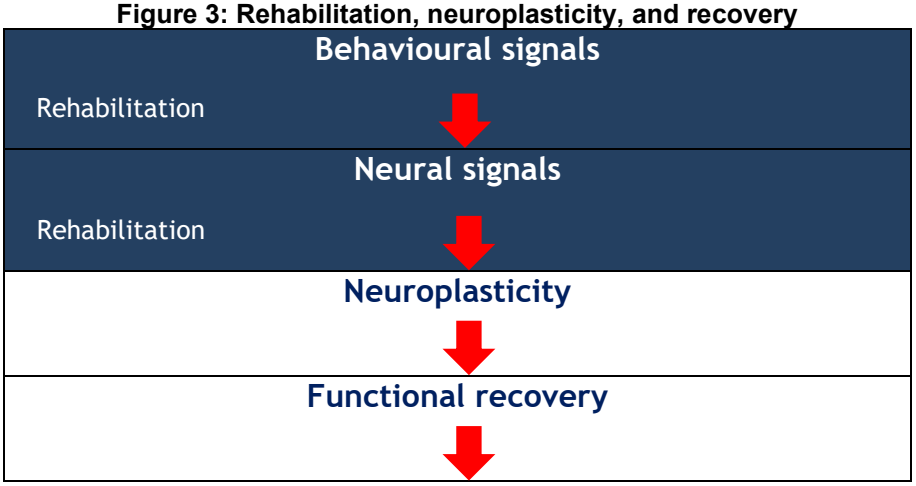


Diagram illustrating that rehabilitation can exploit the neuroplasticity required to generate functional improvement by generating behavioural and neural signals. Adapted from Kleim 2012 (Kleim 2012), available at: Kleim.handout.note (snapuptickets.com) with copyright permission from author.

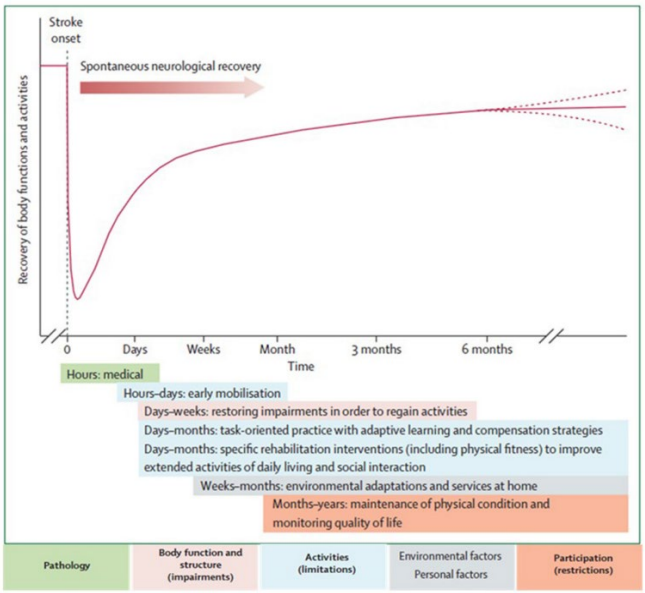
The neuroplasticity that occurs after stroke is often attributed to a combination of two mechanisms. These are (1) true recovery where the disturbed networks, movement patterns/frequencies and functional tasks are restored, and (2) compensatory-based recovery where alternative networks and movement patterns/frequencies, often relying on body parts or aids not previously used, are utilised to accomplish function (World Health Organisation 2001; Levin *et al.* 2009; Bernhardt *et al.* 2017; Hylin *et al.* 2017)

Standardised recovery time points based on these stages of recovery have been defined and recommended for use in stroke recovery research to aid data comparisons and are used throughout this thesis (acute: 1-7 days, early subacute: 7 days to 3 months, late subacute: 3-6 months, chronic >6 month (Bernhardt *et al.* 2017; Kwakkel *et al.* 2017)).

1.2.1.2 Typical recovery pattern

Recovery patterns and outcomes vary after stroke on an individual level. However, prospective observational studies have demonstrated that a non-linear logarithmic trajectory is typically observed where the majority of neurological recovery occurs naturally within the first three months (Figure 4) (Kwakkel *et al.* 2006; Langhorne *et al.* 2011).

Figure 4: Hypothetical pattern of recovery after stroke with timing of intervention strategies



The neurological recovery after stroke displays a nonlinear, logarithmic pattern where the majority of neurological recovery occurs spontaneously (i.e. naturally) within the first three months. Intervention strategies (e.g. medical, rehabilitative, compensatory) used to support stroke recovery are shown with approximate timing and are colour coded to match the ICF categories in Figure 1. Reproduced with permission of Elsevier Science & Technology Journals, from: Langhorne, P., Bernhardt, J. and Kwakkel, G. (2011) 'Stroke rehabilitation', *The Lancet*, 377(9778), 1693-1702, http://dx.doi.org/https://doi.org/10.1016/S0140-6736(11)60325-5, permission conveyed through Copyright Clearance Center, Inc.

Recent systematic review evidence demonstrates an enhanced response to rehabilitation that extends beyond one year (Ballester *et al.* 2019), demonstrating that recovery in the longer term after stroke is clearly possible. However, the non-linear logarithmic pattern of recovery observed has led to widespread acceptance that a critical window of improved neuroplasticity occurs within the first three to six months after stroke (Cramer 2018; Ballester *et al.* 2019) when the effectiveness of rehabilitation may be heightened and exploited to optimise recovery (Nakayama *et al.* 1994; Kwakkel *et al.* 2006). Thus, it is possible that rehabilitation in the acute to subacute phases of recovery may be most beneficial.

1.2.1.3 Overview of key measures utilised to optimise neural repair and recovery

Following a stroke there are many restorative measures undertaken to optimise neural repair and outcomes for stroke survivors. Key measures associated with favourable recovery include:

1. The acute medical management of stroke using thrombolysis (Wardlaw *et al*. 2014; Cramer 2018) (accessed by around 10% of all people experiencing a stroke in the UK (King's College London 2022)) and thrombectomy (Goyal *et al*. 2016) (not routinely available in the UK) (King's College London 2022; Public Health Scotland 2022)). However, these are interventions that can only be delivered by specialists, can only be utilised for ischaemic strokes and are time critical meaning that many people do not reach hospital in time (<first few hours of onset) to be eligible to receive them (Cramer 2018).

2. Managing a stroke service that utilises:

    - Stroke unit care (e.g. specialist expertise, training for staff, carers, and patients, coordinated Multidisciplinary team (MDT) rehabilitation, routine carer involvement) (Stroke Unit Trialists' Collaboration 1997; Stroke Unit Trialists 2013),

    - Early supported discharge for those with mild to moderate disability (specialist care and rehabilitation by a MDT without delay on discharge and at an intensity equivalent to the inpatient setting (Langhorne and Baylan 2017), and

    - Delivering a bundle of evidence-based healthcare practices together (e.g. a brain scan, swallow assessment on the day of hospital admission, admission to a stroke unit and aspirin commenced within one day of hospital admission (Public Health Scotland 2022)), and

3. Stroke rehabilitation, the primary strategy to drive neurological recovery after the initial brain damage is established (Cramer 2018)

The third measure is central to the original work in this thesis and will now be discussed in further detail.

1.2.2 Stroke rehabilitation in general

1.2.2.1 Principles

Definition of rehabilitation

The Chartered Society of Physiotherapy's definition of rehabilitation is:

> "Rehabilitation is about enabling and supporting individuals to recover or adjust, to achieve their full potential and to live as full and active lives as possible." (Chartered Society of Physiotherapy 2020)

Thus, from a physical perspective, rehabilitation is a process that aims to minimise the impact of stroke on an individual to optimise their quality of life either through recovering lost movement(s)/movement control (motor recovery) or adjusting to it using easier adapted movement(s), typically excess movement of unaffected body parts (motor compensation) (Levin *et al*. 2009).

The rehabilitation process

Multidisciplinary team: The wide-ranging problems encountered following a stroke mean that rehabilitation typically involves expert clinicians from multiple disciplines. Core members of the multidisciplinary rehabilitation team include nurses, doctors, physiotherapists, occupational therapists, speech and language therapists and social workers (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2023).

Patient-centred approach with carer involvement: A patient-centred approach to care is a UK government priority (Department of Health 2005a) and is advocated in clinical guidelines (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2023). Actively involving stroke survivors in the decision-making process during rehabilitation is associated with satisfying their overall health service needs (H.K. Kristensen *et al*. 2016). Consistent with this, the provision of therapy tasks by therapists that are motivating and align will a stroke survivors individual recovery goals is perceived by stroke survivors to be key to support therapy engagement (Luker *et al*. 2015; Meads *et al*. 2020).

Similarly, routine involvement of carers in therapy, a component of stroke unit care (Stroke Unit Trialists' Collaboration 1997), is also perceived by stroke survivors to be important to successfully support their therapy engagement (Gallacher *et al*. 2013; Gallacher *et al*. 2018; Meads *et al*. 2020) and is considered to be a key factor contributing to positive outcomes (Stroke Unit Trialists' Collaboration 1997).

Thus, to optimise recovery effective rehabilitation should include the active involvement of patients and carers in conjunction with expert clinicians.

Cyclical rehabilitation process to support therapy engagement/goal achievement: Rehabilitation encompasses a cyclical process involving: (1) the assessment of individual needs/abilities, (2) goal setting and problem solving to try to achieve meaningful recovery for that individual and (3) an intervention to successfully support goal achievement based on their individual needs/abilities (Langhorne *et al*. 2011).

Optimising neuroplasticity and recovery: Research has identified some fundamental principles, a set of critical rehabilitation behaviours/experiences recommended to help generate the neural signals required to drive, or exploit, the neuroplasticity required to optimise functional recovery (Kleim and Jones 2008; Maier *et al*. 2019). These principles are described in Table 1 (overleaf) along with examples of their potential implications for rehabilitation after stroke.

1.2.2.2 Clinical recommendations

Content

To optimise motor recovery after stroke, rehabilitation content is important and should include exercise involving motor (movement) training and the practice of everyday life tasks that are goal-directed i.e. desired (functional-based training/practice) (Veerbeek *et al*. 2014a; Teasell *et al*. 2020; Intercollegiate Stroke Working Party 2023). To support this content and an individual's response to it use of assistive rehabilitation technology, and priming techniques (da Silva *et al*. 2020), such as the repetitive practice of non-goal directed movements, that are likely to enhance the performance of functional-based goal-directed

Table 1: Stroke rehabilitation: Principles to optimise neuroplasticity & recovery

Principle	Description Example of potential rehabilitation implication
1. Use it or lose it	Neural circuits supporting the performance of a particular task degrade if they are not active for an extended time period (Pascual *et al*. 1998) e.g. Only patients successfully enabled to regain sufficient skill in a rehabilitation setting to successfully utilize it in a real-life environment, are likely to retain such skill when formal rehabilitation practice stops.
2. Use it and improve It	Neural circuits supporting the performance of a particular task develop and may lead to enhanced function if that task is trained (Nudo and Milliken 1996; Kleim *et al*. 1998) e.g. Training that targets recovery of a desired task may lead to improvement in the function of that task.
3-5. Salience, repetition, and intensity matters	Neuroplasticity is enhanced when tasks trained are salient (i.e. meaningful/motivating) (Weinberger 2004) and practiced with sufficient repetition (Kleim *et al*. 2003; French *et al*. 2016), and intensity (e.g. duration, frequency) (Kleim *et al*. 2002; Luke *et al*. 2004) e.g. Training must engage stroke survivors in tasks that are meaningful to them/their life and be of a sufficient quantity.
6. Specificity	The neuroplasticity that occurs reflects the specific nature of the training performed (Perez *et al*. 2004; Boyd *et al*. 2010) e.g. Typically training is most effective when it is specifically designed to regain the task desired i.e. training strength alone is likely to improve strength, not performance of an everyday functional task.
7. Time Matters	Neuroplasticity and related recovery appear to be time sensitive, being enhanced when training is performed acutely (Biernaskie *et al*. 2004; Norrie *et al*. 2005) e.g. Training that occurs early/without delay may enhance recovery.
8. Transference	When two or more tasks share similar motor components or contexts (identical elements theory) and/or similar cognitive processing activity (transfer-appropriate processing theory) plasticity, or positive training effects, that occur from the practice of one task specifically trained may transfer to another that has not (Woodworth and Thorndike 1901; Schmidt and Lee 2005; Aune *et al*. 2017) e.g. Training of a task such as grasping and eating an apple may aid the acquisition of tasks involving similar movement components such as grasping and turning a doorknob, thereby offering greater training benefits.
9. Interference	Plasticity in response to one training experience/task may negatively impede the acquisition of another task (Cantarero *et al*. 2013) e.g. Easier compensatory movement strategies adopted to enable the completion of a reach task such as hip flexion to move the hand forward to grasp an object first needs to be untrained if true upper limb recovery (e.g. elbow extension) is to take place.
10. Age Matters	Training-induced plasticity occurs more readily in younger brains (van Praag *et al*. 2005) e.g. Training is most effective when stroke survivors are younger.

Adapted from Kleim and Jones 2008, available at: Principles of experience-dependent neural plasticity: implications for rehabilitation after brain damage - PubMed (nih.gov), source material is copyrighted, and is used with the permission of the American Speech-Language-Hearing Association (ASHA)

activities are also advocated (Veerbeek *et al*. 2014b; Intercollegiate Stroke Working Party 2023).

Dose

In the context of rehabilitation, dose involves the prescription of a particular amount or intensity of a rehabilitation activity (e.g. number of movement repetitions or active minutes of therapy), at a particular frequency, over a specific time period (Lang *et al*. 2015). To produce a desired effect, knowledge of an interventions therapeutic dose, active ingredient and mechanism of action are required. While physical rehabilitation is known to be an active ingredient in post-stroke recovery (Pollock *et al*. 2014a) and neuroplasticity is accepted as being a predominant mechanism involved (Wieloch and Nikolich 2006; Kleim and Jones 2008), knowledge of the relative effectiveness of different physical interventions or their individual components, the specific mechanism of action, (Pollock *et al*. 2014a; Lang *et al*. 2015) and their time course and half-life (Lang *et al*. 2015) is not. In the absence of such essential data, the current evidence-base underpinning dosing recommendations is limited (Clark *et al*. 2017).

A recent meta-analysis involving 37 randomised control trials of non-dose matched rehabilitation interventions, utilising different types of interventions and outcomes offers good quality evidence that scheduled therapy time is a robust predictor of motor recovery regardless of whether patients are months or years poststroke (0.003 to 5.38 years) (Lohse *et al*. 2014). Thus, there is sound evidence that an increased therapy dose improves stroke outcomes. However, evidence to offer more specific guidance on the minimum therapy dose required is lacking (Kwakkel 2004; Lohse *et al*. 2014). Consequently, current recommendations are largely based on debates and decisions made by guideline working groups using limited data and anticipated feasibility (Intercollegiate Stroke Working Party 2023).

A Cochrane review on physical interventions involving 10,401 stroke survivors from 96 studies identified significant benefit from a rehabilitation dose of 30-60 minutes, five to seven days per week compared to no treatment, or treatment involving usual care or attention control (Pollock *et al*. 2014a). This review finding was consistent with National UK Clinical Guideline for Stroke which until recently recommended that stroke survivors should receive a minimum of 45

minutes of each therapy discipline daily (e.g. occupational therapy, physiotherapy etc) for as long as they are able to participate and benefit from it (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2016).

However, a new guideline shared by the four nations of the UK, and the Republic of Ireland has recently increased this recommendation (Intercollegiate Stroke Working Party 2023). It recommends that people with motor recovery goals engaging in stroke rehabilitation should receive ≥3 hours of multidisciplinary therapy a day (exercise, motor retraining and/or functional practice) delivered or supervised by a therapist/therapy support worker (Intercollegiate Stroke Working Party 2023) at least 5/7 days (Intercollegiate Stroke Working Party 2023).

This increase was made in an attempt to transform rehabilitation delivery to improve clinical outcomes as (1) The Sentinel Stroke National Audit Programme continued to highlight that 45 minutes was rarely being met in the UK ((16.8% and 11.9% of patients for occupational and physiotherapy respectively in the year April 2021-22) (King's College London 2022)), (2) outcomes are known to improve with greater amounts of therapy (Kwakkel *et al.* 2004; Lohse *et al.* 2014), and 3) equivalent guidelines in other countries (e.g. Australia (Stroke Foundation 2022), Canada (Teasell *et al.* 2020), Netherlands (Veerbeek *et al.* 2014a)) had already progressed to a three hours daily therapy target (Intercollegiate Stroke Working Party 2023). Thus, from a Healthcare delivery perspective increasing therapy contact time remains is a key UK stroke care priority (Intercollegiate Stroke Working Party 2023).

Self-management

Self-management is widely promoted to maximise recovery and well-being (Scottish Government and Long Term Conditions Alliance 2008; Parke *et al.* 2015; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). While definitions vary most tend to centre around the need for healthcare staff to provide individuals with information resources (e.g. booklets on the principles of recovery and self-managing recovery (Chest Heart and Stroke Scotland 2020; Stroke Association 2020)), skills and confidence to practice new health

behaviours in order to successfully manage a long-term condition (Lorig and Holman 2003; Ryan and Sawin 2009; Sadler *et al*. 2017).

Sadler et al. 2017 has defined self-management as:

> 'a process in which individuals acquire skills, strategies and knowledge to manage the physical, psychological, emotional and social effects of a chronic condition' (Sadler *et al*. 2017, p.1)

'Supported self-management' is recognised as a key component of person-centred care (Chest Heart and Stroke Scotland 2012; National Voices 2014; de Iongh *et al*. 2015; Parke *et al*. 2015). It is increasingly the preferred term given to self-management to highlight that it is not merely about compliance with professionally driven goals and treatment plans (de Iongh et al. 2015). Instead, it highlights that it is a process where people with a chronic health condition can access support they need to self-direct and positively influence their rehabilitation and recovery (de Iongh *et al*. 2015).

Thus, supported self-management typically focusses on teaching individuals core skills that develop self-efficacy (Lorig and Holman 2003; Ryan and Sawin 2009; Parke *et al*. 2015), that is an individual's confidence that they have the capacity (e.g. knowledge/tools/support) to take worthwhile action to enable them to fulfil their rehabilitation goal(s) (Bandura 1978) (Figure 5).

Figure 5: Supporting the adoption of self-management behaviours

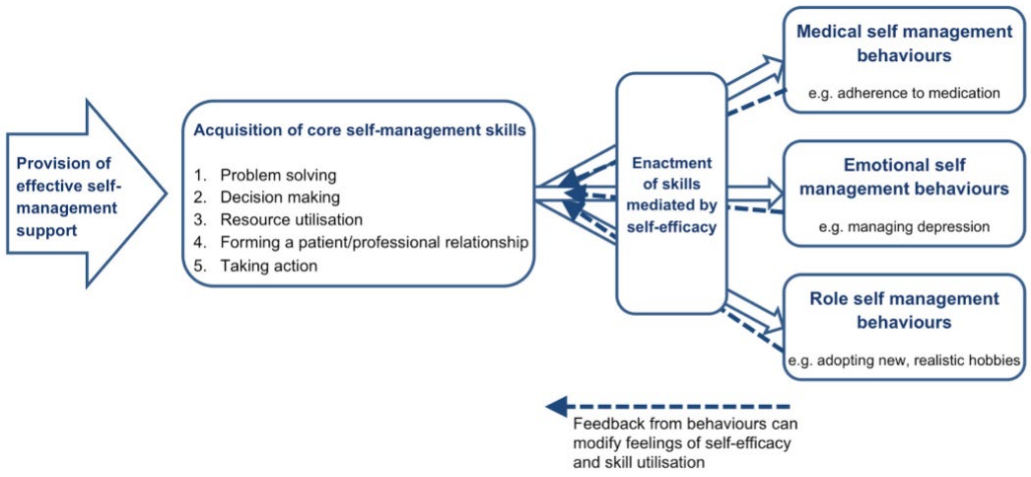


Diagram highlighting the important role of self-efficacy as a mediator between the acquisition of core self-management skills gained and the enactment of self-management behaviours. Taken from © 2015 Parke et al., an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. Full Terms at: Creative Commons — Attribution 4.0 International — CC BY 4.0

Such an action may include stroke survivors self-practicing exercises out with formal (i.e. therapist-directed) therapy i.e. in a self-directed manner independently with/without a carer when directed to by a therapist (Intercollegiate Stroke Working Party 2023). Common examples of core skills that support self-management behaviours are shown in Figure 5 (above) and may include evaluating their current abilities and needs, identifying/setting goals that are relevant/important to them/their lives, self-monitoring their progress in relation to advice given/efforts made and solving/overcoming problems anticipated/experienced engaging in self-management.

In comparison to other chronic conditions, much is still unknown about the use of self-management interventions after stroke, particularly in relation to factors that support it or make it cost-effectiveness (Fryer *et al*. 2016). Nevertheless, a body of systematic review evidence is accumulating to support them to aid physical recovery after stroke (Lennon *et al*. 2013; Parke *et al*. 2015; Warner *et al*. 2015; Da-Silva *et al*. 2018). Additionally, self-management stroke interventions with a self-efficacy focus have been shown to lead to greater improvements in physical recovery outcomes (Jones and Riazi 2011; Korpershoek *et al*. 2011).

Thus, self-efficacy is thought to underpin successful self-management and bridge the gap between the acquisition of self-management knowledge and skills, and the execution of self-management behaviours (Figure 5) (Parke *et al*. 2015; Intercollegiate Stroke Working Party 2023). However, Healthcare resources are limited, increased therapy dose increases motor recovery after stroke (Lohse *et al*. 2014) and self-management interventions are currently lacking or centred around the provision of written/online resources i.e. lack stroke therapy support (NHS National Services Scotland 2022). Thus, implementing well designed supported self-management interventions may also impart benefit by increasing therapy engagement and dose (Intercollegiate Stroke Working Party 2023). Consequently, self-management programmes involving physical rehabilitation that successfully increase self-efficacy, offering psychological benefits in conjunction with physical benefits are likely to effect successful self-management.

1.2.2.3 Unmet needs of stroke survivors

Several UK studies have highlighted the perceived unmet needs of UK stroke survivors (McKevitt *et al*. 2011; Stroke Association 2016; Abrahamson and Wilson 2019). In a survey involving community dwelling stroke survivors (n=1251) unmet post stroke needs were reported by 49%, with 54% of them reporting a need for stroke information to support their recovery (McKevitt *et al*. 2011). Another survey conducted by the Stroke Association, the largest UK stroke charity, revealed that 45% of stroke survivors feel abandoned after being discharged home from hospital as they receive inadequate therapy provision, information and support (Stroke Association 2016). Similarly, a multiple case-study involving three UK sites tracked stroke survivors from discharge up until one year (Abrahamson and Wilson 2019). It concluded that patients consistently reported unmet needs in relation to the provision on therapy, information and education, and support. Thus, it seems that strategies that enhance therapy provision, support and information are required to ameliorate these unmet needs.

A systematic review of 32 qualitative studies involving the experiences of 560 stroke survivors over 10 different countries synthesised their perceptions in relation to the inpatient physical rehabilitation they received (Luker *et al*. 2015). Another key theme, also identified in other qualitative systematic reviews (Luker *et al*. 2015; Meads *et al*. 2020), was that physical rehabilitation was a highly valued component of their stroke care, with many stroke survivors believing that more rehabilitation led to greater physical recovery. Paralleling clinical guidelines which advocate support for stroke survivors to self-manage their stroke recovery (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023), stroke survivors in the systematic review expressed a wish to engage in more self-practice activities out with formal therapy sessions. However, they also expressed a perceived lack of ability to engage in self-practice to self-manage their recovery as services were not set up to enable them to do this. Another theme, “Bored and alone”, highlighted patients experienced their spare time as “depressingly unstimulating” and reinforced their perceived need to be enabled to access more intensive and self-managed therapy training opportunities out with formal therapy.

A patient centred therapy approach encompassing meaningful tasks based on real life activities was strongly supported, with variety and innovations (e.g. computer games, circuit classes) being welcomed by many. Further themes centred around a lack of sense of control, a lack of autonomy and poor communication. The need for staff to empower patients and a collaborative, shared relationship, and style of communication between patients and therapists were felt to be key to instilling positivity, coping and overall recovery. This work offers a valuable and novel contribution to the stroke literature. Uniquely, it offers important insights into the preferences and lived experience of stroke survivors from the perspective of their physical rehabilitation. Going forward, efforts should be made to utilise this new knowledge by structuring existing rehabilitation services and interventions in ways that help to fulfil their needs and preferences.

1.2.2.4 Research challenges inherent in advancing it

Complex interventions

Medical interventions (experimental and control) in stroke research typically involve a single pharmacological intervention (Petticrew 2011). Consequently, they are easily standardised, recorded, and described (e.g. active ingredient(s), dose, timing) making the interpretation and replication of findings relatively straight forward (Stinear et al. 2020; Skivington et al. 2021). Similarly, they often involve taking oral medication which is typically administered easily in seconds/minutes and without the need for staff or tailoring to optimise compliance and are therefore easier to control. Additionally, administration is typically amenable to triple blinding to minimise potential sources of bias (i.e. systematic error and deviation in outcome from the truth beyond chance (Higgins et al. 2019)). Furthermore, they are typically delivered via well-established and resourced research infrastructures (doctors with routine academic training, and doctors/nurses with time dedicated to research activities) (Stinear et al. 2020).

In contrast, the opposite is typically true for stroke rehabilitation interventions. They are typically complex interventions, that is they have several interacting intervention components (e.g. exercise, repetition, support, behavioural

change) and/or depend on the behaviour of those delivering/receiving them (Langhorne *et al*. 2011; Pfadenhauer *et al*. 2017; Skivington *et al*. 2021).

The wide-ranging problems patients often encounter (heterogeneity of the population studied) and associated patient-centred approach required influence rehabilitation priorities, treatment duration/timeframes and interventions utilised at the individual level necessitating intervention tailoring (Langhorne *et al*. 2011; Pfadenhauer *et al*. 2017; Skivington *et al*. 2021). Similarly, administration is typically time consuming and delivering intended treatment plans is challenging due to variable clinical therapy resources and a lack of dedicated therapy research time in clinical and research settings (Moore *et al*. 2015). Additionally, the physical nature of such interventions often limits blinding which may influence the behaviour of implementors introducing bias (Higgins *et al*. 2019).

Thus, this variation in rehabilitation interventions (experimental and control) makes characterising, describing, and replicating effective stroke rehabilitation interventions difficult, particularly at a population level (Pfadenhauer *et al*. 2017). Consequently, for simplicity, complex interventions are often studied as a whole (DeJong *et al*. 2004; Pollock *et al*. 2014a), making identifying and measuring the "active ingredients" or relative effectiveness of each individual component an analytical and statistical challenge. In this way, complex interventions hinder research comparisons in Randomised Controlled Trials (RCTs) and contribute to the complexities involved in progressing the evidence base for specific rehabilitation practices (DeJong *et al*. 2004).

For this reason, limited evidence-based guidance is available to guide clinicians, and stroke rehabilitation is often considered to be a "black box" as relatively little is known about the specific content or relative effectiveness of its individual components or their potential interactions (DeJong *et al*. 2004). (DeJong *et al*. 2004).

Other challenges in stroke rehabilitation

Other research challenges in stroke rehabilitation relate to the wide range of outcomes and varying time periods following stroke onset studied and the poor methodological rigour of published studies (Louw 2002; McIntyre *et al*. 2016; Stinear 2016). Furthermore, longitudinal regression analysis of change scores demonstrates that spontaneous recovery which occurs naturally with time (Figure 4) contributes more to the recovery of function during the first three months than rehabilitation. Thus, spontaneous recovery within this period is a major confounding factor when making therapeutic comparisons in stroke rehabilitation trials (Kwakkel *et al*. 2006).

Recently, guidance on how to develop complex interventions to improve healthcare have been developed (Skivington *et al*. 2021). An international partnership of stroke recovery and rehabilitation experts has also been formed to establish consensus in rehabilitation intervention description, development and evaluation (Bernhardt *et al*. 2016; Kwakkel *et al*. 2017; Walker *et al*. 2017; Bernhardt *et al*. 2019). Both developments aim to address the challenges inherent in rehabilitation research in an attempt to advance rehabilitation and recovery.

So far, this chapter has focused on the scale and nature of stroke, stroke recovery, and stroke rehabilitation in general from a physical perspective. Reduced upper limb function is a significant problem after stroke and recovery is often unacceptably poor in this area (Pollock *et al*. 2014b). The main focus of this thesis is on upper limb recovery following stroke. Thus, the rest of this thesis will now focus on the impact of stroke and stroke recovery from the perspective of the upper limb.

1.3 The stroke affected upper limb

The upper limb is essential for functional independence (Goulding *et al*. 2004; Gates *et al*. 2016). Its primary function is to position the hands in the space around the body during everyday life tasks, such as washing, dressing, cooking and feeding, so that they can then grasp, manipulate and release objects to execute a desired functional task (Amis 1990).

1.3.1 Impaired upper limb motor function

1.3.1.1 Scale & impact

Unfortunately, upper limb motor impairment is a considerable problem after stroke. Of all the deficits that may be experienced it is the most common, with around 80% of stroke survivors experiencing impaired ability to move their upper limb on one side of their body (hemiparesis) acutely (Lawrence *et al*. 2001). Worldwide, this means that over 8-million people experience impaired upper limb function due to stroke annually and over 20-million people live with it every day (Lawrence *et al*. 2001; Feigin *et al*. 2017). Of those experiencing initial upper limb motor impairment, around 25-50% will experience severe motor impairment (Parker *et al*. 1986), over 60% will fail to regain some dexterity (Kwakkel *et al*. 2003), and 50% will still have no upper limb function at six months post stroke, experiencing severe chronic upper limb disability (Broeks *et al*. 1999). Thus, for the majority affected, upper limb dysfunction is a persistent, long-term consequence of stroke, often involving severe disability.

Furthermore, the reduced function, and loss of independence in activities of daily living (ADL) and participation that accompanies upper limb motor impairment (Sveen *et al*. 1999; World Health Organisation 2001; Bleyenheuft and Gordon 2014) is associated with anxiety at six months after stroke (Morris *et al*. 2013), reduced satisfaction (Bonita and Beaglehole 1988) and quality of life (Lai *et al*. 2002; Morris *et al*. 2013).

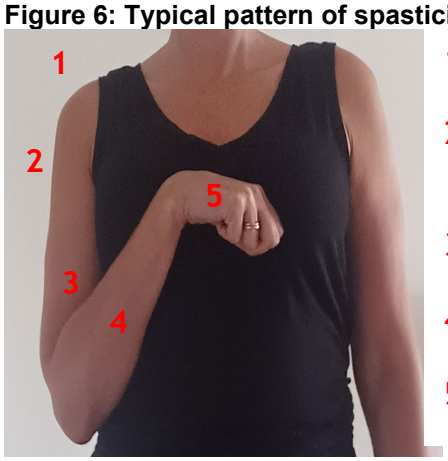
1.3.1.2 Contributing factors

There are many upper limb impairments after stroke that contribute to impaired motor function and the subsequent reduced function and independence experienced (Sveen *et al*. 1999; World Health Organisation 2001). Muscle weakness and the loss of active movement that often results from it are a hallmark of stroke (Goulding *et al*. 2004; Raghavan 2015) and the greatest determinant of dexterity, upper limb function and activities of daily living (Intercollegiate Stroke Working Party 2023). Other common primary motor impairments include altered coordination, dexterity, and spasticity (Goulding *et al*. 2004; Raghavan 2015). Impairments in somatic sensations also occur (e.g. touch, vibration and awareness of limb position) (Doyle *et al*. 2010). They

reduce the quality of sensory information received by the brain and often cause secondary impairments in movement control (Blennerhassett *et al*. 2007; Welmer *et al*. 2008). Similarly, an attentional disorder, known as an inattention, where movement is suppressed due to difficulties attending to stimuli on the stroke affected side of their body also affecting upper limb motor and functional outcomes (Ringman *et al*. 2004).

Following an initial period of hyporeflexia, muscle spasticity often develops in certain muscle groups (Teasell 1991; Goulding *et al*. 2004). Spasticity manifests as an intermittent or sustained involuntary activation of muscles resulting from an upper motor neurone lesion (Pandyan *et al*. 2005), typically around a median of 34 days post stroke (Nam *et al*. 2019). The prevalence increases with time. A recent observational study involving 498 patients with cerebral infarction concluded that the prevalence of spasticity is 12.5%, 20%, 22.5%, 35%, 40%, and 42.5% in two weeks, one month, two months, three months, six months, and 12 months, respectively (Jin and Zhao 2018). While spasticity can affect any muscle, it is most frequently encountered in the muscles that retract and depress the scapula, internally rotate, and adduct the shoulder, flex the elbow, pronate the forearm, and flex the wrist and digits (Figure 6) (Teasell 1991; Carr and Kenney 1992; Kuo and Hu 2018). The spasticity that develops imbalances forces across affected joints reducing movement control (Crone 1993; Mukherjee and Chakravarty 2010) and often leads to a stereotypical flexed resting posture with a closed hand that is held close to the body (Teasell 1991; Kuo and Hu 2018) (Figure 6).

Figure 6: Typical pattern of spasticity in the upper limb after stroke



1 Retraction and depression of scapula

2 Internal rotation and adduction of the shoulder

3 Flexion of the elbow

4 Pronation of the forearm

5 Flexion of wrist and digits

Image used with copyright permission: Jen Alexander (model)

Loss of dexterity and failure to recover useful upper limb function, both of which infer limited upper limb use, are significant predictors of the secondary development of upper extremity contractures (Malhotra et al. 2011; Matozinho et al. 2019).

Other secondary complications relating to the initial upper limb impairments encountered, also associated with poorer post stroke outcomes, typically relate to immobility and muscle imbalance, and include oedema, shoulder subluxation, shoulder hand syndrome, pain and learned non-use (Goulding *et al*. 2004; Kuo and Hu 2018).

Furthermore, the degree of motor impairment demonstrated in stroke survivors has been shown to be less when the non-dominant (i.e. less dextrous) hand is affected (Harris and Eng 2006). Thus, upper limb dominance may also influence the degree of ease or drive to use the upper limb.

1.3.1.3 Digital extensor weakness – A need for special research attention?

Weakness in the digital extensors (which extend/straighten the digits) is thought to be the most common motor impairment after stroke (Parker *et al*. 1986). It restricts hand opening reducing the ability to grasp and release objects in our environment and impairs the organised and simultaneous flexion and extension of joints required to manipulate objects during everyday dextrous functional tasks (Backman *et al*. 1992). Consequently, it also restricts participation in intensive, repetitive, functional-based rehabilitation and self-practice activities that are advocated in national clinical guidelines (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). When digital extensor (hand opening) weakness is accompanied by digital flexor spasticity (which acts to close the hand), active hand opening inevitably becomes an even greater challenge.

Thus, impaired upper limb motor function is very common after stroke and for the majority affected it persists, and often involves severe disability. Many factors contribute to impaired motor function and the subsequent reduced function and independence experienced, including weakness, reduced dexterity, and spasticity. However, the common occurrence of digital extensor weakness

and the crucial role digital extension plays in assisting people to engage in recommended rehabilitation activities (dextrous, functional-based tasks) and to counter involuntary digital flexion if/when flexor spasticity develops suggests that it may merit special research attention.

1.3.2 Key factors known to influence upper limb recovery

1.3.2.1 Severity of initial motor impairment

While functional recovery after stroke is heterogeneous in nature (Wade *et al.* 1983; Nakayama *et al.* 1994; Kwakkel *et al.* 2003), it is clear that on a population level the initial severity of upper limb paresis (i.e. weakness) influences the patterns observed (Nakayama *et al.* 1994; Kwakkel *et al.* 2003; Nijland *et al.* 2010a; Coupar *et al.* 2011). Those with mild to moderate paresis have a much better functional outcome, with over two thirds recovering at least some dexterity at six months (Nijland *et al.* 2010a). In contrast, those with severe initial deficits experience a much poorer prognosis, with only one third recovering some dexterity (Kwakkel *et al.* 2003). Furthermore, only around 18% of stroke patients admitted to hospital with severe upper limb deficit will regain full upper limb function compared to around 79% in those admitted with mild deficits (Nakayama *et al.* 1994).

Additionally, stroke survivors express that upper limb recovery is negatively impacted by a limited availability of meaningful (i.e. salient) upper limb therapy tasks they are physically able to access (Barker and Brauer 2005; Meads *et al.* 2020) and the predominant selection of upper limb compensation strategies by therapists (e.g. one-handed dressing) (Meads *et al.* 2020). Consistent with these views, stroke survivors perceive the greatest barrier to upper limb recovery to be “not having enough movement to work with” (Barker and Brauer 2005). This suggests that current methods of upper limb rehabilitation are perceived by many stroke survivors to be too challenging to engage in when weakness limits the active movement they can generate. Consequently, this increased challenge to select/access active rehabilitation opportunities may in part explain the poorer recovery observed in stroke survivors experiencing more severe weakness.

1.3.2.2 Pattern of network activation shift – contralesional versus ipsilesional

After stroke brain activation patterns change. The initial damage in the ipsilesional hemisphere disrupts original networks causing a distributed activation pattern that is shifted towards the unaffected or contralesional hemisphere (Calautti and Baron 2003; Baron *et al*. 2004). A meta-analysis investigating the changes in neural representation after upper limb rehabilitation in stroke survivors found that rehabilitation refocuses brain activation, shifting it back towards the ipsilesional hemisphere (Richards *et al*. 2008). A favourable functional recovery depends on the degree to which this shift in activation occurs (Calautti and Baron 2003; Baron *et al*. 2004), something known to vary according to the extent of damage to the corticospinal tract (Rehme *et al*. 2012), a major neural tract for motor function, particularly fine motor or dexterous function (Sung 2014).

1.3.2.3 Typical recovery pattern - time

The pattern of upper limb recovery is consistent with the non-linear logarithmic pattern previously described for stroke recovery in general (Langhorne *et al*. 2011; Cramer 2018). Systematic review data involving 17 rehabilitation protocols studying occupational therapy with a virtual reality intervention in people with mild to moderate upper limb paresis has demonstrated that rehabilitation can improve upper limb impairment (Fugl Meyer Upper Extremity Scale) and function (Chedoke Arm and Hand Activity Inventory) at all stages of recovery (Ballester *et al*. 2019). Additionally, it also demonstrated an exponential decrease in treatment effect noted over time for both upper limb impairment and function (Ballester 2019).

Similarly, prospective cohort data indicates that most upper limb recovery appears to occur within the first one to three months after stroke (Wade *et al*. 1983; Olsen 1990; Nakayama *et al*. 1994; Kwakkel *et al*. 2006). Nakayama et al. 1994 observed upper limb recovery in 421 stroke patients admitted to hospital from the time of their hospital admission (<1 week post stroke) on a weekly basis for 12 weeks, and at discharge home (Nakayama *et al*. 1994). Upper limb function, measured using the Barthel Index subscores for feeding and personal care, was found to peak in 80% of stroke survivors at two weeks and six weeks

post stroke for those admitted with mild and severe upper limb paresis respectively (Nakayama *et al*. 1994). At six and 11-weeks post stroke, 95% of stroke survivors admitted with mild and severe paresis respectively had reached peak upper limb function (Nakayama *et al*. 1994). However, the Barthel is a global measure of activities of daily living (Collin *et al*. 1988), not specifically a measure of upper limb function and theoretically full marks may be awarded using only the stroke unaffected upper limb. Thus, findings reported by Nakayama et al., (1994) cannot be assumed to truly reflect peak upper limb recovery as they may instead reflect successful compensation.

However, similar findings were reported by Wade et al. (1983) (Wade *et al*. 1983) measuring performance in seven upper limb functional tasks, albeit with untested psychometric properties.

Thus, collectively current evidence suggests that there is a trend for greater upper limb recovery occurring earlier after stroke, and for the timeframe of upper limb functional recovery being longer with an increased severity of initial upper limb motor paresis.

1.3.2.4 Predictive variables

Many variables have been identified to help predict upper limb recovery. A systematic review by Coupar et al. (2011) has identified that improved upper limb recovery is associated with having a younger age at onset, male gender, less severe stroke (e.g. less disability, less severe stroke type/class, smaller lesion size/volume), less severe focal deficits (e.g. less upper limb or lower limb impairments, more upper limb function), fewer co-existing factors (e.g. no deficits in sitting balance, upper limb sensation, vision etc) and favourable neurophysiological factors (e.g. preservation of the corticospinal tract or presence of motor evoked potentials in descending motor or ascending sensory tracts) (Coupar *et al*. 2011).

Similarly, a lack of gradual motor recovery within the first four weeks after stroke (Fugl Meyer Upper Extremity score <19 points) has been found to indicate poor recovery of dexterity and functional outcome at six months (Kwakkel et al. 2003).

Additionally, a number of predictive models for upper limb motor outcome have been published. Interestingly, digital extensor weakness is included in some of these models which may be a further signal that research involving this particular deficit merits further research attention (Intercollegiate Stroke Working Party 2023). Two well documented models include (1) the SAFE score (Nijland *et al*. 2010a) which predicts recovery based on the degree of shoulder abduction and finger extension strength 72 hours after stroke, and (2) the PREP2 algorithm (Stinear *et al*. 2017) which utilises the SAFE score in conjunction with age, and the additional assessment of corticospinal tract patency (transcranial magnetic stimulation) +/- a bedside test scored on day three (National Institute of Health Stroke Scale (Brott *et al*. 1989)) to add additional predictive value in patients falling below a threshold strength (SAFE score).

Thus, various factors, including greater severity of stroke and stroke related deficits, digital extension weakness and a lack of early recovery, are associated with poor upper limb recovery.

1.3.3 Upper limb rehabilitation

1.3.3.1 Implementation – Professionals and main intervention categories

Occupational and physiotherapists in a stroke specialist multidisciplinary team are principally responsible for providing upper limb rehabilitation support and expertise after stroke with the aim of optimizing upper limb recovery (Pollock *et al*. 2014b; Teasell *et al*. 2020; Intercollegiate Stroke Working Party 2023).

A wide range of post stroke interventions currently exist (Pollock *et al*. 2014b; Hatem *et al*. 2016). Broadly speaking, three main categories of interventions are recommended to improve upper limb motor deficits after stroke (Pollock *et al*. 2014b; Hatem *et al*. 2016; Intercollegiate Stroke Working Party 2023) (Table 2).

Table 2: Three main categories of interventions recommended as a consequence of stroke upper limb deficits

Categories of upper limb rehabilitation recommended after stroke	
1	Training to recover initial upper limb impairments (e.g. strength training)
2	Training to recover upper limb functional activity (e.g. repetitive functional based practice including constraint induced movement therapy)
3	Measures to maintain the upper limb i.e. to prevent secondary complications or impairments (e.g. education, positioning, electrical stimulation to avoid pain, contractures etc)

These categories include those targeting recovery of initial impairments (e.g. weakness), those targeting recovery of functional activity (e.g. activities involving reaching, grasping, and releasing) and those aiming to maintain the upper limb i.e. prevent secondary complications (e.g. positioning to reduce contractures, pain). Like stroke rehabilitation in general, the wide-ranging problems (e.g. weakness severity) and individual needs of patients will influence those selected and may include multiple interventions and different categories (DeJong *et al*. 2004; Pollock *et al*. 2014b; Intercollegiate Stroke Working Party 2023).

ADL may also be practised as a result of upper limb dysfunction but using upper limb adaptive or compensatory motor strategies (upper limb compensation) that avoid using the affected upper limb (e.g. one handed dressing) and therefore do

not aim to recover upper limb motor function (Levin *et al*. 2009; Legg *et al*. 2017). Consequently, this rehabilitation strategy is not classed as an upper limb intervention. Instead, in the context of upper limb rehabilitation, the practice of ADL using the affected upper limb will be categorised as training to recover upper limb functional recovery.

1.3.3.2 Clinical recommendations

Content

Intensive, repetitive, functional-based practice: The mainstay of training to recover upper limb function and the preferred stroke rehabilitation intervention over all others is known as intensive, repetitive, task specific or functional-based practice (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). It involves repetitive practice of:

1. The specific functional tasks/activities a stroke survivor wishes to regain after stroke (e.g. grasping, manipulating, and releasing of objects such as a glass to drinking) (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023), and

2. Functional-based movements performed against increasing resistance to strengthen weak muscles (Eng 2004) if/when weakness limits the specific functional tasks/activities stroke survivors wish to regain (e.g. strengthening digital extensor muscles to achieve sufficient hand opening to enable the practice of grasping a glass to drink) (Hatem *et al*. 2016; Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023).

When active hand/arm movement is present intensive, repetitive functional-based practice is the principal evidence-based intervention recommended for the recovery of upper limb motor function (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). For stroke survivors who have ≥20 degrees of active wrist extension and 10 degrees of active finger extension in the affected hand constraint-induced movement therapy (CIMT) is also recommended for consideration (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). It is a specialised form of

repetitive, functional-based training practiced for six hours a day for two weeks that additionally involves behavioural strategies - constraining the non-paretic arm with a mitt to promote use of the weak arm for 90% of waking hours and training to transfer skills gained in a clinical setting into a real-life environment (Corbetta *et al*. 2015). However, as well as requiring a minimum amount of active wrist and digital extension movement CIMT protocols typically demand considerable one to one therapist contact time resulting in a high economic cost (Smania *et al*. 2012), inevitably require significant motivation and energy from stroke survivors to comply with the intended treatment duration (Smania *et al*. 2012) and cannot be assumed to be suitable for those with cognitive impairment as the systematic review evidence that supports it was gathered from stroke survivors without cognitive impairment (Pollock *et al*. 2014b; Corbetta *et al*. 2015). Thus, these factors are often acknowledged as limiting the application of this specialist form of repetitive, functional-based training (Pollock *et al*. 2014b; Corbetta *et al*. 2015).

Evidence-based interventions have yet to be identified to improve upper limb function in stroke survivors who lack any active hand/arm movement or even the minimum active digital extension movement required to access functional-based interventions including CIMT (Kwakkel *et al*. 2003; Veerbeek *et al*. 2014b; Kwakkel *et al*. 2015b; Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). Consequently, for this subgroup of stroke survivors clinical guidelines recommend that the aim of upper limb rehabilitation then becomes maintaining the upper limb (e.g. passive movements and positioning to prevent secondary complications or impairments) and monitoring with commencement of repetitive functional-based practice if active movement is detected (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023).

Stroke therapy reviews have consistently indicated that increased intensity (or dose) appears to favour improved outcomes (Langhorne *et al*. 1996; Cooke *et al*. 2010; Lohse *et al*. 2014) (see ‘Dose’ section in Chapter 1 below). Similarly, review evidence suggests that training that directly involves the practice of functional activities is more effective than activities that are impairment-based (Van Peppen 2004; French *et al*. 2016).

A Cochrane overview of systematic reviews has identified that no high-quality evidence currently exists for any stroke upper limb treatments used in routine clinical practice (Pollock *et al*. 2014b). It made 127 treatment comparisons. Unfortunately, it was unable to compare the relative effectiveness of these interventions due to inadequate evidence, but found moderate quality evidence for a relatively high dose of therapy involving the repetitive practice of functional activities (whole tasks where ability permitted) selected to improve the performance of functional tasks (>20 hours) (Pollock *et al*. 2014b). It concluded that high-quality evidence is urgently needed on the effectiveness of functional-based practice (Pollock *et al*. 2014b).

Another review by Veerbeek et al. (2014b) reviewed RCTs with a low risk of bias involving physiotherapy interventions not restricted to the upper limb after stroke (Veerbeek *et al*. 2014b). They found strong evidence in favour of intensive, repetitive, functional-based training during all phases of stroke recovery based on post intervention outcomes (Veerbeek *et al*. 2014b).

Similarly, a Cochrane review on repetitive task training by French et al. (2016), concluded that evidence existed for its use to improve arm and hand function after stroke (French *et al*. 2016). However, they highlighted that the quality of this evidence was low owing to small sample sizes, heterogeneous findings and poor reporting of study details (French *et al*. 2016).

Adjunctive interventions: Many other interventions have been proposed to aid upper limb motor recovery e.g. by improving weakness, reducing motor impairment, promoting neuroplasticity, activating the motor cortex, increasing therapy intensity (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). However, evidence only supports the use of these as adjunctive interventions to be considered and/or provided over and above (i) repetitive, functional-based training if movement is present or (ii) maintenance and monitoring with commencement of repetitive functional-based practice if active movement previously absent is detected (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023).

Adjunctive interventions that do not necessitate active movement in the affected upper limb include self-directed upper limb rehabilitation to increase

therapy time/dose, mental practice with motor imagery, electrical stimulation, mirror therapy, robot-assisted movement therapy, (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023).

Additional adjunctive interventions recommended that require partial active digital extension and involve practicing functional-based movements include transcutaneous vagus nerve stimulation in people with mild-moderate arm weakness (if available) (Intercollegiate Stroke Working Party 2023) and the self-directed Graded Repetitive Arm Supplementary Programme (GRASP) that involves a combination of range of movement, strengthening and functional based exercises (Harris *et al*. 2009).

Intensive, repetitive, functional-based training fulfils many of the principles known to drive neuroplasticity, particularly specificity, repetition, intensity and salience (Table 1 above) (Kleim and Jones 2008). This may help to explain the evidence-base supporting it. In contrast, the replication of such principles in stroke survivors who lack any active hand/arm movement or lack active digital extension is a significant rehabilitation challenge and likely explains why no evidence-based interventions currently exist for improving upper limb function desired in this subgroup.

Dose

As mentioned in Section 1.2.2.2 (above), National Clinical Guideline for Stroke recommend that stroke survivors with motor recovery goals engaging in stroke rehabilitation should receive ≥3 hours of multidisciplinary therapy a day of recommended therapy content delivered or supervised by a therapist/therapy support worker (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023) at least 5/7 days (Teasell *et al*. 2020; Intercollegiate Stroke Working Party 2023). While these guidelines recommend practice with high repetitions, they do not offer specific guidance on the therapeutic dose for the upper limb and ≥3 hours are assumed to cover rehabilitation for all motor recovery goals.

Research suggests that optimal brain recovery occurs when stroke patients carry out more than 100 daily movement repetitions in the upper limb (Carey *et al*. 2002). However, failure to deliver this intensity during upper limb therapy is

common in the UK (Lang *et al*. 2009; Hayward and Brauer 2015). Data from small trials investigating the feasibility of carrying out high repetition functional-based upper limb training found a consistent, moderate relationship with upper limb function (r = 0.5 - 0.6) (Birkenmeier *et al*. 2010; Waddell *et al*. 2014). These trials suggest that therapy dose may account for around one third of outcome variance (Birkenmeier *et al*. 2010; Waddell *et al*. 2014).

Consistent with these trials, a number of RCTs have reported neutral treatment effects in response to 19-36 hours of additional upper limb therapy in active intervention groups (functional-based, robotics or extra usual based upper limb care) involving stroke survivors with predominantly or exclusively moderate to severe chronic upper limb impairment with ((Lang *et al*. 2016), 19 hours) or with/without ((Rodgers *et al*. 2019), 36 hours) some active digital extension. The same can be said for stroke survivors with moderate subacute upper limb motor impairment with some active digital extension ((Winstein *et al*. 2016b), 30 hours).

However, significant treatment effects (FMUE increase: 8-11) have been reported in stroke survivors with severe or moderate to severe chronic upper limb impairment with wrist extension contractility in RCTs delivering around 300 additional therapy hours (functional-based with/without robotics or Functional Electrical Stimulation) ((McCabe *et al*. 2015; Daly *et al*. 2019). Furthermore, significant treatment effects (FMUE increase: 11) have also been reported in a similar group of stroke survivors (predominantly moderate to severe impairment with wrist +/- digital extensor contractility) in response to 90 hours of functional-based and strengthening based training delivered via a single-centre clinical service (Ward *et al*. 2019). Such work highlights the need for an adequate upper limb training dose to fulfil upper limb functional potential.

Self-Management

Most interventions for the upper limb after stroke require direct (i.e. 1:1) contact with a therapist, particularly in individuals who are more severely affected (Prange *et al*. 2006). As increased therapy dose improves stroke outcomes and healthcare staffing resources are limited at all stages of recovery (Lohse *et al*. 2014; Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate

Stroke Working Party 2023) identifying effective, resource efficient treatments that increase therapy dose after stroke is likely to be key to optimising recovery.

As mentioned previously in Section 1.2.2.2 (above) supported self-management is a recognised stroke care priority and in conjunction with standard rehabilitation may optimise the dose of evidence-based upper limb rehabilitation activities practiced after stroke (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). Furthermore, such strategies typically require only occasional direct therapist contact (Da-Silva *et al*. 2018). Additionally, a recent systematic review involving stroke survivors with any stroke related arm deficits regardless of time post stroke concluded that interventions that involve repetitive functional-based practice delivered in a self-directed context can improve upper limb function and independence in ADL after stroke (Da-Silva *et al*. 2018). Thus, novel upper limb interventions that enable stroke survivors with upper limb motor impairment to access an increased dose of functional, guideline-based interventions during a one-to-one and self-directed therapy context, even in the presence of severe motor impairment are likely to offer the greatest benefit.

Timing

There is currently some debate in the stroke literature about the optimal timing of upper limb rehabilitation. Dromerick et al. (2009) studied two different doses of CIMT early after stroke, commenced on average nine days after stroke (Dromerick *et al*. 2009). They found that the improvement in outcome was inferior in the group receiving a higher dose at 90 days, but ultimately equivalent to the low dose group by one year suggesting that a higher early dose of upper limb rehabilitation is not superior to a lower early dose (Dromerick *et al*. 2009).

A systematic review by Veerbeek et al. (2014b) found evidence that high intensity CIMT may be beneficial early after stroke (Veerbeek *et al*. 2014b). They found a significant positive effect for acute to early subacute phase rehabilitation (24hrs to three months post stroke) for basic ADL using high intensity CIMT and a non-significant effect for the chronic phase (>6 months post stroke) (Veerbeek *et al*. 2014b), with no studies reported during the late subacute rehabilitation phase (three to six months post stroke). Subsequently,

Kwakkel et al. (2016) compared usual upper limb care (30 minutes of exercise therapy every working day for three weeks) to modified CIMT (60 minutes every working day for three weeks) starting within two weeks of ischaemic stroke (Kwakkel *et al.* 2016). Outcomes in the higher dose modified CIMT group were significantly improved in upper limb function (Action Research Arm Test) 5, 8 and 12 weeks post stroke and perceived hand function (Stroke Impact Scale hand) eight weeks post stroke compared to the usual care only group (Kwakkel *et al.* 2016). However, delayed functional improvements in the usual care only group meant, at least in part, that this significant difference in favour of a higher versus lower early therapy dose was no longer present at 26 weeks (Kwakkel *et al.* 2016).

As previously mentioned in 1.3.2.3, upper limb recovery generally peaks early after stroke but continues with a decrease in treatment effect over time (Ballester *et al.* 2019). Consequently, clinical guidelines recommend that stroke rehabilitation should start early after stroke (<48 hours typically) and be needs-led rather than time-limited (Teasell *et al.* 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). Thus, it should be available to stroke survivors with stroke recovery needs identified by stroke survivors themselves, their carers or multidisciplinary team regardless of the timing of such needs.

Additionally, as previously mentioned in 1.3.1.2, other impairments such as spasticity and contractures (e.g. in the digital flexors) increase over time (Malhotra *et al.* 2011; Jin and Zhao 2018; Matozinho *et al.* 2019) further reducing motor function (e.g. hand opening) making the practice of recommended functional-based activities an even greater challenge. Moreover, secondary complications known to hinder rehabilitation progress such as learned non-use may be reduced if targeted early after stroke before becoming habitual. Thus, some potential to recover may theoretically be lost if training is insufficient during this critical early period. Consequently, while some stroke survivors may not tolerate intensive rehabilitation in the acute phase (Parry *et al.* 1999; Shutter and Whyte 1999), on balance, there is a strong argument to support the use of strategies that increase access to guideline-based upper limb interventions early after stroke for those who wish it and can tolerate it.

1.3.3.3 Current therapy

Content

Therapy provision with direct therapist contact: Research from a recent UK cross-sectional survey collected information on the treatment practices of 154 occupational and physiotherapists in people with mild, moderate and severe upper limb stroke deficits across the full stroke care pathway (Stockley *et al*. 2019). The treatments listed as being utilised by over 10% of respondents were reported (Stockley *et al*. 2019) (Table 3).

Table 3: Percentage (no.) of occupational and physiotherapists selecting listed treatments by severity of upper limb deficit

Treatments listed by over 10% of respondents	Percentage (no.) of respondents using treatment for…		
	…mild upper limb deficits	…moderate upper limb deficits	…severe upper limb deficits
Functional training	67 (101)	42 (63)	-
GRASP*	35 (53)	35 (52)	-
Active and weighted (i.e. strengthening) exercises	19 (29)	38 (58)	-
CIMT*	17 (25)	15 (23)	-
Task (i.e. functional-based) repetitive strength training	14 (21)	-	-
Mirror box therapy	-	19 (29)	14 (20)
Passive range of movement exercises	-	-	19 (28)
Functional electrical stimulation	-	-	14 (20)

CIMT: Constraint Induced Movement Therapy (Taub et al. 1994), GRASP: Graded Repetitive Arm Supplementary Programme (Harris et al. 2009), *Require partial active hand opening and include repetitive functional-based training (Taub et al. 1994; Harris et al. 2009). Table adapted from Stockley, R., Peel, R., Jarvis, K. and Connell, L. (2019) 'Current therapy for the upper limb after stroke: a cross-sectional survey of UK therapists', *BMJ open*, 9(9), e030262-e030262, available: http://dx.doi.org/10.1136/bmjopen-2019-030262 , an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. Full Terms at: Creative Commons — Attribution-NonCommercial 4.0 International — CC BY-NC 4.0

Interestingly, similar to a previous UK survey (McHugh *et al*. 2014), in people experiencing mild and moderate deficits, therapists reported that the most frequently used intervention was functional training (67% and 42% respectively) (Stockley *et al*. 2019). Additionally, 4/6 interventions selected for these groups included interventions that are solely (Functional training and functional-based

repetitive strength training) or primarily (GRASP (Harris *et al*. 2009), CIMT (Taub *et al*. 1994)) functional-based and 1/6 included other active (active and weighted) exercises.

In contrast, treatments involving functional-based, active and strengthening based training were not selected for people with severe deficits (Stockley *et al*. 2019). Instead respondents reported using only passive interventions, predominantly passive range of movement exercises which are not recommended to improve upper limb function (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). Other passive interventions selected included functional electrical stimulation and mirror box therapy, interventions only recommended for consideration as adjunctive interventions (Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023).

Therapy provision that is self-directed: The majority of respondents in the UK survey of therapist practices favoured a self-management approach (>70%), reporting that they provided unsupervised therapy activities to all three groups to practice over and above therapist facing rehabilitation (Stockley *et al*. 2019).

Self-management activities provided to the mild and moderate group were primarily functional and strengthening based i.e. consistent with recommendations targeting the restoration of functional movement (Stockley *et al*. 2019). However, the majority of respondents reported providing the severe group with self-management activities consistent with recommendations targeting maintenance/secondary prevention (e.g. massage/sensory re-education, positioning, advice and education, and splinting) and not functional recovery (Intercollegiate Stroke Working Party 2023).

Dose

A systematic review by Hayward and Brauer (2015) investigated the dose of activity related arm training therapy (i.e. functional-based task practice) using observational methods during acute and early to late subacute inpatient rehabilitation (mean time post-stroke 5.6 – 161 days, mild to severe arm function) (Hayward and Brauer 2015). Eight studies reported dose in time and were included (two acute and six subacute, 1009 participants from three

different countries, observational methods included behavioural mapping (n=3), video recording (n=2), or self-reporting (n=3)). Activity related arm physiotherapy and occupational therapy was practiced for a mean of 0.9-7.9 and 9.3-28.9 minutes respectively and made up 2-17% and 23-70% of a physiotherapy and occupational therapy treatment session respectively. Two additional studies reported the dose of activity related arm training as the combined mean number of movement repetitions delivered by occupational therapy and physiotherapy, and were also included (both subacute, 215 participants from two different countries, both used observation by a researcher to capture data). The mean number of arm related arm training repetitions was 32 and 23 per therapy session.

The recent UK survey on the upper limb treatment practices of 154 occupational and physiotherapists previously mentioned, reported that therapists treated the upper limb a mean of 28.9 minutes in a session (SD 18, range 7.5-80, n=154), a median of 3 sessions a week with the frequency being highest during the inpatient stay and lowest in the community (Stockley *et al*. 2019). This survey recorded the mean number of minutes engaged in *any* upper limb treatment (e.g. passive, active and functional-based) and treatment time was self-reported. These two factors may explain the increased duration of upper limb treatment reported in this survey compared to those reported in the systematic review by Hayward and Brauer (2015) (Hayward and Brauer 2015). Interestingly, in the UK survey, despite having the greatest need, the proportion of each therapy session dedicated to upper limb rehabilitation was reported to be least in those with severe upper limb deficits, 35% versus 45% and 41% in those with moderate and mild deficits respectively (Stockley *et al*. 2019). Perhaps owing to the increased difficulty standardising and recording movement repetitions in the upper limb, repetitions were not recorded in the survey.

Inequity compared to lower limb: The findings on upper limb dose reported in the systematic review by Hayward and Brauer (2015) (Hayward and Brauer 2015) and the UK survey by Stockley et al. (2019) (Stockley *et al*. 2019) are consistent with other studies which suggest that there is an increased emphasis on lower limb and mobility rehabilitation compared to upper limb rehabilitation (Bernhardt *et al*. 2004; Lang *et al*. 2009; Meadmore *et al*. 2019; Meads *et al*.

2020). For example, an observational study by Lang et al. (2009), included in the systematic review by Hayward and Brauer (2015), has previously demonstrated that around a quarter of all therapy sessions and half of all upper limb therapy sessions, involve the practice of functional-based upper limb movements, with an average of 32 functional movement repetitions (Lang *et al*. 2009). In contrast, 74% of all therapy sessions involved practicing gait and/or stairs with an average of 357 steps being performed per session (Lang *et al*. 2009).

This increased emphasis on lower limb rehabilitation compared to the upper limb likely reflects the perceived need expressed by healthcare professionals and stroke survivors to prioritise lower limb/mobility rehabilitation early after stroke to meet requirements for a safe and prompt discharge home (Meadmore *et al*. 2019; Meads *et al*. 2020). Additionally, reduced upper limb training time in the presence of greater severity (Stockley *et al*. 2019) may also, in part, reflect the increased challenges encountered restoring the more complex and varied functional-based movements typically executed by the upper limb (e.g. self-care, leisure and work) in comparison to gait which has a single purpose and utilises cyclical functional activity (Goulding *et al*. 2004; Gates *et al*. 2016).

Interestingly, recovery of the upper limb is not comparable to that observed in the lower limb. While the degree of weakness has been found to be comparable in both upper and lower limbs after stroke (Tyson *et al*. 2006), 70-80% recover walking ability (Dean and Mackey 1992; Warlow *et al*. 2003), while only around half regain some upper limb function (Broeks *et al*. 1999). Thus, as increased therapy dose is known to improve recovery (Lohse *et al*. 2014) it is possible that the difference in upper and lower limb outcomes reflects an inequitable upper limb therapy dose compared to the lower limb.

Consequently, research efforts that attempt to identify ways to successfully increase upper limb therapy dose in line with the lower limb/mobility, ideally accessible within a self-management context and to stroke survivors regardless of motor impairment severity, may greatly improve upper limb outcomes.

1.3.3.4 Summary of key challenges encompassing upper limb recovery

The high incidence and impact of upper limb dysfunction after stroke, and limited functional prognosis despite current rehabilitation efforts makes it a key stroke care priority (Pollock *et al*. 2014c).

A number of factors encompassing upper limb rehabilitation and recovery have been discussed. Once the initial injury and its severity is established, rehabilitation efforts must acknowledge potential challenges and take steps to overcome them to optimise upper limb recovery.

The pre-stroke dominance of the upper limb appears to influence the extent of upper limb motor impairment experienced by stroke survivors (Harris and Eng 2006), which may influence their drive to use it to regain lost function. The complexity and variety of upper limb movements that must be re-learned pose a considerable challenge (Gates *et al*. 2016). Currently, lower limb rehabilitation appears to be prioritised over the upper limb (Bernhardt *et al*. 2004; Lang *et al*. 2009), and the content and dose of upper limb therapy recommended for functional restoration is often not delivered, particularly in people experiencing more severe upper limb deficits (Lang *et al*. 2009; Stockley *et al*. 2019).

Increased severity of upper limb motor impairment and dysfunction predicts poor recovery (Nakayama *et al*. 1994; Kwakkel *et al*. 2003; Nijland *et al*. 2010a; Coupar *et al*. 2011). Research suggests that this more severely affected group receive less rehabilitation and less active, functional-based rehabilitation. It also suggests that this is likely due to the increased difficulties therapists and patients experience when active movement is limited (Barker and Brauer 2005; Galvin *et al*. 2009; Stockley *et al*. 2019).

The particularly poor upper limb prognosis in the presence of severe group motor impairment may well occur, at least in part, as the content and dose of rehabilitation they receive are not adequate to drive neuroplasticity to recover useful function (Wieloch and Nikolich 2006; Kleim and Jones 2008) or sufficient to minimise the secondary complications associated with reduced function and immobility (Goulding *et al*. 2004; Malhotra *et al*. 2011; Kuo and Hu 2018; Matozinho *et al*. 2019).

Impaired active digital extension is thought to be the most common motor impairment after stroke (Parker *et al*. 1986), limits functional-based rehabilitation (e.g. GRASP (Harris *et al*. 2009), CIMT (Taub *et al*. 1994)), and is associated with poor recovery (Nijland *et al*. 2010a; Stinear *et al*. 2017). Additionally, currently no principal evidence-based rehabilitation intervention has been identified to improve function in stroke survivors who lack initial active digital extension and are unable to access functional-based methods (Kwakkel *et al*. 2003; Langhorne *et al*. 2009; Langhorne *et al*. 2011; Veerbeek *et al*. 2014b; Kwakkel *et al*. 2015b). Thus, the common occurrence of active digital extension weakness and the crucial role this movement plays in assisting people to engage in recommended rehabilitation activities may be contributing to the poor upper limb outcomes observed.

1.3.4 Reducing the upper limb recovery challenge: Non-robotic dynamic hand orthoses

High-quality evidence is urgently needed on the effectiveness of novel upper limb interventions (Pollock *et al*. 2014b). Such interventions are a particular priority for stroke survivors with severe deficits, including a lack of active digital extension, who wish to regain upper limb function. Interventions that aim to permit this group to successfully access interventions such as repetitive functional-based rehabilitation that fulfil neuroplasticity principles are likely to be most beneficial.

Non-robotic dynamic hand orthoses (DHOs) are aids that are designed to assist digital extension when reduced/absent to enable improved access to functional-based upper limb activities during one-to-one and independent (i.e. self-directed) therapy. They are not controlled by a computer program, sensory feedback or information processing (Sciencing 2018; Samiksha 2020) and are, therefore, likely to be lighter, simpler to use, lower in cost and a more feasible option for use within an NHS environment.

They offer prolonged periods of stretch to the wrist and digital flexors using extensor support/tensioners (e.g. elastic bands or a system of metal springs) (Figure 7) (Franck *et al*. 2019; Saebo UK 2020).

Figure 7: A non-robotic dynamic hand orthosis

(a)



(b)



An example of a dynamic hand orthosis, the SaeboGlove (Saebo UK 2020). The orthosis consists of a glove velcroed inside a wrist splint, and elastic bands that offer variable extensor assistance. This assistance increases hand opening when it is limited, improving access to recommended rehabilitation activities. Images used with copyright permissions (Figure 7(a): Martijn Kaan (hand model), Figure 7(b): Saebo UK).

This stretch may negate secondary complications such as contractures and stiffness that occur due to stroke impairments (e.g. weakness, spasticity) (Franck *et al*. 2019; Saebo UK 2020). Such aids typically require users to have some limited active finger flexion to grasp objects when worn. Vitally, when voluntary finger flexion is relaxed the extensor supports offer extension assistance at weak joints to enable both grasp and release of objects (Figure 7) (Franck *et al*. 2019; Saebo UK 2020).

This assistance enables hand opening, even in the presence of severe digital extensor weakness (i.e. even when active extension is absent) and may allow the hand and arm to engage more actively and independently in functional rehabilitation. Additionally, it may create an opportunity to improve muscle balance, restore complex functional movements in a more manageable and staged way, and enhance “true” recovery (Franck *et al*. 2019; Saebo UK 2020). Given the complex and varied movement combinations necessary to successfully utilise the upper limb in function, such an aid may also ameliorate some of the difficulties therapists and patients experience when active movement is limited. Additionally, when worn, a DHO may act as a visual reminder to use the affected upper limb, something that may be particularly useful when spontaneous drive to use the paretic upper limb is reduced (e.g. in the presence of an inattention

or learned non-use). By enabling more self-directed and functional-based practice, DHOs may also offer a self-management intervention to improve therapy dose and functional outcomes, and when used early after stroke may reduce secondary complications associated with immobility including oedema, shoulder hand syndrome and learned non-use.

1.4 Conclusions

Stroke is a significant global health and socioeconomic concern (Feigin *et al*. 2017; Katan and Luft 2018) that is predicted to rise due to medical advances, an increase in lifestyle risk factors and an ageing and growing population (Stroke Association 2017). Investigating effective methods for its prevention, treatment, and rehabilitation is therefore essential.

Upper limb function is required for independence in everyday life tasks such as washing, dressing, cooking, and feeding (Amis 1990; Goulding *et al*. 2004; Gates *et al*. 2016). However, upper limb motor impairment (Lawrence *et al*. 2001), in particular hand opening (digital extension) weakness (Parker *et al*. 1986), is the most common impairment experienced after stroke and results in limited grasp, release and manipulation ability (Backman *et al*. 1992) and often a persistent loss of ADL independence (Sveen *et al*. 1999; Bleyenheuft and Gordon 2014).

Research suggests that upper limb recovery is likely to be best when rehabilitation includes intensive, repetitive, functional-based training (Pollock *et al*. 2014b; Veerbeek *et al*. 2014b; French *et al*. 2016; Intercollegiate Stroke Working Party 2023) and self-management interventions that facilitate self-efficacy and increased therapy engagement (Da-Silva *et al*. 2018). Although the optimal timing of upper limb rehabilitation remains uncertain (Dromerick *et al*. 2009; Veerbeek *et al*. 2014b; Kwakkel *et al*. 2016), meta-analysis evidence highlights a positive trend in favour of rehabilitation delivered in the acute to early subacute phase of recovery (i.e. <3 months post stroke) (Veerbeek *et al*. 2014b). Furthermore, early rehabilitation may also counter involuntary digital flexion if/when flexor spasticity develops and instil healthy movement behaviours early thereby enhancing true versus compensatory-based recovery.

Delivering the optimal type, amount and timing of rehabilitation is a challenge, particularly within the resource restraints in the NHS (Lang *et al*. 2009; Stockley *et al*. 2019). Additionally, this may be compounded further due to competing therapy priorities, factors that influence an individual's motivations/behaviours and call for a patient-centred treatment approach (e.g. post stroke fatigue) (Meads *et al*. 2020) or the complexity of upper limb function. Furthermore, those with severe upper limb deficits often lack sufficient voluntary movement to effectively engage in recommended rehabilitation activities in clinical and research settings creating an even bigger rehabilitation challenge (Barker and Brauer 2005; Galvin *et al*. 2009; Stockley *et al*. 2019). This may account for the particularly poor functional prognosis observed in this subgroup.

Identifying effective upper limb interventions is a high research priority for stroke survivors (Pollock *et al*. 2014b) and high-quality evidence is urgently needed on the effectiveness of repetitive functional-based rehabilitation and novel approaches (Pollock *et al*. 2014b). Non-robotic DHOs are mechanical rehabilitation aids that could enable stroke survivors with digital extensor weakness to better access intensive, repetitive, functional-based upper limb rehabilitation that is recommended for improved upper limb outcomes early after stroke, regardless of digital extensor weakness severity and in a 1:1 and self-practice format (Franck *et al*. 2019; Saebo UK 2020). Thus non-robotic DHOs may have the potential to improve upper limb outcomes thereby helping to address a key stroke care need.

1.5 Research aims

This programme of research aimed to summarise and progress the existing evidence base on the use of non-robotic DHOs as a novel rehabilitation aid with potential to improve upper limb recovery after stroke.

1.5.1 Research objectives

1. Summarise the current evidence base on the use of non-robotic DHOs after stroke by carrying out a:

    a. Scoping review to map and synthesis existing research on it, and

   b. A systematic review of RCTs to assess the evidence on its effect on upper limb recovery

2. Progress the current evidence base on the use of non-robotic DHOs after stroke. This will involve conducting research involving a non-robotic DHO intervention developed by the author prior to this doctorate (The EMPOWER Help for Hands Programme) to:

   a. Refine and evaluate its effectiveness on upper limb function
   b. Explore factors relating to support that moderate implementation of/engagement with it from a stroke survivor, carer, and therapist perspective

These aims and objectives will be addressed through a programme of research.

Chapter 2 reports the scoping review and systematic review of RCTs on non-robotic DHOs after stroke.

Chapter 3 describes the methodology for a study conducted as part of this thesis to evaluate upper limb recovery outcomes (outcome evaluation) and processes influencing them (process evaluation) in relation to the EMPOWER Help for Hands Programme.

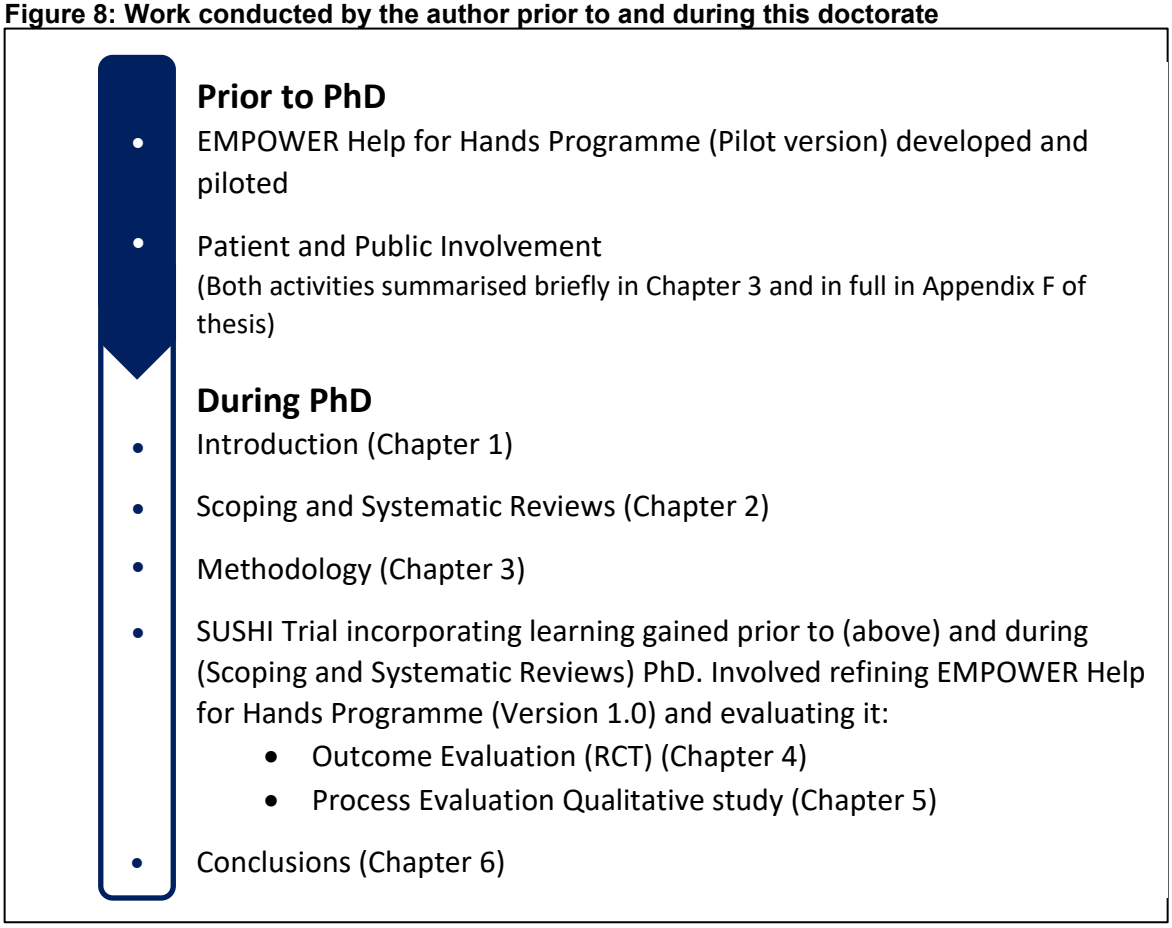
Chapter 4 reports the design, methods, and findings of the outcome evaluation (a RCT) of the EMPOWER Help for Hands Programme.

Chapter 5 reports the design, methods, and findings of a process evaluation on the EMPOWER Help for Hands Programme that was delivered and embedded within the outcome evaluation. It involved a descriptive qualitative analysis of patient, carer and therapist perceived self-management support needs, barriers, and facilitators for clinical implementation from interviews.

The concluding chapter, Chapter 6, will highlight the key findings and limitations of the programme of research presented and offer some direction for future related research.

Figure 8 below summarises work conducted by the author prior to and during this thesis.

Figure 8: Work conducted by the author prior to and during this doctorate



Chapter 2

Non-robotic dynamic hand orthoses in stroke rehabilitation: A scoping and systematic review of the current evidence-base

2 Chapter 2: Non-robotic dynamic hand orthoses in stroke rehabilitation: A scoping and systematic review of the current evidence-base

2.1 Introduction

As previously outlined in Chapter 1, upper limb dysfunction after stroke has a high incidence (Broeks *et al*. 1999; Lawrence *et al*. 2001; Feigin *et al*. 2017), and personal and societal impact (Bonita and Beaglehole 1988; Lai *et al*. 2002; Morris *et al*. 2013), making identifying new evidence-based upper limb interventions a recognised stroke care priority (Pollock *et al*. 2014c). In particular, the current absence of evidence-based interventions identified to improve function in those with impaired active digital extension was discussed (Kwakkel *et al*. 2003; Langhorne *et al*. 2009; Langhorne *et al*. 2011; Veerbeek *et al*. 2014b; Kwakkel *et al*. 2015b) and the need to progress the evidence-base for this group was highlighted as meriting special research attention.

In Chapter 1, non-robotic dynamic hand orthoses (DHOs) were also proposed as offering a possible means to enable this group to overcome the difficulties they currently encounter accessing rehabilitation activities recommended to improve upper limb recovery in clinical guidelines (functional-based practice and self-practice activities) (Scottish Intercollegiate Guidelines Network 2010; Intercollegiate Stroke Working Party 2016; Winstein *et al*. 2016a; Teasell *et al*. 2020; Stroke Foundation 2022). Given that impaired active digital extension is thought to be the most common motor impairment experienced after stroke (Parker *et al*. 1986), and is one of the factors known to accurately predict poor recovery (Smania *et al*. 2007; Nijland *et al*. 2010a; Stinear 2010), identifying an evidence-based intervention for this group could address a key stroke care need.

This chapter will examine the current evidence-base on the use of non-robotic DHOs after stroke. Part 1 will include a scoping review to identify and summarise the breadth of evidence available. Part 2 will include a systematic review with meta-analysis of Randomised Controlled Trials (RCTs). This will allow the author to develop skills in both research methods and offer both a broad subjective overview of the existing stroke literature (Part 1), and an

objective analysis of the best evidence (Part 2) currently available on the use of non-DHOs after stroke.

2.2 Part 1: Non-robotic DHOs in stroke rehabilitation: A scoping review of the current evidence-base

2.2.1 The role of a scoping review

Scoping reviews are increasingly utilised to review health research evidence (Munn *et al*. 2018). They aim to systematically identify and map the range of evidence that is available on a specific subject (Davis *et al*. 2009; Munn *et al*. 2018; Munn *et al*. 2022) i.e. to provide a broad overview of the evidence. They are defined as:

> "…a type of evidence synthesis that aims to systematically identify and map the breadth of evidence available on a particular topic, field, concept, or issue, often irrespective of source (i.e. primary research, reviews, non-empirical evidence) within or across particular contexts." (Munn *et al*. 2022, p.950)

Scoping reviews are useful for examining emerging evidence, particularly in new areas when it is still uncertain what evidence is available (e.g. the type of studies conducted, intervention formats tested, patients selected, timing/content of treatment provided etc). This can be particularly useful when it is unclear what other, more specific questions (e.g. on treatment feasibility or effectiveness) can be addressed by a more structured and focused systematic review (Armstrong *et al*. 2011).

2.2.2 Objective

The use of non-robotic DHOs in stroke is a new area of research thus, a scoping review was conducted:

1. To identify and summarise the existing evidence on the use of non-robotic DHOs in stroke rehabilitation in adults including any RCTs available that could subsequently be used to conduct a systematic review of RCTs

2.2.3 Methods

The scoping review followed a predefined protocol for a systematic review of RCTs (Alexander *et al*. 2021a) (Appendix A) registered on PROSPERO, an international database of prospectively registered **systematic reviews** in health and social care for a systematic review (National Institute for Health Research 2020) (CRD42020179180, 20/05/2020, Appendix B) with one main exception. As well as including RCTs, other study designs were also included as described below.

Relevant reporting guidelines for scoping reviews were followed (Preferred Reporting Items for Systematic reviews and Meta-Analysis Extension for Scoping Reviews (PRISMA-ScR) (Tricco *et al*. 2018).

2.2.3.1 Eligibility criteria

The eligibility criteria for included studies are listed below by population, intervention, comparator, outcomes and study characteristics, according to the PICOS (Population, Intervention, Comparison, Outcomes, Study) strategy recommended in the PRISMA guidelines (Moher *et al*. 2009; Page *et al*. 2021). Criteria were adapted from an existing Cochrane upper limb rehabilitation review (Coupar *et al*. 2012).

Participants: Adults (≥18 years) with a clinical diagnosis of stroke including ischaemic, intracerebral haemorrhage or subarachnoid haemorrhage and any anatomical location, as defined by the World Health Organisation's definition "rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours.." (Hatano 1976, p.541) were included if they had associated upper limb impairment. Participants were permitted from any setting (e.g. hospital, community, home), and groups of participants with other neurological diagnoses were included if ≥50% had a stroke.

Intervention: The study intervention included a non-robotic dynamic hand orthosis (DHO) rehabilitation programme with the main goal being to provide repetitive, functional practice to improve upper limb functional recovery. RCTs

and Systematic reviews of RCTs were included where one group received the study intervention if it was the only intervention or the only intervention over and above usual care where the intervention was provided and supervised by a healthcare professional. Other studies were included where one group received the study intervention if it was the only intervention or provided in combination with a secondary intervention.

Studies involving resting hand orthoses were excluded as they immobilise the hand with the goal of providing a low-load prolonged static stretch to prevent soft tissue contractures and preclude functional upper limb use when worn.

Comparator: RCTs and systematic reviews of RCTs were included where a comparator group received either placebo or no intervention, or usual care. Other studies (e.g. non-RCTs) were included if a comparator group received one or more interventions or if no comparator group was included.

Outcome measures: Studies were included if they measured upper limb recovery in one of the following pre-defined outcome domains (Coupar *et al.* 2012):

Co-primary outcomes

Functional movement of the upper limb (such as measures of active movement, co-ordination, dexterity, manipulation and grasp/grip/pinch)

Performance in Activities of Daily Living (ADL) (including feeding, toileting, dressing, bathing, grooming, continence, simple mobility and transfers)

Secondary outcomes

Performance in instrumental ADL (including shopping and household tasks)

Motor impairment of the upper limb (such as measures of general upper limb impairment, muscle strength and muscle tone)

Additional outcomes

Adverse events (such as death and pain)

Timings of outcomes were recorded, and analyses were performed on data on the outcomes of interest post intervention and at follow-up visit, if available.

Study type: RCTs and systematic reviews of RCTs were included where each participant had an equivalent chance of being allocated to a given treatment. Other studies (e.g. non-RCTs) were included if they fulfilled the eligibility criteria. Limits for geographical location or language were not set. Studies were selected from the year 2000 to reflect the time period that repetitive functional-based practice started to attract interest as a potentially beneficial post-stroke intervention (Van Peppen *et al*. 2004; French *et al*. 2009; Cooke *et al*. 2010; Lohse *et al*. 2014; Pollock *et al*. 2014b; Veerbeek *et al*. 2014b; French *et al*. 2016; Intercollegiate Stroke Working Party 2016).

2.2.3.2 Search strategy and study selection

A systematic search of available literature between 1st January 2000 – 27th September 2019 was performed. The search strategy, shown below, was generated using key search terms identified for the population and intervention using keywords, medical subject headings and search terms used in a Cochrane review (Coupar *et al*. 2012) in conjunction with a medical librarian (CD) within NHS Greater Glasgow and Clyde and two researchers in the authors supervisory team.

Search strategy

1 Orthotic Devices/
2 Splints/
3 (dynamic or functional or outrigger or dorsal or extended or extension or soft or saebo or dynsyst).mp.
4 (splint* or orthos* or orthotic or device* or glove*).mp.
5 3 and 4
6 upper extremity/ or arm/ or elbow/ or forearm/ or hand/ or fingers/ or thumb/ or metacarpus/ or wrist/ or shoulder/
7 (upper adj3 (limb* or extremit*)).mp.
8 (arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder*).mp.

9 6 or 7 or 8
10 1 or 2
11 3 and 10
12 exp stroke/
13 cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebrovascular trauma/ or exp intracranial arterial diseases/ or intracranial arteriovenous malformations/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or vasospasm, intracranial/
14 exp brain infarction/
15 (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc* or cva* or apoplex* or SAH).mp.
16 ((brain* or cerebr* or cerebell* or intracran* or intracerebral) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus*)).mp.
17 ((brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)).mp.
18 12 or 13 or 14 or 15 or 16 or 17
19 Hemiplegia/
20 exp Paresis/
21 (hemipleg* or hemipar* or paresis or paretic or impair* or weakness).mp.
22 19 or 20 or 21
23 5 or 11
24 9 and 18 and 22 and 23
25 limit 24 to yr="2000 -Current"
26 limit 25 to english language
27 25 not 26

Grey literature was included to reduce publication bias by performing additional searches for doctoral theses and dissertations in The British library (EThOS), conference proceedings in Web of Science (Core Collection) and registered trials in clinicaltrials.gov (Appendix C). Additionally, secondary citations from

included studies, including any reviews, were searched to identify further relevant studies.

Resources advocated to improve transparency, accuracy and reproducibility of reviews were utilised to identify eligible studies from searches performed (Columbia University Irving Medical Center Health Sciences Library 2020; The Cochrane Collaboration 2020b) . Bibliographic software (EndNote Basic X9) (Web of Sciences Group 2020) contributed to the systematic search methods utilised by providing a means to store, organise and manage references.

Covidence software (Covidence 2020) that enables multiple investigators to simultaneously include or exclude references on a shared web-based system was the primary method utilised to identify and screen papers, and record accurate records on the selection process.

Three reviewers were involved in applying the eligibility criteria and selecting studies for inclusion in the review (JA, JD, PL). Initially one reviewer (JA) uploaded and screened all database titles identified in EndNote software (Web of Sciences Group 2020), deleted duplicates and excluded any that were clearly not eligible for inclusion.

Due to resource limitations the screening process differed slightly for RCTs and non-RCTs:

RCTs: Remaining titles were then uploaded to Covidence software (Covidence 2020) along with their abstracts. In Covidence, two reviewers then independently screened all abstracts for RCT eligibility, rating them by selecting either "No", "Maybe" or "Yes" (JA and either JD or PL). Disagreements between individual judgements were resolved through discussion, with the help of a third reviewer where appropriate. Studies were considered ineligible only if both reviewers selected "No". The full texts of all remaining studies were then uploaded to Covidence where two reviewers independently screened them, rating them by selecting either "Include" or "Exclude" (JA and either JD or PL). Disagreements between individual judgements were resolved through discussion, with the help of a third reviewer where appropriate. Studies were considered

ineligible if both reviewers rated the full text of a study with "Exclude". All remaining studies were included in the review.

Non-RCTs: Abstracts of remaining non-RCTs were screened for eligibility, rating them as either "No", "Maybe" or "Yes" (JA). Any studies judged to 'maybe' be eligible were accessed in full and, if necessary, shared and discussed with a second reviewer (JD or PL). Such studies were considered ineligible only if both reviewers selected "No" after discussion or if full text for these studies could not be found. All remaining studies were included in the review.

2.2.3.3 Extraction of data from included studies

To improve reliability, the data to be extracted was agreed collaboratively by all reviewers (JA, JD, and PL). The extraction form was then pilot tested using four included papers in excel (JA) and utilised for data extracted for non-RCTs (JA). An electronic version of the form was created in the Covidence software (Covidence 2020) for all reviewers to access and use for RCTs (JA and either JD or PL).

Reviewers extracted data on characteristics of included studies where available: study (author, year, design), country, setting, population (no. of participants recruited, inclusion/exclusion criteria, other), intervention and comparator treatment details (intervention period, training duration & frequency, format (e.g. 1:1, group, self-practice), training task type (e.g. stretching, repetitive functional practice etc), number, training intensity set (e.g. time/repetitions), support (e.g. therapist, carer), adherence (1:1, self-practice, etc), outcome measures of interest and follow up timeline. Similarly, the same reviewer(s) independently extracted data on characteristics of participants in the included studies by group: number recruited, age, gender (male/female), stroke type (ischaemic/haemorrhagic), time since stroke, number of participants who's affected upper limb was right, left and dominant, severity descriptors (e.g. cognition, upper limb impairment/function). Due to resource limitations authors of RCTs only were contacted in an attempt to seek clarification when required (JA).

2.2.3.4 Data synthesis and analysis

No evaluation of methodological quality was carried out as the goal was to give an overview of the study field rather than to analyse the strength of the supporting data for a particular intervention (Arksey and O'Malley 2005).

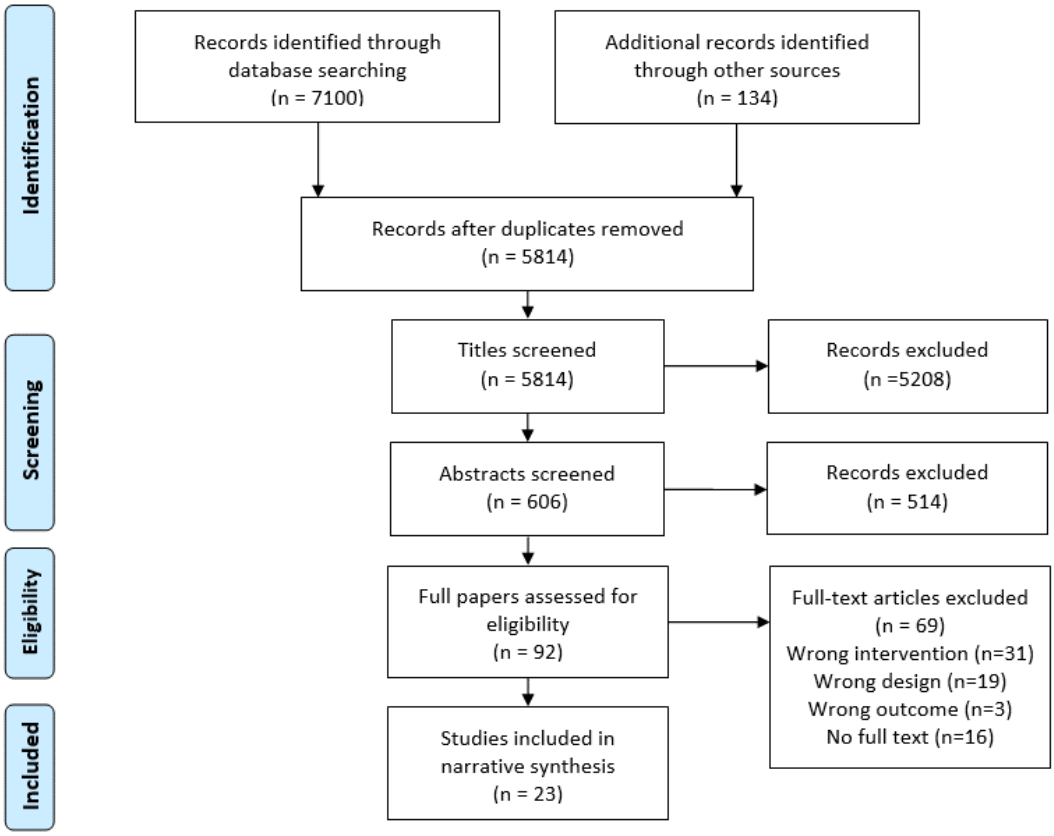
Extracted data were tabulated and a narrative synthesis was provided summarising the existing evidence on the use of non-robotic DHOs in stroke rehabilitation in adult stroke survivors with upper limb impairment.

2.2.4 Results

2.2.4.1 Search

The search identified 7234 titles leaving 5814 titles after 1420 duplicates were removed. Title review identified 606 records for abstract review. Of these, 92 records were sought in full text and screened leaving 23 studies for inclusion (Figure 9).

Figure 9: Study selection flow diagram for scoping reviews



PRISMA study selection flow diagram adapted from Page et al. 2021, available at: The PRISMA 2020 statement: an updated guideline for reporting systematic reviews (bmj.com) under a Creative Commons CC BY 4.0. Full Terms at: Creative Commons — Attribution 4.0 International — CC BY 4.0

2.2.4.2 A narrative synthesis of included studies

Characteristics of included non-RCT participants and studies are summarised in Table 4 (overleaf). Characteristics of included RCT participants and studies are summarised in Tables 5 and 6 (overleaf) respectively.

Table 4: Details of included non-RCT participants and studies

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Davenport *et al*. 2005; CR; UK; NR - assume 1 week in clinic, then home	2; Inclusion: NR ; Exclusion NR P1 : Male, 12 months post stroke, 33 years, reduced proximal ROM, increased distal flexor and pronation spasticity, main goal to open hand to shake hands P2: Female, 12 months post stroke, 52 years, reduced proximal movement, increased distal weakness (flicker in index, nil activity in other digits), main goal to hold object e.g. saucepan.	1:1 input daily from trainer over 5 days in 1 week – Task specific training activities wearing a DHO (SaeboFlex) (45 minutes, up to 6 times, mean 4 times), FES of wrist/digital extensors (one, 20 minute session), SaeboGlide (1-2 sessions to facilitate shoulder activity). Trainer discipline NR but author(s) include PT. Self-practice – Advice to work actively in DHO for 1-2 hrs daily for 6 months. Help NR.	N/A	Upper limb ROM, upper limb section of Motor Activity Scale, patient set goals scored on a Likert and Visual Analogue Scale, grasp and release of different objects, 10 m walk, adverse events: NR; at end of week 1, 3 months into intervention, post intervention.
		Adherence: mean of 4 daily 45 minute sessions in week 1.		

CR: Case Report, DHO: Dynamic Hand Orthosis, FES: Functional Electrical Stimulation, NR: Not Reported, P: Participant, PT: Physiotherapist, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Barry *et al.* 2006 ; PTPT; USA; NR - assume in clinic and home	5; Inclusion: Chronic hemiparesis post stroke and did not qualify for CIMT due to limited active wrist/digital extension, Exclusion: NR. Mean time post stroke = 5.98 years; 1 woman and 4 men, mean age = 58.2 years; all right handed, 3 exhibited right and 2 left hemiparesis.	Self-practice with carer involvement – Advice to practice task specific training activities wearing a DHO (SaeboFlex) using a HEP provided (45 minutes, twice daily, 6 weeks). 1:1 PT weekly check of DHO fit and compliance.	N/A	ARAT, grip strength with a dynamometer, wrist extension passive ROM and wrist and finger extension manual muscle test, adverse events: NR; post intervention.
		Adherence: NR		

ARAT: Action Research Arm Test, CIMT: Constraint Induced Movement Therapy, DHO: Dynamic Hand Orthosis, HEP: Home Exercise Programme, NR: Not Reported, PT: Physiotherapist, PTPT: Pretest-posttest design, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Butler *et al*. 2006; CR; USA; NR - assume in clinic and home	1; Inclusion: NR; Exclusion NR P1: Male, 12 months post stroke, 44 years, expressive aphasia, MMSE ≥24, able to follow procedures, 120° ROM against gravity at the shoulder and elbow with flexor synergy, 20° against gravity at the wrist, and no finger extension, light touch and proprioception were intact, extremely motivated, reliable family support, medically well, did not qualify for CIMT due to limited active wrist/digital extension, FMUE 41-46.	1:1 OT input, 6 hours daily over 10 days in 2 week – Task specific training activities wearing a DHO (SaeboFlex) (45 minutes, 4 times, mean 4 times), stretching (two, 25 minute sessions), FES of wrist/digital extensors (two, 20 minute sessions). Self-practice – After initial 2 weeks advised to work actively in the DHO for 45 minutes, stretch with the Unilateral SaeboGlide for 20 minutes and use FES for 20 minutes daily (duration: NR), training diary used.	N/A	FMUE, active/passive range of motion, mAS, Wolf Motor Function Test, SIS, MAL, self-report pain and fatigue levels on a Likert 0-10 scale, adverse events reported; at end of week 2, 3 and 7 months into self-practice.
		Adherence: compliant with advice 5 days a week for 9 weeks then stopped - surgery.		

CIMT: Constraint Induced Movement Therapy, CR: Case Report, DHO: Dynamic Hand Orthosis, FES: Functional Electrical Stimulation, FMUE: Fugl Meyer Upper Extremity Score, MAL: Motor Activity Log, mAS: modified Ashworth Scale, MMSE: Mini Mental State Examination (Cognitive impairment) - ≤9 = severe, 10-19 = moderate, 20-25 = mild, 26-30 = nil (Vertesi *et al.* 2001), NR: Not Reported, OT: Occupational Therapist, P: Participant, ROM: Range of Movement, SIS: Stroke Impact Scale

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Farrell *et al*. 2007; PTPT; USA; NR - assume in clinic	13; Inclusion: >6 months post stroke, ≥18 years, follows verbal multi-part instructions, Active ROM ≥10◦ shoulder flexion/abduction and elbow flexion/extension, ¼ finger flexion with wrist and fingers held in extension, can stand up from a chair and stand for 2 minutes without an assistive device, independent in self-care or caretaker; Exclusion: Flaccid upper limb, hand/wrist deformities/contractures, full active ROM wrist and finger extension. 6 woman and 7 men, mean (SD) time post stroke = 4.1 (3.9) years, age = 54.1 (13.8) years; 9 were paretic on the left and 4 were paretic on the right, FMUE 25.7 (5.7).	1:1 input from trainer, 6 hours daily over 5 days in 1 week – Task specific training activities with light objects e.g. a ball wearing a DHO (SaeboFlex) plus customised exercise (2-3, 30 minute sessions of strengthening (proximal mainly), motor control and range of motion) and FES of wrist/digital extensors with active ROM (20 minute session). Trainer discipline NR but author(s) include PT.	N/A	Active ROM shoulder, elbow, wrist (goniometer), fingers (full/partial), FMUE, Motor Status Score, mAS in 9 muscle groups, adverse events; post intervention.
		Adherence: NR		

DHO: Dynamic Hand Orthosis, FES: Functional Electrical Stimulation, FMUE: Fugl Meyer Upper Extremity Score, mAS: modified Ashworth Scale, NR: Not Reported, PT: Physiotherapist, PTPT: Pretest-posttest design, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Heise *et al*. 2010; PTPT; Germany; NR - assume in clinic then home	13; Inclusion: chronic hemiparesis with initial severe impairment of UL function (inability to actively extend fingers and wrist), Exclusion: NR. Mean (SD) time post stroke = 38.1 (34.1) months, age = 51.8 (14.5) years; FMUE 22.7 (6.2), 6 were paretic on the left and 7 were paretic on the right, Gender: NR.	1:1 with trainer over 5 consecutive days to train participants how to use a DHO (SaeboFlex). Trainer discipline NR but author(s) include PT. Self-practice (with/without carer) – After 1:1 input advised to practice & log adherence in tailored grasp/release programme e.g. of ball for at least 1 hour/day (duration: NR)	N/A	Active ROM, FMUE, ARAT, grip force, adverse events: NR; post intervention, 4 weeks follow-up (4wFU) and 3 months (3mFU) after initial training phase
		Adherence: NR		
Gollega *et al*. 2012; PTPT; Canada; NR - assume home	6; Inclusion: stroke greater than 2 years with reduced grasp/release function; Exclusion: NR Baseline characteristics: NR	SaeboFlex orthosis used 3–4 times/week over a 6 months period to practice grasp and release oriented tasks. Trainer details NR but author(s) from brain rehabilitation centre.	N/A	ROM, mAS, Grip Strength, ARAT, Manual Functional Test, Chedoke McMaster Inventory (Arm/hand portion), COPM, adverse events: NR; post intervention.
		Adherence: NR		

ARAT: Action Research Arm Test, COPM: Canadian Occupational Performance Measure, DHO: Dynamic Hand Orthosis, FMUE: Fugl Meyer Upper Extremity Score, mAS: modified Ashworth Scale, NR: Not Reported, PT: Physiotherapist, PTPT: Pretest-posttest design, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Franck *et al.* 2013; CE; Netherlands; outpatient group setting and home	8; Inclusion: <3 months post stroke, problems with ADL due to a moderately to severely impaired upper limb, no severe cognitive or communication problems, clinically diagnosed with a paresis of the arm and hand (Active ROM ≥10-20◦ shoulder flexion/abduction and elbow flexion/extension, finger flexion ≥1/4 active interphalangeal flexion during passive wrist extension >15◦ starting with full extension of the fingers, passive ROM wrist extension (≥15-35◦ with metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints in extension; Exclusion: serious problems regarding vision or hearing, severe arm oedema, severe shoulder pain, insufficient understanding of the Dutch language. Mean (SD) time post stroke = 9.3 (5.2) weeks, age = 54.5 (16.9) years, 2 were paretic on the left and 6 were paretic on the right.	Conventional therapy plus meaningful goal setting x3 with OT, teaching regarding training possibilities, care and daily life integration of hand/arm, 5 minutes goal work then 45 minutes of task specific training activities e.g. with a ball wearing a DHO (SaeboFlex) fitted by a certified therapist then 15 minutes goal work five days/week (3 in rehabilitation group setting, 2 at home), 6 weeks). Adherence: NR	N/A	ARAT, ABILHAND, adverse events; measurement during and post intervention.

ADL: Activities of Daily Living, ARAT: Action Research Arm Test, CE: Case Experiment, DHO: Dynamic Hand Orthosis, NR: Not Reported, OT: Occupational Therapist, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Prange et al. 2014 ; PTPT ; Netherlands, UK, Italy; home	23; Inclusion: 6 months - 5 years post stroke, 18-80 years, active ROM (≥15˚ active elbow flexion, ≥1/4 finger flexion), not full active function of wrist and hand, able to accommodate the SCRIPT1 system at home; Exclusion: NR. Mean age 58 years, mean time post-stroke 17 months, Gender: NR.	Self-practice - Advised to do 180 minutes per week (or more/less if preferred) for 6 weeks with a custom DHO (SCRIPT) plus SaeboMAS proximal arm training with 100% of arm weight compensation. Involved using custom-designed games displayed on a touchscreen and grasp of cube(s) while supervised remotely, off-line, by a trained healthcare professional. 1:1 home visit – Health care professional adjusted DHO support and tasks performed weekly.	N/A	FMUE, ARAT, adverse events: NR; post intervention and 2 months follow up.
		Adherence: Mean 107 minutes/week.		

ARAT: Action Research Arm Test, DHO: Dynamic Hand Orthosis, FMUE: Fugl Meyer Upper Extremity Score, NR: Not Reported, PTPT: Pretest-posttest design, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Woo *et al*. 2013; CE; Korea; NR – assume in clinic	5; Inclusion: unilateral hemiparesis without orthopaedic or surgical histories, >6 months post-stroke, MMSE ≥23; active ROM (≥10° of shoulder flexion/abduction, ≥10° of elbow flexion/extension, ≥30° of interphalangeal proximal joints, ≥20° of interphalangeal distal joints with wrist/finger held in extension); Exclusion: NR. 2 males, 3 females, age 40-73 years, MMSE 26-30, 19-40 months post stroke, 3 were paretic on the left and 2 were paretic on the right, ARAT 22.20 (14.60).	1 hour of task specific training activities (9 ball moving tasks) wearing a DHO (SaeboFlex), five days per week for 4 weeks. Format: NR. Trainer discipline NR but author(s) include PTs. Adherence: NR	N/A	FMUE, BBT, ARAT, and Kinematics using a three-dimensional motion analysis system, adverse events: NR; post intervention.

ARAT: Action Research Arm Test, BBT: Box and Block Test, CR: Case Report, DHO: Dynamic Hand Orthosis, FMUE: Fugl Meyer Upper Extremity Score, MMSE: Mini Mental State Examination (Cognitive impairment) - ≤9 = severe, 10-19 = moderate, 20-25 = mild, 26-30 = nil (Vertesi *et al.* 2001), NR: Not Reported, PT: Physiotherapist, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Chang & Lai 2015; PTPT; China; rehabilitation dept in medical centre	10; Inclusion: Brunnstrom stage III for the ipsilateral upper extremity and distal hand movements, with scores of <2.5 on the motor activity log, and MMSE >24; Exclusion: Aphasia. Mean (SD) age 50.21 (13.27) years, time post-stroke 3.17 (0.98) years, FMUE 38.2 (2.32), Gender: NR.	Conventional rehabilitation plus self-practice - Advised to do 30 minutes per session, 5 times/week for 3 months with a DHO (customised). 1:1: Therapists involved but input NR, Self-practice involved following a rehabilitation programme that targeted recovery of finger extension for function, trained by a PT.	N/A	Maximal voluntary contraction by electromyography, grip and finger strength appraisals, FMUE, adverse events: NR; 1 and 3 months into intervention.
		Adherence: NR		

DHO: Dynamic Hand Orthosis, FMUE: Fugl Meyer Upper Extremity Score, MMSE: Mini Mental State Examination (Cognitive impairment) - ≤9 = severe, 10-19 = moderate, 20-25 = mild, 26-30 = nil (Vertesi *et al.* 2001), NR: Not Reported, PT: Physiotherapist, PTPT: Pretest-posttest design

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Chen *et al.* 2017; PTPT; China; clinic and home	10; Inclusion: >6 months post-stroke, reduced active ROM hand opening, difficulty performing reach and grasp tasks, trace ability to extend the wrist and fingers and full passive wrist ROM. Exclusion: NR. 7 males, 3 females, age 36-69 years, 15-106 months post stroke, 6 were paretic on the left and 4 were paretic on the right, ARAT 9-33.	Self-practice - Advised to do 90 minutes per session, 5 times/week for 4 weeks with a DHO (HandSOME). Self-practice involved following object manipulation tasks prescribed by a PT (e.g. water bottle, pill bottle, pen, large object (3-4" width), small object (1/2-3/4" width), jar with lid). 1:1 home visit – PT adjusted DHO support and tasks performed weekly.	N/A	FMUE, ARAT, MAL, mAS elbow, wrist and fingers, active ROM thumb/fingers, hand path ratio during reach, grasp and release, and grip strength, adverse events: NR; post intervention and follow up 3 months after intervention finished.
		Adherence: 448 ± 651 movements per day recorded by device.		

ARAT: Action Research Arm Test, CE: Case Experiment, DHO: Dynamic Hand Orthosis, FMUE: Fugl Meyer Upper Extremity Score, MAL: Motor Activity Log, mAS: modified Ashworth Scale, NR: Not Reported, PT: Physiotherapist, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Doucet et al. 2018; PTPT; USA; NR - assume clinic	4; Inclusion: Ischemic or haemorrhagic stroke >6 months ago, 20-85 years, active ROM (approximately 10˚ wrist or digit movement), able to communicate orally and provide informed consent; Exclusion: People with conditions that contraindicate electrical stimulation (implanted electronics, pacemakers, etc). All male and non-dominant left hemiparesis, age 28-63 years, time post-stroke 8-18 months.	1:1 – Participants carried out repetitive task training using a 4 inch foam ball, wearing a DHO (SaeboFlex) daily for 30 min, 5 day/week for 6 weeks followed by a 15 minute FES session involving the wrist/digital extensors guided by an OT. Adherence: NR	N/A	Grip strength and AROM of the wrist and third metacarpophalangeal (MCP) joint (flexion/extension), EMG data of forearm extrinsic hand muscles during grasp release in the hemiplegic hand, AMPS, adverse events; post intervention.

DHO: Dynamic Hand Orthosis, FES: Functional Electrical Stimulation, NR: Not Reported, OT: Occupational Therapist, PTPT: Pretest-posttest design, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Pooyania and Semenko 2014; 3 year RCR; Canada; outpatient occupational therapy setting & home	14; Inclusion: All stroke patients referred to outpatient occupational therapy for an upper extremity rehabilitation program; Exclusion: NR. 12 males, 2 females, mean age 56 (21-76) years, 7-74 months post stroke, 9 were paretic on the left and 5 were paretic on the right.	Upper extremity rehabilitation program, which included the use of a DHO (SaeboFlex) at home and with OT visits (n=11), intended dose/duration: NR.	Upper extremity rehabilitation program, which included the use of a DHO (SaeboFlex) guided by an OT plus concurrent botulinum toxin type-A (n=3).	Active ROM (shoulder, elbow, wrist, digits), grip and lateral pinch strength, mAS (elbow, wrist and finger flexors (summed)), FMUE and the COPM scores, adverse events: NR; post intervention.
		Adherence: 1-14 sessions/week.		

COPM: Canadian Occupational Performance Measure, DHO: Dynamic Hand Orthosis, FMUE: Fugl Meyer Upper Extremity Score, mAS: modified Ashworth Scale, NR: Not Reported, OT: Occupational Therapist, PTPT: Pretest-posttest design, RCR: Retrospective Chart Review, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Davenport et al. 2011; PTPT; UK; acute ward or home	10; Inclusion: ≤12 weeks of first stroke, active ROM (≥10◦ shoulder and elbow, ≥1/4 range finger flexion in their affected upper limb, able to follow a rehabilitation programme. 7 male, 3 female, age 50-83 years, 6 were ≤6 weeks post stroke and 4 were 6-12 weeks post stroke, Mean (SD) ARAT 1.7 (2.6).	Conventional therapy plus 20, 45 minute therapy sessions (duration: NR) using a DHO (SaeboFlex) with/without help to perform task orientated reach and grasp activities involving moving and placing foam balls. A home exercise programme was developed for each participant to allow continuance of practice during and at the end of the intervention. 1:1 therapy inferred but detail NR, Trainer discipline NR but author(s) include PTs.	N/A	ARAT, other NR secondary measures, adverse events; post intervention and 6 month follow up.
		Adherence: NR		

ARAT: Action Research Arm Test, DHO: Dynamic Hand Orthosis, NR: Not Reported, PT: Physiotherapist, PTPT: Pretest-posttest design, ROM: Range of Movement

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Rickards et al. 2014; PTPT; UK; acute setting	19; Inclusion: Fulfilled DHO (SaeboFlex) inclusion criteria (i.e. hand weakness, unable to use hand in ADL (Saebo UK 2023)); Exclusion: NR Baseline characteristics: NR.	Self-practice - 45 minute therapy sessions using a DHO (SaeboFlex) to perform task orientated reach and grasp activities (intended duration: NR). 1:1 – Review by OT or PT once a week or less once established.	N/A	FMUE and video analysis, adverse events: NR; post intervention.
		Adherence: Mean duration of use 12 (2-24) weeks, training time: NR.		

ADL: Activities of Daily Living, DHO: Dynamic Hand Orthosis, FMUE: Fugl Meyer Upper Extremity Score, NR: Not Reported, OT: Occupational Therapist, PT: Physiotherapist, PTPT: Pretest-posttest design

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Stuck et al. 2014; CR; UK; inpatient or home	8; Inclusion: Anterior circulation stroke patients, ≤12 weeks post stroke, substantial paresis of the arm and hand (≥15° active ROM elbow and shoulder, some active finger flexion, pre-morbid fully functional upper limb, and medically fit to participate in therapy; Exclusion: NR. 4 male, 4 female, mean (SD) age 70 (15) years, days post stroke 21 (13.1), ARAT 10 (8.2).	Conventional therapy, plus self-practice – 12 week therapy programme using a DHO (SaeboFlex) (maximum intensity: 3 × 45 minutes a day). 1:1 – Review at least once a week by therapist (discipline NR).	N/A	ARAT, upper limb MI, MAS (upper limb section), MBI, Visual Analogue Scale, SIS, End of study questionnaire, adverse events; post intervention. Interim measures taken at 4 and 8 weeks: ARAT, MI and MBI.
		Adherence: 1-2 sessions/day, 5-15 minutes/day, grasp/release repetitions 12-500/day.		

ARAT: Action Research Arm Test, CR: Case Report, DHO: Dynamic Hand Orthosis, mAS: modified Ashworth Scale, MAS: Motor Assessment Scale, MBI: Modified Barthel Index, MI: Motricity Index, NR: Not Reported, ROM: Range of Movement, SIS: Stroke Impact Scale

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Alexander and Dawson 2019; PTPT; UK; inpatient setting then home	12; Inclusion: stroke inpatients with reduced active finger extension judged to be able to participate in rehabilitation (with/without help of a carer).; Exclusion: NR. Mean (range) age 62 (47– 80) years, days post stroke 27 (4–80), ARAT score 15.9 (0–44), Gender: NR.	Conventional therapy, plus self-practice – 4 week repetitive functional-based therapy programme using a DHO (SaeboGlove) to work towards individual goals. 1:1 – Review by PT once a week.	N/A	ARAT, BBT, MAL (quality, quantity and percentage of tasks executed), adverse events; post intervention plus adverse events and glove durability.
		Adherence: All participants completed the trial performing therapy on 85% of available days (mean repetitions 81.2 per session).		

ARAT: Action Research Arm Test, BBT: Box and Block Test, DHO: Dynamic Hand Orthosis, MAL: Motor Activity Log, NR: Not Reported, PT: Physiotherapist, PTPT: Pretest-posttest design

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Semenko 2017; CE; Canada; inpatient setting then home	2; Inclusion: ≥18 years, first stroke ≤6 months, well, use of DHO (SaeboFlex) began as inpatient with discharge planned in catchment, ≥15˚ passive ROM wrist extension (all finger joints held straight with slight force), active ROM: ≥15˚ shoulder/elbow flexion, ≥½ finger flexion, able to comply with study/instructions, caregiver to assist therapy as needed; Exclusion: Shoulder pain (1-3 in CMSA-II), mAS ≥3 in elbow/wrist/finger flexors, wrist/hand deformities/contractures, history of skin breakdown, <6 in FMUE sensory scale, significant cognitive impairment (MOCA ≤21), can fully extend fingers 10 times in elbow extension and neutral wrist P1/P2: male/male, 58/49 years, 8.5/9 weeks post stroke, right non-dominant/ right dominant paresis, MOCA 26/22.	Self-practice – Advised to practice reach, grasp, release therapy tasks using a 4 inch ball (5 tasks, 10 minutes each) using a DHO (SaeboFlex) ≥3 times/week over 8 weeks. 1:1 – After discharge reviewed for 1 hour, 3 times/week for 2 weeks then for 1 hour, once/week for 6 weeks Review by OT or PT once a week or less once established.	N/A	Arm Activity Measure and Chedoke Arm and Hand Activity Inventory-7, SIS, FMUE, mAS, grip strength, COPM, adverse events: NR; 4 and 8 weeks into intervention.
		Adherence: P1 – 32 sessions and 6320 repetitions over 8 weeks, P2 – 31 sessions and 2455 repetitions over 8 weeks.		

CE: Case Experiment, CMSA-II: Chedoke McMaster Stroke Assessment - Impairment Inventory, DHO: Dynamic Hand Orthosis, FMUE: Fugl Meyer Upper Extremity Score, mAS: modified Ashworth Scale, MOCA: Montreal Cognitive Assessment (Cognitive impairment: <26/30) (Nasreddine *et al.* 2005), ROM: Range of Movement, SIS: Stroke Impact Scale

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion Other	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Franck et al. 2019; CE; Netherlands; inpatient setting then assume clinic but NR	8; Inclusion: Admitted to inpatient stroke ward, moderately to severely impaired arm-hand (UAT 1 or 2), age ≥18 years, <3 months post stroke, able to understand study questionnaires and measurement instructions; independent sitting balance, passive ROM wrist extension >-5 with digit joints straight; Exclusion: visual issues prevent object location/recognition, oedema or inflammation severe enough to limit active movement/training intensity, intolerance to electrical stimulation; insufficient understanding of the Dutch language, no informed consent. 6 males, 2 females, mean (SD) age 58.4 (9.2) years, time post stroke 6.1 (3.2) weeks, ARAT 1.1 (NR), 4 right dominant and 4 left non-dominant hemiparesis.	Self-practice – 1.5 hours/day, 3 days per week for six weeks (5-10 minutes practice of goals set then 45 minutes of task specific training activities wearing a DHO (SaeboGlove) with electrical stimulation of wrist/digital flexors then 5-10 minutes practice of goals). 1:1 – Review by OT or PT for initial set up and at the start of each self-practice session to get set up. Adherence: NR	N/A	UAT, ARAT, adverse events; post intervention plus adverse events.

ARAT: Action Research Arm Test, CE: Case Experiment, DHO: Dynamic Hand Orthosis, NR: Not Reported, OT: Occupational Therapist, PT: Physiotherapist, ROM: Range of Movement, UAT: Utrecht arm/hand test

Table 5: Details of included RCT participants

Study	Number of participants randomised	Age: Mean (SD)	Gender (M/F)	Stroke type (I/H)	Time since stroke (months) : Mean (SD)	Side Affected (L/R), Dominant side affected	Measures of severity
Barry *et al.* 2012	Intervention 11	52.7 (16.1)	4/6	6/4	49.2 (27.6)	5/5, 5	**MMSE: Mean (SD)** 27.6 (2.6), **Arm involvement (Moderate/ Severe)*** 6/4
	Comparison 11	50.3 (7.5)	6/3	5/4	61.2 (68.4)	5/4, 4	**MMSE: Mean (SD)** 26.2 (4.5), **Arm involvement (Moderate/ Severe)*** 3/6
Huang *et al.* 2019	Intervention 5	59.6 (8.0)	5/0	NR	51.6 (41.7)	3/2, NR	**MMSE: Mean (SD)** 27.8 (0.5), **FMUE: Mean (SD)** 30.6 (12.4)
	Comparison 5	56.6 (7.9)	4/1	NR	49.6 (26.0)	4/1, NR	**MMSE: Mean (SD)** 28.0 (0.7), **FMUE: Mean (SD)** 31.4 (12.3)
Jeon *et al.* 2012	Intervention 7	51.0 (13.5)	3/2	NR	29.6 (9.2)	3/2	**MMSE: Mean (SD, range)** 28.8 (1.8, 26-30), **FMUE: Mean (SD)** 33 (16), **ARAT: Mean (SD)** 22.2 (14.6)
	Comparison 8	51.2 (12.5)	4/1	NR	27.6 (16.5)	2/3	**MMSE: Mean (SD, range)** 29.2 (1.8, 26-30), **FMUE: Mean (SD)** 29.8 (14.9), **ARAT: Mean (SD)** 22.2 (16.4)
Lannin *et al.* 2016	Intervention 5	63.0 (10.4)	5/0	NR	2.5 (1.7)	2/3	**MMSE ≥21, Motor weakness (Mild/ Significant)*** 2/3
	Comparison 4	51.0 (21.2)	2/2	NR	4.7 (6.1)	3/1	**MMSE ≥21, Motor weakness (Mild/ Significant)*** 1/3

ARAT: Action Research Arm Test, Brunnstrom's stage (Degree of motor recovery) – 1 = Flaccid limb, no active movement, 3 = Spasticity is severe, some voluntary control, 6 = Spasticity disappears, individual joint movements possible (Naghdi *et al.* 2010), FMUE: Fugl Meyer Upper Extremity score (Motor impairment) - ≤22 = no upper limb capacity, 23-31 = poor upper limb capacity, 32-47 = limited upper limb capacity, 48-52 = notable upper limb capacity, 53-66 = full upper limb capacity (Hoonhorst *et al.* 2015), I/H: Ischaemic/ Haemorrhagic, L/R: Left/Right, M/F: Male/Female, NR: Not reported, MMSE: Mini Mental State Examination (Cognitive impairment) - ≤9 = severe, 10-19 = moderate, 20-25 = mild, 26-30 = nil (Vertesi *et al.* 2001), SD: Standard Deviation, *Not defined

Table 6: Details of included RCT studies

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Barry *et al.* 2012; RCT; USA; NR - assume clinic	22; Inclusion: >6 months post stroke, ≥21 years, AROM ≥15° shoulder elevation, ≥15° elbow flexion, ≥25%, PROM ≥15° wrist extension with fingers straight; Exclusion: Ability to grasp/release a 7.6-cm diameter ball, botulinum toxin injections upper limb ≤12 weeks, swan neck deformities, prone to skin breakdown, severe aphasia, or a MMSE <17/30.	6 weeks - Task specific motor training activities wearing a DHO (SaeboFlex) in different formats (1:1 with a PT (1 hour, 1/week) and self-practice +/- carer assistance (20 reps of 6 exercises twice daily, 4 days/week)) with preparatory stretches.	6 weeks - Task specific motor training activities in different formats (1:1 with a therapist (1 hour, 1/week) and self-practice (20 reps of 6 exercises twice daily, 4 days/week)) with preparatory stretches.	ARAT, BBT, SIS – arm ability, SIS - % recovery, Grip strength, occurrence of DHO discomfort, SIS – strength domain, adverse events: NR; post intervention.
		Adherence: 1:1: 84% attended at all (6/6; 100%) visits, 16% attended at five (5/6; 83%) visits, Self-practice: Only 8/19 (42%) diaries returned therefore not analysed.		

ARAT: Action Research Arm Test, AROM: Active Range of Movement, BBT: Box and Block Test, DHO: Dynamic Hand Orthosis, MMSE: Mini Mental State Examination (Cognitive impairment) - ≤9 = severe, 10-19 = moderate, 20-25 = mild, 26-30 = nil (Vertesi *et al.* 2001), NR: Not reported, PROM: Passive Range of Movement, PT: Physiotherapist, RCT: Randomised Controlled Trial, SIS: Stroke Impact Scale

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Huang *et al*. 2019; RCT; China; NR - assume clinic	10; Inclusion: >6 months post stroke, ≥20 years, upper limb weakness, proximal Brunnstrom stage IV, distal Brunnstrom stage III to IV, able to understand/follow orders, MMSE >24; Exclusion: upper limb deformity/contracture, unable to commit to trial.	4 weeks - Task specific motor training activities wearing a DHO (customised) (1:1 with an OT (30 minutes, 2/week) and self-practice (30 minutes, 5/week, unclear if carer involved) with preparatory stretches. 2 weeks follow up - self-practice with DHO (30 minutes, daily).	4 weeks - Task specific motor training activities in different formats (1:1 with a therapist (30 minutes, 2/week) and self-practice (30 minutes, 5/week) with preparatory stretches. 2 weeks follow up - self-practice (30 minutes, daily).	BBT, Grip strength, Lateral pinch, Palmar pinch, adverse events: NR; post intervention with follow up 2 weeks later.
		Adherence: 1:1: 100% attended at all (8/8; 100%) visits, Self-practice: Weeks 1-4: NR, 2 week follow-up: Mean (p value) Intervention 56.8 minutes daily, Comparison 26.2 minutes daily (0.019).		

BBT: Box and Block Test, DHO: Dynamic Hand Orthosis, MMSE: Mini Mental State Examination (Cognitive impairment) - ≤9 = severe, 10-19 = moderate, 20-25 = mild, 26-30 = nil (Vertesi *et al.* 2001), NR: Not reported, OT: Occupational therapist, RCT: Randomised Controlled Trial

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Jeon *et al.*2012; RCT; Republic of Korea; rehabilitation hospital, assume clinic	15; Inclusion: >6 months post stroke, upper limb weakness, AROM ≥10° shoulder elevation, ≥10° elbow flexion/extension, ≥30 PIP or 20° DIP joint flexion with wrist/fingers straight, MMSE (Korean) ≥23; Exclusion: NR.	4 weeks - Task specific motor training activities wearing a DHO (SaeboFlex) in a 1:1 format with a PT (1 hour, 5/week) plus conventional therapy (undefined) (1 hour, 5/week).	4 weeks – Placebo (Same quantity and type of elbow/shoulder movements as intervention group but no grasp/release), wearing a DHO in a 1:1 format with a therapist (1 hour, 5/week) plus usual care (undefined) (1 hour, 5/week).	ARAT, BBT, FMUE, resultant velocity of movement smoothness, adverse events: NR; post intervention.
		Adherence: 1:1: NR		

ARAT: Action Research Arm Test, AROM: Active Range of Movement, BBT: Box and Block Test, DHO: Dynamic Hand Orthosis, DIP: Distal Interphalangeal joints, FMUE: Fugl Meyer Upper Extremity score, MMSE: Mini Mental State Examination (Cognitive impairment) - ≤9 = severe, 10-19 = moderate, 20-25 = mild, 26-30 = nil (Vertesi *et al.* 2001), NR: Not reported, PIP: Proximal Interphalangeal joints, PT: Physiotherapist, RCT: Randomised Controlled Trial

Study: Author with year; design; country; setting	Population; Inclusion; Exclusion	Intervention	Comparison	Outcomes: Outcomes of interest; follow up timeline
Lannin *et al.* 2016; RCT; Australia; inpatient rehabilitation	9; Inclusion: Inpatient with first stroke in Acute stroke unit, ≥18 years, upper limb weakness, <6 on item 6 or 7 of the Motor Assessment Scale, AROM ≥10° shoulder elevation, ≥10° elbow flexion/extension, MMSE ≥21, follow one step commands; Exclusion: Able to grasp/release tennis ball 10 times, deformity/contractures, hypermobility.	8 weeks - Task specific motor training activities wearing a DHO (SaeboFlex) in different formats (1:1 with an OT (45 minutes, 5/week) and self-practice +/- carer assistance (≤45 minutes, daily) plus conventional therapy (comparison group therapy minus group sessions (permitted, not used).	8 weeks - Task specific motor training activities plus FES as appropriate in different formats (1:1 with a therapist (≥45 minutes, 4/week), self-practice (undefined intensity) and in a group (45 minutes, 3/week)).	BBT, SIS – arm ability, SIS - % recovery, SIS – strength domain (upper limb only), Grip strength, Occurrence of problems with circulation, skin and joint pressure, MAS, adverse events; post intervention.
		Adherence: Intervention 1:1: 2 participants (2/5; 40%) completed 20-30min sessions twice/day, 5/week, 3 participants (3/5; 60%) completed 45-60 minutes once/day, 5/week), Self-practice: NR. Usual care: NR, Comparison: NR.		

AROM: Active Range of Movement, BBT: Box and Block Test, DHO: Dynamic Hand Orthosis, FES: Functional Electrical stimulation, MAS: Motor Assessment Scale, MMSE: Mini Mental State Examination (Cognitive impairment) - ≤9 = severe, 10-19 = moderate, 20-25 = mild, 26-30 = nil (Vertesi *et al.* 2001), NR: Not reported, OT: Occupational therapist, RCT: Randomised Controlled Trial, SIS: Stroke Impact Scale

Study design: No systematic reviews were found (0/23; 0%). Studies identified included RCTs (4/23; 17%) (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019), and non-RCTs (19/23; 83.0%). Of the non-RCTs pretest-posttest designs where statistical data was used to assess a measure(s) of interest in a group pre and post-delivery of a treatment (Roberts and Ilardi 2003)) were the most common (11/23; 48%) (Barry *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Davenport *et al*. 2011; Gollega and Renton 2012; Prange *et al*. 2014; Rickards *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Doucet 2018; Alexander and Dawson 2019). However, other designs were also found - case experiments where variables were manipulated to assess the correlation between them e.g. the effect of introducing then withdrawing a treatment of interest with each case/participant serving as its own control (Follette 2001)) (3/23; 13%) (Franck *et al*. 2013; Semenko 2017; Franck *et al*. 2019), case reports providing an in-depth description of one or more individual cases (Roberta and Alison 2018)) (4/23; 17%) (Davenport 2005; Butler *et al*. 2006; Woo *et al*. 2013; Stuck *et al*. 2014) and a retrospective chart review (Antje *et al*. 2019) where existing patient data from clinical records collected prior to research commencing was extracted and evaluated (1/23; 4%) (Pooyania and Semenko 2014).

Non-RCTs accounted for most participants (173/229; 76%) (Davenport 2005; Barry *et al*. 2006; Butler *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Davenport *et al*. 2011; Gollega and Renton 2012; Franck *et al*. 2013; Woo *et al*. 2013; Prange *et al*. 2014; Rickards *et al*. 2014; Stuck *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Semenko 2017; Doucet 2018; Alexander and Dawson 2019; Franck *et al*. 2019; Pooyania and Semenko 2014) (pretest-posttest designs: 125/229; 55% (Barry *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Davenport *et al*. 2011; Gollega and Renton 2012; Prange *et al*. 2014; Rickards *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Doucet 2018; Alexander and Dawson 2019), case experiments: 18/229; 8% (Franck *et al*. 2013; Semenko 2017; Franck *et al*. 2019), case reports: 16/229; 7% (Davenport 2005; Butler *et al*. 2006; Woo *et al*. 2013; Stuck *et al*. 2014)) and a retrospective chart review: 14/229; 6% (Pooyania and Semenko 2014) with RCTs accounting for 24% of participants (56/229) (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019).

Additionally, none of the included studies reported any involvement of stakeholders such as stroke survivors, carers or therapists in the design of these studies (0/23; 0%) (Davenport 2005; Barry *et al*. 2006; Butler *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Davenport *et al*. 2011; Barry *et al*. 2012; Gollega and Renton 2012; Jeon *et al*. 2012; Franck *et al*. 2013; Woo *et al*. 2013; Prange *et al*. 2014; Rickards *et al*. 2014; Stuck *et al*. 2014; Chang and Lai 2015; Lannin *et al*. 2016; Chen *et al*. 2017; Semenko 2017; Doucet 2018; Alexander and Dawson 2019; Franck *et al*. 2019; Huang *et al*. 2019; Pooyania and Semenko 2014).

Rehabilitation setting and geographic location: All studies appeared to be single site, except one (22/23; 96%) (Prange *et al*. 2014). Nearly half of included studies did not report the setting where participants carried out study treatment (11/23; 48%) (Davenport 2005; Barry *et al*. 2006; Butler *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Barry *et al*. 2012; Gollega and Renton 2012; Jeon *et al*. 2012; Woo *et al*. 2013; Doucet 2018; Huang *et al*. 2019). However, the settings for these studies were all assumed to involve a clinic/outpatient and/or home setting as these studies all recruited participants in the chronic phase of recovery. Five (5/23; 22%) of the remaining included studies were reported to take place in a clinic/outpatient and/or home (Franck *et al*. 2013; Prange *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Pooyania and Semenko 2014) and seven (7/23; 30%) took place in an inpatient and/or home setting (Davenport *et al*. 2011; Rickards *et al*. 2014; Stuck *et al*. 2014; Lannin *et al*. 2016; Semenko 2017; Alexander and Dawson 2019; Franck *et al*. 2019).

The geographical location of studies included Europe (10/23; 43%) (Davenport 2005; Farrell *et al*. 2007; Heise *et al*. 2010; Davenport *et al*. 2011; Franck *et al*. 2013; Prange *et al*. 2014; Rickards *et al*. 2014; Stuck *et al*. 2014; Alexander and Dawson 2019; Franck *et al*. 2019), Asia (5/23; 22%) (Jeon *et al*. 2012; Woo *et al*. 2013; Chang and Lai 2015; Chen *et al*. 2017; Huang *et al*. 2019), North America (5/23; 22%) (Butler *et al*. 2006; Gollega and Renton 2012; Semenko 2017; Doucet 2018; Pooyania and Semenko 2014), South America (2/23; 9%) (Barry *et al*. 2006; Barry *et al*. 2012) and Oceania (1/23; 4%) (Lannin *et al*. 2016).

Population: Study sample sizes ranged from one (Butler *et al*. 2006) to 23 (Prange *et al*. 2014) participants (mean (SD) 9.96 (5.96)) with 229 participants

recruited in total (Tables 4-5). Of the 23 included studies six (6/23; 26%) did not report participants gender at all (Heise *et al*. 2010; Gollega and Renton 2012; Prange *et al*. 2014; Rickards *et al*. 2014; Chang and Lai 2015; Alexander and Dawson 2019), two (2/23; 9%) reported gender of participants who completed the study only (male: 17/29; 59%) (Barry *et al*. 2012; Jeon *et al*. 2012). The proportion of male recruits in the remaining 15 studies was 71% (77/109) (Davenport 2005; Barry *et al*. 2006; Butler *et al*. 2006; Farrell *et al*. 2007; Davenport *et al*. 2011; Franck *et al*. 2013; Woo *et al*. 2013; Stuck *et al*. 2014; Lannin *et al*. 2016; Chen *et al*. 2017; Semenko 2017; Doucet 2018; Franck *et al*. 2019; Huang *et al*. 2019; Pooyania and Semenko 2014). No studies (0/23; 0%) reported the ethnicity of recruits.

Of the 23 included studies one did not specify when recruitment occurred, only that participants were recruited in an acute ward (1/23; 4% of studies, 19/229; 8% of participants) (Rickards *et al*. 2014). The number of studies reporting recruitment of participants in the acute to early subacute phase of recovery (i.e. ≤3 months (Kwakkel *et al*. 2017)) was six (6/23; 26%) (participants: 48/229; 21%) (Davenport *et al*. 2011; Franck *et al*. 2013; Stuck *et al*. 2014; Semenko 2017; Alexander and Dawson 2019; Franck *et al*. 2019). The corresponding figures for studies recruiting participants during the acute to late subacute phase (i.e. ≤6 months (Kwakkel *et al*. 2017)) and chronic phase (i.e. >6 months (Kwakkel *et al*. 2017)) were one study (1/23; 4%) (participants: 9/229; 4%) (Lannin *et al*. 2016) and 15 studies (15/23; 65%) (participants: 153/229; 67%) (Davenport 2005; Barry *et al*. 2006; Butler *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Barry *et al*. 2012; Gollega and Renton 2012; Jeon *et al*. 2012; Woo *et al*. 2013; Prange *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Doucet 2018; Huang *et al*. 2019; Pooyania and Semenko 2014) respectively.

Two studies did not report the age of participants (2/23; 9%) (Gollega and Renton 2012; Rickards *et al*. 2014). In the remaining 21 studies (21/23; 91%) age was reported in different ways, sometimes without raw or descriptive statistical data. Participants in these studies included participants aged 23-83 years (Tables 4-5).

Two studies (2/23; 9%) did not report sufficient detail to quantify the severity of baseline upper limb functional capacity (Doucet 2018; Pooyania and Semenko

2014). Characterisation of baseline upper limb functional capacity in the remaining studies (21/23; 91%) varied but appeared moderate to severe across all studies e.g. recruited participants with difficulty performing reach, grasp and release/ADL and/or reduced or no hand opening (Davenport 2005; Butler *et al*. 2006; Heise *et al*. 2010; Barry *et al*. 2012; Gollega and Renton 2012; Franck *et al*. 2013; Prange *et al*. 2014; Rickards *et al*. 2014; Lannin *et al*. 2016; Chen *et al*. 2017; Semenko 2017), active movement that was too limited to permit access to constraint induced movement therapy (Barry *et al*. 2006; Butler *et al*. 2006) or reported Fugl Meyer Upper Extremity (FMUE) or Action Research Arm Test (ARAT) scores (Hoonhorst *et al*. 2015) indicative of no functional capacity (FMUE 0-22, ARAT 0-10) (Davenport *et al*. 2011; Jeon *et al*. 2012; Woo *et al*. 2013; Stuck *et al*. 2014; Chen *et al*. 2017; Alexander and Dawson 2019; Franck *et al*. 2019; Huang *et al*. 2019), poor functional capacity (FMUE 23-31, ARAT 11-21) (Farrell *et al*. 2007; Heise *et al*. 2010; Jeon *et al*. 2012; Woo *et al*. 2013; Stuck *et al*. 2014; Chen *et al*. 2017; Alexander and Dawson 2019; Huang *et al*. 2019) or limited functional capacity (FMUE 32-47, ARAT 22-42) (Heise *et al*. 2010; Jeon *et al*. 2012; Woo *et al*. 2013; Chang and Lai 2015; Chen *et al*. 2017; Alexander and Dawson 2019; Huang *et al*. 2019).

The cognition of included participants was not reported in 10 studies (10/23; 43%) (Davenport 2005; Barry *et al*. 2006; Heise *et al*. 2010; Davenport *et al*. 2011; Gollega and Renton 2012; Prange *et al*. 2014; Rickards *et al*. 2014; Stuck *et al*. 2014; Chen *et al*. 2017; Pooyania and Semenko 2014), reported to be normal in three studies (3/23; 13%) (Jeon *et al*. 2012; Woo *et al*. 2013; Huang *et al*. 2019), reported to include participants with some impairment in five studies (5/23; 22%) (Butler *et al*. 2006; Barry *et al*. 2012; Chang and Lai 2015; Lannin *et al*. 2016; Semenko 2017) and was considered by the author to likely be mild or normal in the five remaining studies which only included participants who e.g. could only follow multi-part instructions (Farrell *et al*. 2007), give informed consent (Doucet 2018), were judged not to have severe cognitive or communication issues (Franck *et al*. 2013) or were considered to be capable of understanding/adhering to protocol procedures (Alexander and Dawson 2019; Franck *et al*. 2019) (5/23; 22%).

Intervention

All intervention groups received therapy involving the performance of task specific motor training activities in different formats that involved wearing a DHO (Tables 4 and 6). In two studies (2/23; 9%) the therapy format utilised was not clear (e.g. 1:1 only, self-practice only, 1:1 and self-practice combined etc.) (Gollega and Renton 2012; Woo *et al*. 2013). Three studies (3/23; 13%) appeared to utilise a 1:1 therapy format (Farrell *et al*. 2007; Jeon *et al*. 2012; Doucet 2018), one study (1/23; 4%) utilised a combination of a 1:1, group and self-practice therapy (Franck *et al*. 2013) and 17 (17/23; 74%) utilised a combination of 1:1 and self-practice therapy (Davenport 2005; Barry *et al*. 2006; Butler *et al*. 2006; Heise *et al*. 2010; Davenport *et al*. 2011; Barry *et al*. 2012; Prange *et al*. 2014; Rickards *et al*. 2014; Stuck *et al*. 2014; Chang and Lai 2015; Lannin *et al*. 2016; Chen *et al*. 2017; Semenko 2017; Alexander and Dawson 2019; Franck *et al*. 2019; Huang *et al*. 2019; Pooyania and Semenko 2014).

Therapy delivery in intervention groups was mainly supported by physiotherapists and/or occupational therapists. This was clear in fifteen studies (15/23; 65%) (physiotherapists: 6/23; 26% (Barry *et al*. 2006; Barry *et al*. 2012; Jeon *et al*. 2012; Chang and Lai 2015; Chen *et al*. 2017; Alexander and Dawson 2019), occupational therapists: 6/23; 26% (Butler *et al*. 2006; Franck *et al*. 2013; Lannin *et al*. 2016; Doucet 2018; Huang *et al*. 2019; Pooyania and Semenko 2014), physiotherapist or occupation therapist: 3/23; 13% (Rickards *et al*. 2014; Semenko 2017; Franck *et al*. 2019). However, therapy support was provided by a 'therapist' of unknown discipline in one study (1/23; 4%) (Stuck *et al*. 2014) and a 'health care professional' of unknown discipline in another study (1/23; 4%) (Prange *et al*. 2014). Similarly, the discipline supporting therapy was unclear in six further studies (6/23; 26%) but were assumed to involve therapists/healthcare professionals as authors from five of these studies included physiotherapists (Davenport 2005; Farrell *et al*. 2007; Heise *et al*. 2010; Davenport *et al*. 2011; Woo *et al*. 2013) and the remaining sixth study was run in a rehabilitation unit (Gollega and Renton 2012). Help from carers (as needed for participants to successfully participate) was only listed in study inclusion criteria in one study (1/23; 4%) (Alexander and Dawson 2019). However, four additional studies referenced using carer help as part of the intervention (4/23; 17%) (Barry *et al*. 2006; Heise *et al*. 2010; Barry *et al*. 2012; Lannin *et al*. 2016).

Intervention dose: Five studies (5/23; 22%) did not report the duration of the intervention period (Butler *et al*. 2006; Heise *et al*. 2010; Davenport *et al*. 2011; Rickards *et al*. 2014; Pooyania and Semenko 2014). The duration of the intervention in the remaining studies ranged widely from one week (Farrell *et al*. 2007) to six months (Davenport 2005; Gollega and Renton 2012) with six weeks being most commonly reported (6/23; 26%) (Barry *et al*. 2006; Barry *et al*. 2012; Franck *et al*. 2013; Prange *et al*. 2014; Doucet 2018; Franck *et al*. 2019). Seven studies (7/23; 30%) delivered the intervention in conjunction with conventional therapy, possibly, in part, as it had already stopped in many instances as many of the studies took place in the chronic phase of recovery (Davenport *et al*. 2011; Jeon *et al*. 2012; Franck *et al*. 2013; Stuck *et al*. 2014; Chang and Lai 2015; Lannin *et al*. 2016; Alexander and Dawson 2019). Further details on therapy dose (e.g. time, frequency) can be found in Tables 4 and 6.

Non-robotic DHOs: Non-robotic DHOs utilised in the included studies comprised:

- The SaeboFlex (17/23; 74%)
  (Recovery phase: acute to early subacute - 6/17; 35% (Davenport 2005; Davenport *et al*. 2011; Franck *et al*. 2013; Rickards *et al*. 2014; Stuck *et al*. 2014; Semenko 2017), acute to late subacute - 1/17; 6% (Lannin *et al*. 2016), and chronic - 10/17; 59%) (Barry *et al*. 2006; Butler *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Barry *et al*. 2012; Gollega and Renton 2012; Jeon *et al*. 2012; Woo *et al*. 2013; Doucet 2018; Pooyania and Semenko 2014),

- The SaeboGlove (2/23; 9%)
  (Recovery phase: acute to early subacute – 2/2; 100%) (Alexander and Dawson 2019; Franck *et al*. 2019),

- The Hand Spring Operated Movement Enabler (HandSOME) (1/23; 4%)
  (Recovery phase: chronic – 1/1; 100%) (Chen *et al*. 2017), and

- Customised DHOs (3/23; 13%)
  (Recovery phase: chronic – 3/3; 100%) (Prange *et al*. 2014; Chang and Lai 2015; Huang *et al*. 2019).

Adherence: One study reported adherence in full individually for the two participants it recruited (1/23; 4%) (Semenko 2017), 11 studies (11/23; 48%) did

not report adherence to intended therapy at all (Barry *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Davenport *et al*. 2011; Gollega and Renton 2012; Jeon *et al*. 2012; Franck *et al*. 2013; Woo *et al*. 2013; Chang and Lai 2015; Doucet 2018; Franck *et al*. 2019), and the remaining 11 studies (11/23; 48%) reported some adherence data but with limited information (e.g. omitting training time, descriptive statistics or including 1:1 therapy but not self-practice) (Davenport 2005; Butler *et al*. 2006; Barry *et al*. 2012; Prange *et al*. 2014; Rickards *et al*. 2014; Stuck *et al*. 2014; Lannin *et al*. 2016; Chen *et al*. 2017; Alexander and Dawson 2019; Huang *et al*. 2019; Pooyania and Semenko 2014).

Outcome measures

All studies assessed outcomes immediately after the intervention period. Only 22% (5/23) of studies had a further follow up period with outcomes repeated after a two week (Huang *et al*. 2019), four week (Heise *et al*. 2010), two month (Prange *et al*. 2014), three month (Heise *et al*. 2010; Chen *et al*. 2017) and six month (Davenport *et al*. 2011) interval. Similarly, while all studies included measures of motor impairment and/or functional upper limb movement, only 17% (4/23) and 13% (3/23) of studies (all non-RCTS), reported outcomes that measured ADL (Modified Barthel Index (Stuck *et al*. 2014), Canadian Occupational Performance Measure (Gollega and Renton 2012; Semenko 2017; Pooyania and Semenko 2014)) or instrumental ADL (Canadian Occupational Performance Measure (Gollega and Renton 2012; Semenko 2017; Pooyania and Semenko 2014)) respectively. Additionally, 61% (14/23) of studies did not report any information on adverse events (Davenport 2005; Barry *et al*. 2006; Heise *et al*. 2010; Barry *et al*. 2012; Gollega and Renton 2012; Jeon *et al*. 2012; Woo *et al*. 2013; Prange *et al*. 2014; Rickards *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Semenko 2017; Huang *et al*. 2019; Pooyania and Semenko 2014).

2.2.5 Discussion

2.2.5.1 Summary of findings

This scoping review identified and summarised the existing evidence (up to and including September 2019) on the use of non-robotic DHOs in stroke rehabilitation with the goal of providing repetitive, functional practice and

promote upper limb functional recovery in adults, and highlights gaps in the current evidence base.

Twenty-three studies exploring the use of non-robotic DHOs in stroke rehabilitation in adults were identified, all involving small sample sizes. Included studies predominantly involved non-RCT study designs (mainly single group pretest-posttest designs) with the most common geographic study location being Europe. No systematic reviews were identified. However, four small RCTs were identified that could be used to conduct a systematic review of RCTs on the effect of the intervention.

All included participants were considered to have moderate to severe upper limb functional capacity. Additionally, they predominantly were in the chronic phase of recovery, carried out rehabilitation in a clinic/outpatient and/or home setting, had a wide age range and appeared to have mild or no cognitive impairment and a slightly higher prevalence of male gender in studies reporting this information.

Non-robotic DHO interventions provided in included studies primarily utilised a combined 1:1 and self-practice therapy delivery format, was supported by occupational and/or physiotherapists over a wide range of intervention periods (up to six months, most commonly six weeks) and without conventional therapy.

Gaps in the evidence: The scoping review highlights the lack of evidence available to inform the use of non-robotic DHOs in stroke rehabilitation in adults. Key gaps include a lack of research involving larger samples that represent the stroke population (e.g. incidence: global - males 47% (World Stroke Organization 2022), Scotland - males 52% (Public Health Scotland 2022)); stakeholder informed research, use of outcomes that measure ADL, instrumental ADL and adverse events, studies with follow up beyond the intervention end and the acute to subacute phase of recovery.

Additionally, a systematic review has yet to be done. While a variety of study designs are required during the development phase of an intervention (Skivington *et al.* 2021), high-quality RCTs are crucial in establishing the body of knowledge regarding treatment effectiveness (National Institute for Health and

Care Excellence 2014; Hariton and Locascio 2018). Only 4 of the 23 papers included in this study were RCTs, which is much fewer than other reviews involving stroke rehabilitation interventions (e.g. 65 RCTs were identified on neglect recently) (Longley *et al*. 2021). Thus, more RCTs are needed.

Furthermore, generalisability and/or intervention replicability was often hindered by poor reporting, particularly on ethnicity, intended intervention delivery and adherence to it (e.g. planned and actual intervention period, training time, discipline of trainer, carer support, and training setting e.g. to aid understanding of logistical arrangements (e.g. transport, mobility independence)).

2.2.5.2 Limitations

Although two reviewers screened all abstracts and extracted data for all included RCTs, only one reviewer did this for non-RCTs due to resource limitations. Thus, despite thorough search efforts, it is possible that relevant non-RCT papers or data extracted from them may have more easily been missed.

This review does not provide an evaluation of the methodological quality or generalisability of findings in included studies as this is not the purpose of a scoping review.

2.2.5.3 Strengths

The main strengths of this scoping review are that it utilised a broad and rigorous search of electronic databases and Grey literature and included researchers with expertise in review methodologies, stroke rehabilitation and the intervention of interest.

Additionally, to the author's knowledge, this is the first time that research involving the use of non-robotic DHOs to improve upper limb stroke recovery has been mapped. Furthermore, the intervention has been studied in stroke survivors with moderate to severe upper limb functional capacity including people with reduced or no active digital extension, a sizable group with a limited prognosis and guideline-based treatment options available to improve functional recovery. Thus, this review is likely to generate research interest

into the use of non-robotic DHOs as a novel intervention as it may have the potential to improve outcomes in an area of high clinical need.

2.2.5.4 Implications for clinical practice

As the purpose of scoping reviews is not to directly influence clinical practice (Munn *et al*. 2018; Tricco *et al*. 2018; Munn *et al*. 2022) there are no implications for clinical practice.

2.2.5.5 Implications for research

This scoping review highlighted that a systematic review of the literature involving RCTs had not yet been done and that only four small RCTs were identified. To progress the evidence-base on the effect of non-robotic DHOs after stroke, a systematic review of the RCTs identified in this review and good quality, multi-site, adequately powered, RCTs are indicated with representation by sex and stakeholder involvement to optimise the usefulness and accessibility of findings.

Additionally, other research priorities include using follow up assessments conducted beyond the immediate post intervention period to assess the sustainability of intervention effects, more studies that recruit participants during the acute to subacute recovery period to better represent this group and outcomes that measure ADL, instrumental ADL, and adverse events, as well as motor impairment and functional upper limb movement to track intervention effects in these areas. Research should also be extended to include willing recruits with more severe cognitive impairment if found to be safe, feasible, acceptable, and effective in recruits with mild or no cognitive impairment. Furthermore, to improve research quality and transparency future research should follow Equator reporting guidelines (Equator Network 2023), include raw and descriptive statistical data, and optimise recording and reporting of ethnicity, an indicator of baseline cognition, and intended intervention delivery and adherence to that.

2.3 Part 2: Non-robotic DHOs in stroke rehabilitation: A systematic review of the current evidence-base to improve upper limb recovery

When selecting clinical interventions, treatment decisions must be governed by the best available evidence (Sackett *et al*. 1996; National Institute for Health and Care Excellence 2014). RCTs of interventions use quantitative research methods to measure and compare the outcomes of different interventions. They provide the highest level of evidence from an individual study and are therefore considered to be the cornerstone of the evidence that underpins them (National Institute for Health and Care Excellence 2014; Hariton and Locascio 2018). As highlighted in the scoping review in Part 1 of this chapter, a rigorous systematic review of the best available evidence surrounding the use of non-robotic DHOs after stroke is still required to enable the strongest inferences to be drawn on the effectiveness of this intervention.

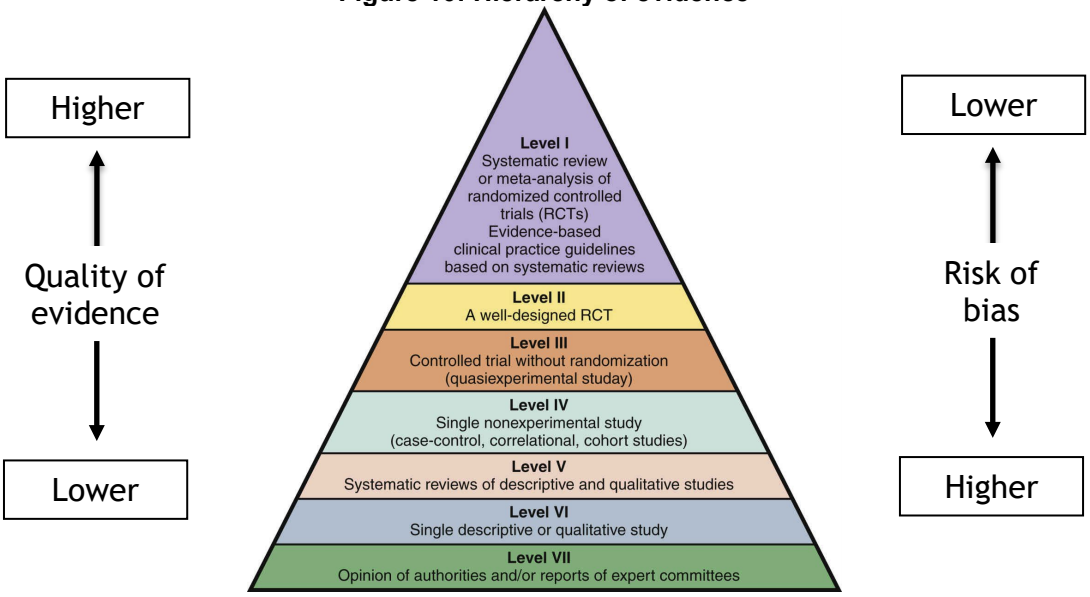
2.3.1 The role of a Systematic review

A systematic review aims to identify all evidence relevant to a particular research question (Charrois 2015). It is defined as:

> "A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review." (The Cochrane Collaboration 2005, p.45)

When available, systematic reviews of RCTs offer the highest quality of evidence in the hierarchy of evidence (Figure 10) (Golden and Bass 2013; LoBiondo-Wood and Haber 2013; Charrois 2015; The Cochrane Collaboration 2020a).

Figure 10: Hierarchy of evidence



Level of evidence assigned to studies based on methodological strength/quality. Used with permission of Elsevier Science & Technology Journals, from LoBiondo-Wood, G. and Haber, J. (2013) Nursing research: methods and critical appraisal for evidence-based practice., 8th ed., St. Louis, Missouri: Elsevier, permission conveyed through Copyright Clearance Center, Inc. (LoBiondo-Wood and Haber 2013)

Importantly, they offer invaluable support in clinical decision making by providing a reliable synthesis of, often, ever accumulating and sometimes inconsistent evidence (Greenhalgh 1997; Egger *et al*. 2001; Charrois 2015). They are particularly valuable in assessing the effect of interventions when RCTs lack statistical power due to small sample sizes (Egger *et al*. 2001; Charrois 2015). While all systematic reviews provide a narrative evidence synthesis, when the methodological, clinical and statistical diversity of studies included in a systematic review are reasoned to be sufficiently aligned, numerical data from these studies can also be pooled and combined using statistical techniques (Higgins *et al*. 2019). This is a process known as a meta-analysis (Higgins *et al*. 2019). It generates a numerical synthesis with a higher statistical power and certainty of the overall effect of an intervention (Charrois 2015; Higgins *et al*. 2019). Thus, when included studies are reasoned to be sufficiently homogeneous and it is appropriate to do so, a systematic review with a meta-analysis is preferable (Charrois 2015; Higgins *et al*. 2019).

In order to establish the best available evidence for the use of non-robotic DHOs in stroke a systematic review of RCTs was carried out (Alexander *et al*. 2021a) (Appendix A) following the standardised process outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins *et al*. 2019).

The research question was, do non-robotic DHOs improve the recovery of hand and arm function in adults after stroke?

The review to answer this question will now be reported.

2.3.2 Objective

The objective of this systematic review was:

1. To provide a systematic review of the current evidence on the use of non-robotic DHOs to improve upper limb recovery in people with upper limb impairment after stroke from RCTs

2. To determine whether non-robotic DHOs improve upper limb recovery in people with upper limb impairment after stroke in comparison to:

    - Placebo or no intervention and
    - Usual care

2.3.3 Methods

The PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analysis) guidelines (online supplement) (Moher *et al*. 2009; Page *et al*. 2021) were followed to guide the design and reporting of this review. The review protocol was registered on PROSPERO, an international database of prospectively registered **systematic reviews** in health and social care (National Institute for Health Research 2020) (CRD42020179180, 20/05/2020) prior to data extraction commencing to increase transparency and accountability, and reduce the risk of subsequent reporting bias (Liberati *et al*. 2009). The protocol registered with Prospero is shown in Appendix B.

2.3.3.1 Eligibility criteria

The eligibility criteria for participants, intervention, comparator, outcome measures and study were the same as those for RCTs in Part 1 of this literature review chapter.

2.3.3.2 Search strategy and study selection

The search strategy was the same as the strategy used for RCTs in Part 1 of this literature review chapter.

2.3.3.3 Extraction of data from included studies

The extraction of data was the same as the strategy used for RCTs in Part 1 of this literature review chapter.

2.3.3.4 Assessment of risk of bias

Bias in research occurs when prejudice or selectivity arises that introduces a systematic error and deviation in outcome beyond chance, an outcome that deviates from the truth (Higgins *et al*. 2019). In the context of a systematic review of RCTs involving a clinical intervention, this means that bias has the potential to under or over-estimate the true effect of the intervention being studied (Higgins *et al*. 2019). Thus, the risk of bias in each included study in a review must be assessed to inform the certainty of the intervention effect (Sterne *et al*. 2019). The Cochrane Risk of Bias tool 1.0 (Appendix D) is a reputable tool used to assess risk of bias for domains within five types of bias (Higgins and Green 2011). It assesses bias that can occur due to randomisation procedures used (selection bias), unblinding (performance and detection bias), incomplete outcome data (attrition bias) and selective outcome reporting (reporting bias) (Higgins and Green 2011). Additionally, it also offers the additional possibility of assessing other sources of bias only present in more specific situations not relevant here (Higgins and Green 2011).

An overview of the domains scored in this tool with a description of bias scored is shown in Table 7 (Higgins and Green 2011).

Table 7: Overview of sources of bias scored in Cochranes risk of bias tool 1.0

Type of bias	Description of bias that may deviate outcome from truth	Domains scored by type of bias
Selection bias	Systematic differences between baseline characteristics of the groups that are compared as allocation sequence is not random/concealed.	Sequence generation Allocation concealment
Performance bias	Systematic differences between groups in the care that is being provided, or in exposure to factors other than the interventions of interest as participants/personnel are unblinded.	Blinding of participants and personnel.
Detection bias	Systematic differences between groups in how outcomes are determined as outcome assessor is unblinded.	Blinding of outcome assessors
Attrition bias	Systematic differences between characteristics of groups due to different drop-out rates.	Incomplete outcome data
Reporting bias	Systematic differences between reported and unreported findings.	Selective outcome reporting
Other bias	Systematic differences between groups in other areas relevant in certain situations e.g. contamination.	

Reprinted and adapted from Table 8.4a from http://handbook-5-1.cochrane.org, accessed 18/05/2020 (Freely available)

The Cochrane risk of bias tool 1.0 (Appendix D) and the Cochrane criteria for judging risk of bias (low, high or unclear) in each domain of this tool (Appendix E) was used to assess bias in the included studies (Higgins and Green 2011) (Table 7). However, performance bias was omitted due to the very visible nature of the experimental intervention which was felt to reflect the nature of the intervention, rather than poor methodological quality.

Two reviewers independently assessed the risk of bias in each eligible study (JA and either JD or PL) in Covidence (Covidence 2020). Disagreements between individual judgements were resolved through discussion, or with the help of a third reviewer where appropriate.

2.3.3.5 Data synthesis and analysis

To fulfil Objective 1 of this review, a narrative synthesis of the current evidence on non-robotic DHOs to improve upper limb recovery in people with upper limb impairment after stroke from included RCTs was performed.

To fulfil Objective 2 of this review, extracted data and risk of bias scores collated in Covidence were exported to the Cochrane Review Manager 5 software (The Cochrane Collaboration 2014) where all analyses were performed. All outcomes of interest that were analysed, used continuous data. For each outcome category that was used in more than two included studies, a summary value using a random-effects model was reported, either as a weighted mean difference with 95% confidence intervals (CIs) if the measure was consistent across trials, or as the standard mean difference with 95% CI if different measures were used. A p value <0.05 was considered statistically significant. When individual studies used multiple outcomes within a domain, the measure most used across all included studies in the analysis was included.

Heterogeneity: Heterogeneity was assessed using the inconsistency I^2 test, with values above 25% and 50% representing moderate and high heterogeneity respectively (West *et al*. 2010; Cochrane Library 2022).

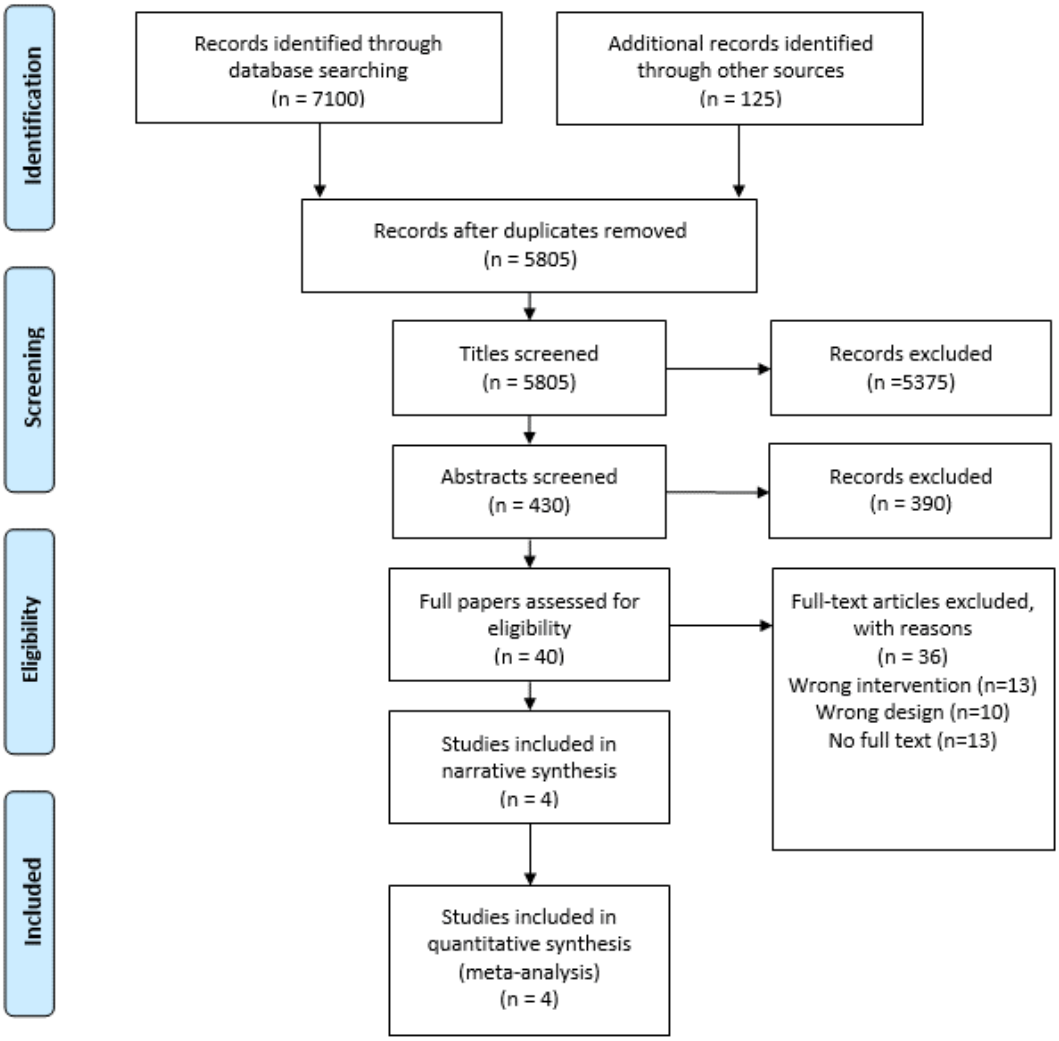
Subgroup and sensitivity analyses: Subgroup analyses were planned on (i) Time from stroke using standard definitions recommended in neurorehabilitation trials (acute/early sub-acute, late sub-acute and chronic) (Bernhardt *et al*. 2017) and (ii) Severity of upper limb functional impairment using criteria from Hoonhorst et al. 2015 if data permitted (Hoonhorst *et al*. 2015). Subgroup analyses were not done due to limited data. Sensitivity analyses were planned if indicated.

2.3.4 Results

2.3.4.1 Search

The search identified 5805 titles after 1420 duplicates were removed. Title review identified 430 records for abstract review. Of these, 40 records were obtained and screened in full text leaving four studies for inclusion (Figure 11).

Figure 11: Study selection flow diagram for Systematic Reviews and Meta-Analyses



PRISMA study selection flow diagram adapted from Page et al. 2021, available at: The PRISMA 2020 statement: an updated guideline for reporting systematic reviews (bmj.com) under a Creative Commons CC BY 4.0. Full Terms at: Creative Commons — Attribution 4.0 International — CC BY 4.0

2.3.4.2 A narrative synthesis of included RCTs

The main characteristics of included studies and included participants are summarized in fully in Tables 5 and 6 in Part 1 of this chapter.

Study design: All four of the included studies were parallel-group RCTs (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019). None of the included studies reported any involvement of key stakeholders (0/4; 0%). Similarly, no studies (0/4; 0%) reported the ethnicity of recruits.

Rehabilitation setting and geographic location: All four studies appeared to be single site (4/4; 100%). In one study, rehabilitation was carried out in an acute to late subacute phase in an inpatient setting in Australia (Oceania) (Lannin *et al*. 2016). The other three involved chronic stroke patients (>6 months post stroke) and were all assumed to be in a clinic/outpatient rehabilitation setting: one from a rehabilitation hospital in the Republic of Korea (Asia) (Jeon *et al*. 2012) and two undefined settings in the USA (South America) (Barry *et al*. 2012) and China (Asia) (Huang et al. 2019).

Population: Study sample sizes ranged from 9 to 22 participants (mean (SD) 14.0 (5.94)) with 56 participants recruited in total. Of the 48 participants included in the analysis (19/22 (Barry *et al*. 2012), 10/15 (Jeon *et al*. 2012), 9/9 (Lannin *et al*. 2016) and 10/10 (Huang et al. 2019)), 33 (69%) were males, mean (SD) age was 54.0 (12.5) years, mean (SD) time post-stroke was 38.9 months (39.9), and 21 (44%) had a right-sided hemiplegia. Three of the studies (Barry *et al*. 2012; Jeon *et al*. 2012; Huang *et al*. 2019) reported baseline cognition measured using the Mini Mental State Examination (MMSE) (n=39 of 48 participants analysed) scoring a mean (SD) 27.7 points (2.8), representing, on average, no cognitive impairment (Oxford Medical Education 2020). The remaining study (Lannin *et al*. 2016) only included participants with minimal to no cognitive impairment (MMSE ≥21) (Oxford Medical Education 2020), but did not report baseline measures. Characterisation of baseline upper limb functional capacity varied but appeared moderate to severe. In one study, 67% had “significant”, undefined, motor weakness and participants were unable to grasp/release a tennis ball 10 times (Lannin *et al*. 2016), in another, 47% had “moderate” and 53% had “severe” undefined arm involvement and participants were unable to grasp/release a 7.6cm diameter ball at all (Barry *et al*. 2012), and in the remaining two studies, participants had a mean (SD) FMUE or Brunnstrom score of 31 (11.7) (Huang et al. 2019) or 2.9 (0.86) (Jeon *et al*. 2012) respectively, representing poor capacity (Hoonhorst et al. 2015).

Comparison groups: Three of the studies compared the effects of rehabilitation using a DHO with usual care in isolation (Barry *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019), which involved the performance of task specific motor training activities in different formats (1:1 with a therapist (Barry *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019), self-practice (Barry *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) or in a group (Lannin *et al*. 2016)) with (Barry *et al*. 2012; Huang *et al*. 2019) or, possibly without (Lannin *et al*. 2016) preparatory stretches. This was performed in conjunction with functional electrical stimulation in one study (Lannin *et al*. 2016). The remaining study compared rehabilitation using a DHO with a combination of usual care that was not defined plus a placebo intervention (Jeon *et al*. 2012) that involved wearing a DHO to practice the same quantity and type of elbow and shoulder movements as the intervention group but without the same grasping and releasing hand movements. Stretching was not reported (Jeon *et al*. 2012). A placebo intervention, in isolation, was a pre-defined comparison group in this review. A combined placebo and usual care intervention was not but was considered to be relevant and is included as an additional comparison.

Interventions: Like the comparator groups, intervention groups received therapy involving the performance of task specific motor training activities in different formats (1:1 with a therapist (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) and self-practice (Barry *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019)) with (Barry *et al*. 2012; Huang *et al*. 2019) or possibly without preparatory stretches (Jeon *et al*. 2012; Lannin *et al*. 2016), but wearing a DHO. Diaries were provided to record compliance with self-practice (Barry *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019). Two of the three studies utilising self-directed practice reported that carer assistance was utilised as needed (e.g. to don/doff the DHO, record compliance) (Barry *et al*. 2012; Lannin *et al*. 2016). The third did not state if carer help was utilised or not (Huang *et al*. 2019). A SaeboFlex (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016) and customised 3-Dimensional DHO (Huang et al. 2019) were used for the task specific training. Therapy delivery in intervention groups was supported by physiotherapists and/or occupational therapists (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019).

Intervention dose: The intervention period for the included studies were four weeks (Jeon *et al*. 2012; Huang *et al*. 2019), six weeks (Barry *et al*. 2012) and eight weeks (Lannin *et al*. 2016). Two studies delivered the experimental intervention in isolation (Barry *et al*. 2012; Huang *et al*. 2019), and the other two in addition to usual care (Jeon *et al*. 2012; Lannin *et al*. 2016). All comparison groups were dose matched except in the study by Lannin et al. 2016 (Lannin *et al*. 2016) where the intervention group received more therapy. Further details on therapy dose (duration, frequency and repetitions) can be found in the 'Details of included RCT studies' table (Table 6).

Adherence: Adherence with 1:1 (intervention (Jeon *et al*. 2012), comparison (Jeon *et al*. 2012; Lannin *et al*. 2016)), self-directed (intervention (Barry *et al*. 2012; Lannin *et al*. 2016), comparison (Barry *et al*. 2012; Lannin *et al*. 2016)) and group therapy (comparison (Lannin *et al*. 2016)) was not always reported. Poor return of self-directed therapy diaries was reported to contribute to this in one study (Barry *et al*. 2012). Reported adherence for 1:1 (intervention (Barry *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019), comparison (Barry *et al*. 2012; Huang *et al*. 2019)) and self-directed (intervention (Huang et al. 2019), comparison (Huang et al. 2019)) was good and one study reported self-reported adherence to be significantly greater in the intervention group (p 0.019) (Huang et al. 2019).

Outcome measures: All four studies assessed outcomes immediately after the intervention period (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019). Only one study had a further follow up period (Huang et al. 2019), with outcomes repeated after a two week interval. None of the included studies reported outcomes that measured ADL or instrumental ADL (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019). Consequently, follow-up data, ADL and instrumental ADL domains were not included in the meta-analysis.

Only one study (1/4; 25%) appeared to formally assess adverse events including problems with blood circulation, skin breakdown and increased joint pressure but reported none had occurred (Lannin *et al*. 2016). However, a second study reported that a participant in the intervention group dropped out due to discomfort associated with the DHO (Barry *et al*. 2012).

Outcome measures assessed immediately after the intervention period that were included in the meta-analysis for each of the remaining predefined outcome domains are presented in Table 8. Five comparisons were made.

Table 8: Outcome measures assessed immediately after the intervention period that were included in the meta-analysis

	Comparison				
	Co-primary outcomes: Functional movement of the upper limb				**Secondary outcomes: Motor impairment of the upper limb**
Study	**1**	**2**	**3**	**4**	**5**
Barry *et al*. 2012	ARAT	BBT	SIS - Arm ability	SIS - % recovery	Grip force
Huang *et al*. 2019	-	BBT	-	-	Grip force
Jeon *et al*. 2012	ARAT	BBT	-	-	FMUE
Lannin *et al*. 2016	-	BBT	SIS - Arm ability	SIS - % recovery	Grip force

ARAT: Action Research Arm Test, BBT: Box and Block Test, FMUE: Fugl Meyer Upper Extremity score, SIS: Stroke Impact Scale

Two out of four studies included data on the Minimal Clinically Important Difference (MCID) (Barry *et al*. 2012; Lannin *et al*. 2016).

In one study (Huang et al. 2019), four missing SDs were calculated from p-values provided using the TINV function in Microsoft excel (Grip strength and Box and Block Test (BBT) for the active and control groups post intervention) and two means (Grip strength and BBT for the control group post intervention) were extracted from graphs provided using a digital web-based tool (Rohatgi 2020).

2.3.4.3 Risk of bias in included studies

We did not use funnel plots to assess publication bias as too few studies were included for this to be considered useful.

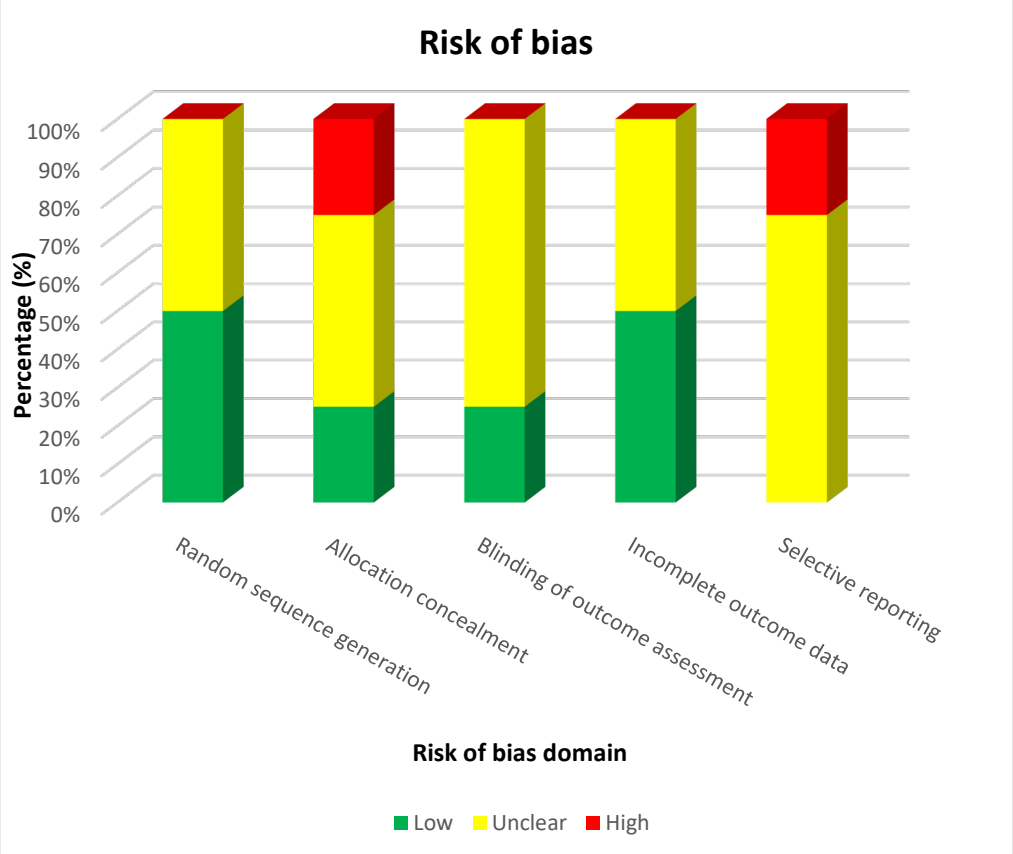
The risk of bias was generally considered to be high (Table 9, Figure 12).

Table 9: Risk of bias summary for methods reported in included studies

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Barry *et al*. 2012	?	?	+	+	?
Huang *et al*. 2019	?	?	?	+	?
Jeon *et al*. 2012	+	-	?	-	?
Lannin *et al*. 2016	+	+	?	-	-

+ Methods adequate (low bias), - Methods not adequate (high bias), ? Methods unclear (unclear bias)

Figure 12: Risk of bias by domain as percentages across all included studies



Limited methodological reporting by the included studies meant that bias using the Cochrane Risk of Bias 1.0 tool was judged to be unclear in 50% of the sub-scores collectively across all included studies (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) (Table 9, Figure 12). The corresponding Figure for low bias in individual studies ranged from 20% (Jeon *et al*. 2012; Huang *et al*. 2019) to 40% (Barry *et al*. 2012; Lannin *et al*. 2016) (Table 9, Figure 12). Random sequence generation and concealment of group allocation at randomization was reported to be adequate in two (Jeon *et al*. 2012; Lannin *et al*. 2016) and one (Lannin *et al*. 2016) of the studies, respectively (Table 9, Figure 12). Blinding of outcome assessors was not explicitly reported in three of the studies (Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019), but was reported and considered to be adequate in the remaining study (Barry *et al*. 2012) (Table 9, Figure 12). Two of the studies reported no dropouts and were judged to have low attrition bias (Lannin *et al*. 2016; Huang *et al*. 2019) (Table 9, Figure 12). No protocol papers were found for any of the included studies, preventing a true comparison of planned and reported outcomes to judge reporting bias. Consequently, reporting bias was judged to be unclear in three of the studies (Barry *et al*. 2012; Jeon *et al*. 2012; Huang *et al*. 2019) (Table 9, Figure 12). The remaining study was judged to have a high risk of reporting bias as authors stated that two secondary outcomes (spasticity and passive range of movement) were measured but failed to report them or explain why (Lannin *et al*. 2016).

2.3.4.4 Effects of interventions: Meta-Analysis

Meta-analysis – Co-primary outcomes

Comparison 1 - Functional movement of the upper limb (ARAT): Two studies measured recovery of functional upper limb movement using the ARAT score. There was a difference in favour of non-robotic DHOs on this measure: mean difference 6.23, 95% confidence interval 0.28 to 12.19 ($p = 0.04$). Statistical heterogeneity was low ($I^2 = 0\%$).

Comparison 2 - Functional movement of the upper limb (BBT): All four studies measured recovery of functional upper limb movement using the BBT. There was a difference in favour of non-robotic DHOs on this measure: mean difference

2.99, 95% confidence interval 0.39 to 5.60 (p = 0.02). Statistical heterogeneity was low (I^2 = 0%).

Comparison 3 - Functional movement of the upper limb (Stroke Impact Scale (SIS) - Arm ability): Two studies measured recovery of functional upper limb movement using the self-reported arm ability domain of the SIS. There was no difference in this measure: mean difference 9.75, 95% confidence interval -3.38 to 22.89 (p = 0.15). Statistical heterogeneity was low (I^2 = 0%).

Comparison 4 - Functional movement of the upper limb (SIS - % overall stroke recovery): Two studies measured recovery of functional upper limb movement using the self-reported % (global) recovery domain of the SIS. There was no difference in this measure: mean difference -5.77, 95% confidence interval -26.70 to 15.17 (p = 0.59). Statistical heterogeneity was moderate (I^2 = 47%).

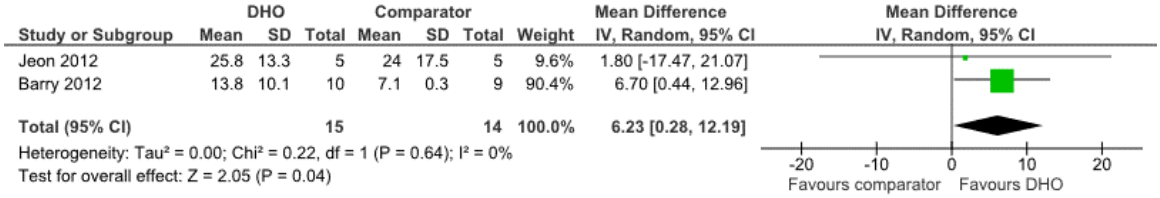
Meta-analysis - Secondary outcomes

Comparison 5 - Motor impairment of the upper limb (Grip strength and FMUE): Recovery of upper limb motor impairment was measured using grip strength and the FMUE in three and one studies respectively. There was no difference in this measure: standard mean difference 0.27, 95% confidence interval -0.30 to 0.84 (p = 0.36). Statistical heterogeneity was low (I^2 = 0%).

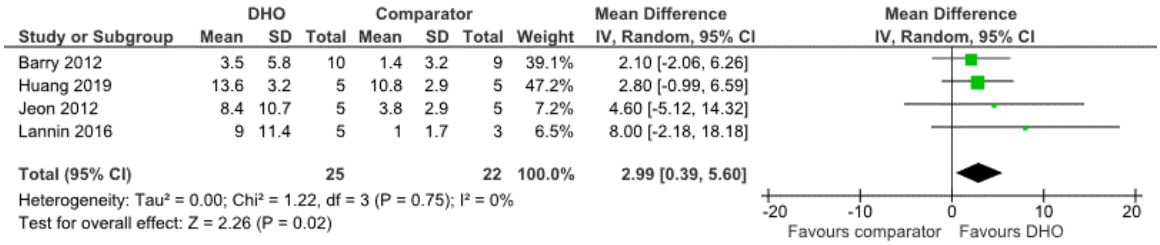
Forest plots for each comparison are presented in Figure 13.

Figure 13: Meta-analyses of outcome domains of interest

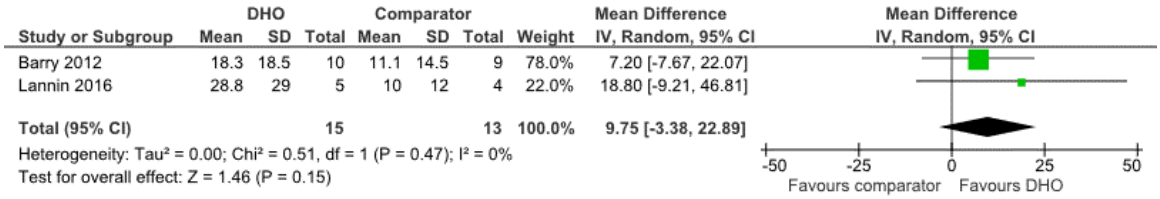
Comparison 1 - Functional movement of the upper limb (ARAT)



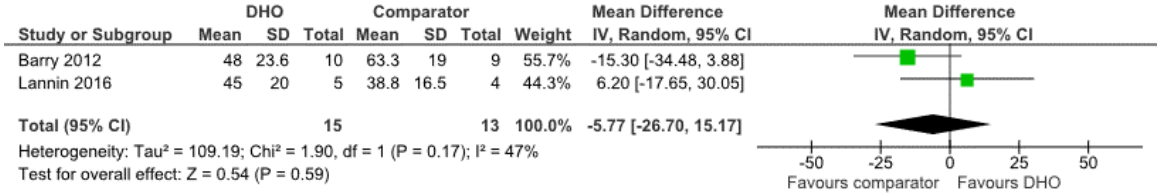
Comparison 2 - Functional movement of the upper limb (BBT)



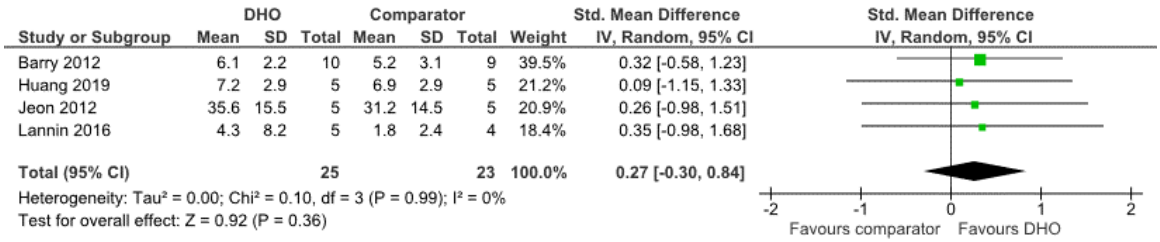
Comparison 3 - Functional movement of the upper limb (SIS - Arm ability)



Comparison 4 - Functional movement of the upper limb (SIS - % overall stroke recovery)



Comparison 5 - Motor impairment of the upper limb (Grip strength and FMUE)



ARAT: Action Research Arm Test, BBT: Box and Block Test, FMUE: Fugl Meyer Upper Extremity score, SIS: Stroke Impact Scale.
DHO represents task specific motor training with a DHO with (Jeon *et al.* 2012; Lannin *et al.* 2016) or without (Barry *et al.* 2012; Huang *et al.* 2019) usual care, Comparator represents task specific motor training without a DHO (Barry *et al.* 2012; Lannin *et al.* 2016; Huang *et al.* 2019), or Placebo + usual care (Jeon *et al.* 2012).

2.3.4.5 Sensitivity analyses

As described in the narrative review, the intervention group received more therapy than the control group in the study by Lannin et al. (2016) (Lannin *et al*. 2016). Additionally, with the exception of Lannin et al. (2016) (Lannin *et al*. 2016) which recruited participants in the subacute phase of recover, all other included studies recruited participants in the chronic phase. Consequently, this study was removed from comparison two (upper limb function measured using the BBT) and five (upper limb motor impairment), the comparisons involving Lannin et al. (2016) (Lannin *et al*. 2016) where two or more studies remained. Despite this, the effects observed in comparison two (mean difference 2.65, 95% CI -0.04 to 5.33) (p 0.05) and five (standard mean difference 0.25, 95% CI -0.38 to 0.88) (p 0.44) remained unchanged. Statistical heterogeneity remained low (I^2 = 0%).

2.3.5 Discussion

2.3.5.1 Summary of findings

This review included four RCTs. Data were analysed for 48 participants who had moderate to severe upper limb functional capacity (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) and included participants who were in the acute to subacute (Lannin *et al*. 2016) and chronic (n=3) (Barry *et al*. 2012; Jeon *et al*. 2012; Huang *et al*. 2019) phases of recovery. A positive effect in favour of the use of non-robotic DHOs was observed with regards to upper limb function and dexterity after stroke. This may be an indicator that DHOs offer an environmental mechanism that enables people with moderate to severe upper limb functional capacity to participate more intensively and effectively in repetitive, functional-based rehabilitation. However, the lack of precision due to the small number of studies included with small sample sizes (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019), and the high risk of bias due, largely, to poor methodological reporting (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) means that there is a low certainty that the positive effects observed are true. There were no reports of significant safety issues in the included studies.

This review identified potentially promising effects of DHOs on recovery of hand and arm function when delivered over a relatively short intervention period (four (Jeon *et al*. 2012; Huang *et al*. 2019), six (Barry *et al*. 2012) and eight (Lannin *et al*. 2016) weeks) but the results are based on only four small trials at risk of bias (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019). No studies compared therapy using a non-robotic DHO with a placebo (in isolation) or no intervention. Two studies were included that compared therapy using a non-robotic DHO in isolation to usual care in isolation (Barry *et al*. 2012; Huang *et al*. 2019) and one compared therapy using a non-robotic DHO plus usual care to usual care in isolation (Lannin *et al*. 2016). An additional comparison was identified and included in one of the included studies (Jeon *et al*. 2012). It compared therapy using a non-robotic DHO plus usual care to a placebo intervention plus usual care.

None of the RCTs reported outcomes relating to performance in ADL or instrumental ADL (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019). However, all included studies reported measures relating to functional movement and motor impairment of the upper limb (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019).

All studies had small sample sizes, involved single sites and were not adequately powered (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019). Risk of bias was generally considered to be high, primarily due to poor methodological reporting. Heterogeneity was low in all comparisons (main and sensitivity analyses), except one (comparison 4 in main comparison) which was moderate.

Favourable clinically important changes were observed in gross manual dexterity (BBT) in participants receiving non-robotic DHOs in the acute to late subacute phase of recovery (mean difference between groups was 8.6 blocks in favour of the intervention group, 95% CI -4.1 to 21.3, MCID: 8 blocks) (Lannin et al. 2016) but not in the chronic phase of recovery (mean difference between groups was 0.6 blocks in favour of intervention group, 95% CI not reported, MCID: 5.5 blocks) (Barry et al. 2012). However, favourable clinically important changes were also observed in the SIS recovery scale in participants receiving the comparator intervention in the chronic phase of recovery (mean difference between groups

was 13.6% in favour of the comparator group, 95% CI not reported, MCID: ≥10% increase) (Barry et al. 2012).

2.3.5.2 Limitations

This review involved a rigorous search of the stroke literature. However, it is possible that some eligible studies were missed, introducing potential bias.

As previously mentioned, in one paper (Huang et al. 2019), four missing SDs were calculated from p-values provided using the TINV function in Microsoft excel (Grip strength and BBT) for the active and control groups post intervention) and two means were extracted from graphs provided using a digital web-based tool (Rohatgi 2020) (Grip strength and BBT for the control group post intervention). This process may have introduced bias. Furthermore, the assessment of publication bias using funnel plots was not possible as too few studies were included for this to be considered useful. Additionally, performance bias was not formally scored in the included studies as the visible nature of the experimental intervention would inevitably mean that both participants and their therapist would be unblinded to group allocation. Consequently, this unblinding may have contributed further to the high level of bias possible in the included studies.

Most strokes occur in people ≥65 years old and post-stroke cognitive impairment is common (Middleton *et al*. 2014). The studies in this review included participants with a mean age (SD) of 54.0 (12.5) years (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) and good cognitive function (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) who were mainly in the chronic phase of recovery (Barry *et al*. 2012; Jeon *et al*. 2012; Huang *et al*. 2019). Furthermore, none of the included studies reported ethnicity. Thus, generalizability of the review findings to people who are older, have cognitive impairment, use a DHO in the acute to subacute phases, or individuals with a particular ethnicity is limited. While good cognition is likely to be useful when delivered in a self-practice format, help appears to be needed from carers to don/doff the glove (Barry *et al*. 2012; Lannin *et al*. 2016), at least in some cases, and it is possible that participants with cognitive impairment could access the intervention in either a self-directed format with sufficient

guidance from informal carers or in a 1:1 format with occupational therapists/physiotherapists.

2.3.5.3 Strengths

The main strength of this review relates to the rigorous methodology used in the review process reported. Studies included participants with good cognition and upper limb functional capacity considered to be moderate to severe. Thus, clinical and statistical heterogeneity both appeared low. This offers some support for the effects observed.

Unlike conventional therapy, DHOs appear to enable people with more severe hand impairment after stroke to access greater participation in guideline-based therapy (Heise *et al*. 2010; Chang and Lai 2015; Franck *et al*. 2019). This review is likely to generate research interest in the potential use of DHOs to improve poor outcomes in this sizable group.

2.3.5.4 Implications for clinical practice

While some comparisons in this review found positive effects in favour of the use of non-robotic DHOs after stroke, the findings indicate that there is low certainty that the effects observed are true. Therefore, there is currently insufficient evidence to recommend the implementation of such devices into clinical practice. Similarly, as no negative effect was found, there is no evidence from RCTs to stop using DHOs in clinical practice after stroke if they are already being utilised. There were no reports of significant safety issues in the included studies and adherence with 1:1 (Barry *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) and self-practice (Huang *et al*. 2019) therapy participation when reported was good (Table 6) suggesting that non-robotic DHOs may offer a safe and feasible post-stroke intervention that may enable people with moderate to severe upper limb functional capacity to access repetitive, functional-based rehabilitation. To ensure safety, it seems reasonable that users are assessed for problems with blood circulation, skin breakdown and increased joint pressure. Prior to commencing any self-directed therapy, establishing reliable physical (to don/doff the DHO, complete therapy diaries) and cognitive support (exercise guidance etc) is likely to be key in

people experiencing moderate to severe upper limb functional capacity, particularly in the presence of cognitive impairment. Given the evidence reviewed, an intervention period of four to eight weeks appears reasonable. The ARAT and BBT are easy and quick to administered, and as the small sample included in this review found positive effects in them both, these outcomes may be responsive measures to assess change.

2.3.5.5 Implications for research

A systematic review of the current evidence on non-robotic DHOs to improve upper limb recovery in people with upper limb impairment after stroke from RCTs has been provided (Objective 1). However, further research is needed to strengthen the evidence base to determine whether non-robotic DHOs improve upper limb recovery in people with upper limb impairment after stroke in comparison to Placebo or no intervention and Usual care (Objective 2). A large, good quality, multi-site, adequately powered RCT is indicated to provide increased certainty on the effect of non-robotic DHOs after stroke. Where possible, such a trial should include; (i) older participants, (ii) participants with cognitive impairment where sufficient support is available, (iii) participants in the acute to subacute phase of recovery, (iv) reporting of ethnicity, (v) measurement of ADL, instrumental ADL and adverse events, and (vi) Consolidated Standards of Reporting Trials (CONSORT) standards for reporting methodological details in a RCT (Moher *et al*. 2012; Page *et al*. 2021).

2.4 Conclusions

Part 1 of this chapter reported a scoping review that included 19 non-RCTs (mainly single group pretest-posttest designs) and four RCTs. All studies included small sample sizes with participants considered to have moderate to severe upper limb functional capacity. Most included participants were from non-RCTs and in the chronic phase of stroke recovery and most studies lacked long term follow up. The scoping review provides a comprehensive summary of the existing evidence on the use of non-robotic DHOs in stroke rehabilitation in adults and highlights that the use of this intervention to improve upper limb function after stroke is currently under researched.

Evidence gaps identified in the scoping review indicate that a systematic review of RCTs identified in this review and good quality, multisite, adequately powered RCTs should be prioritised to progress the current evidence on the effect of non-robotic DHOs after stroke.

Part 2 of this chapter reported a narrative and systematic review that included the four RCTs identified in the scoping review in Part 1 of this chapter. Consequently, like the scoping review in Part 1, all four RCTs included participants with upper limb functional capacity that was considered to be moderate to severe. One and three of the included RCTs involved participants in the acute to late subacute (Lannin *et al*. 2016) and chronic (Barry *et al*. 2012; Jeon *et al*. 2012; Huang *et al*. 2019) phases of recovery respectively. Only one RCT included follow up beyond the intervention end (Huang *et al*. 2019). A positive effect in favour of the use of non-robotic DHOs in comparison to usual care ((Barry *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) and usual care plus placebo (Jeon *et al*. 2012) was observed with regard to upper limb function and dexterity (but not impairment) after stroke. No significant safety issues were reported in the studies included in this review.

Despite the positive effect observed in the systematic review the high risk of bias reported in the RCTs included, largely due to poor methodological reporting, small sample size and lack of long term follow up prevents robust conclusions being drawn on the overall effectiveness of non-robotic DHOs to improve upper limb recovery after stroke.

Taken together, these reviews provide a clear indication that a good quality (i.e. low risk of bias), multisite, adequately powered RCT with long term follow up was required to generate sufficient high-quality evidence to determine if findings in the systematic review could be reproduced, thereby offering support to implement the intervention into clinical practice. Additionally, research gaps shared by both reviews that future research needs to address include a lack of research involving larger samples representative of the target population (e.g. in gender, ethnicity), stakeholder informed research, use of outcomes that measure ADL, instrumental ADL and adverse events, and studies with follow up beyond the intervention end and conducted in the acute to subacute phase of recovery.

Furthermore, reporting in both reviews was often poor, particularly on ethnicity, intended intervention delivery and adherence to it (e.g. the intervention period and training time/repetitions, discipline of trainer, and carer support and training setting, two factors likely to significantly influence logistics, participation burden and the feasibility of successful participation)). Thus, future studies should aim to adopt rigorous reporting in line with Equator Guidelines (Equator Network 2023).

Chapter 3

Methodology to evaluate the EMPOWER Help for Hands Intervention in the SUSHI trial: A mixed methods approach

3 Chapter 3 Methodology to evaluate the EMPOWER Help for Hands Intervention in the SUSHI trial: A mixed methods approach

3.1 Introduction

Chapter 2 summarised the current evidence base on the use of non-robotic dynamic hand orthoses (DHOs) after stroke and recommended that a high quality randomised controlled trial (RCT) was required to progress it. This chapter reports the chosen methodology for the work conducted in this programme of work to progress this existing evidence.

3.1.1 Research purpose & objectives

The Department of Health's framework for the governance of health and social care research in the UK define research as:

> "…the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods." (Department of Health 2005b, p.3)

In the quest for new knowledge to better understand a phenomenon of interest, research takes many forms. Research that seeks to study relationships with a phenomenon of interest typically has one of two overarching objectives (Kimmelman *et al*. 2014; Nilsen *et al*. 2020):

- To confirm or refute an existing theory/hypothesis e.g. to determine if a suspected relationship exists between two phenomena or not - **confirmatory research, or**

- To explore a topic to generate a new theory/hypothesis e.g. to understand what factors appear to influence a phenomenon of interest - **exploratory research**

3.1.2 The role of methods & methodology in research

According to Giddings and Grant (2007), the methods of a research study are the "doing tools" utilised to collect and analyse information in order to address a particular research objective and gain new knowledge (e.g. a measurement tool, questionnaire, interview) (Giddings and Grant 2007). However, it is the methodology that serves as the "thinking tool"(Giddings and Grant 2007), or backbone to a study, providing an overarching research strategy with sound theoretical underpinning that subsequently identifies the chosen methods to best obtain the knowledge sought (Hanson *et al*. 2005; Giddings and Grant 2007; Morgan 2007).

This chapter will discuss the rationale for the methodological approach selected for (i) a RCT conducted to evaluate upper limb recovery outcomes (outcome evaluation) in relation to a non-robotic dynamic hand orthosis (DHO) intervention, and (ii) an evaluation of processes that influenced these outcomes (process evaluation) (exploratory qualitative study). The programme of research conducted is titled the **S**aeboGlove therapy for **U**pper limb disability and **S**evere **H**and **I**mpairment after stroke (SUSHI) trial. The overarching methodological approach chosen and the theoretical assumptions underpinning it will first be discussed. The specific methodological design selected will then be justified.

3.2 Objective

The objective of this chapter is:

- To describe and provide the rationale behind the methodological approach and design used in the outcome and process evaluation conducted in SUSHI trial

3.3 Methodology

3.3.1 Complex intervention & the Medical Research Council guidance for their development and evaluation

As discussed in Chapter 1, the multiple and potentially interacting components in a complex interventions (Campbell et al. 2007) hinder the identification of

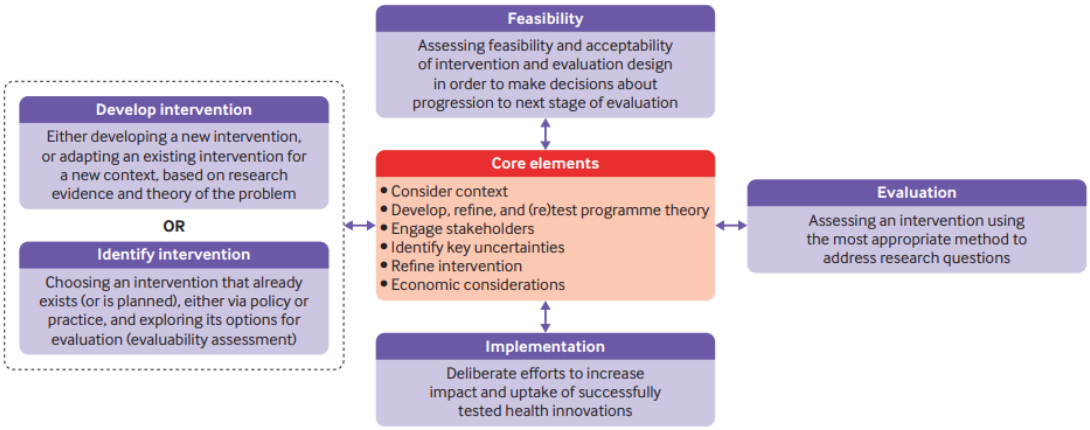
"active" ingredients (DeJong et al. 2004). These potential interactions along with the heterogeneous and often complex sequelae experienced after stroke add complexity to an intervention. Additionally, behavioural changes the intervention requires, differing motivations, environmental and organisational circumstances of service providers and users (e.g. staffing levels and competence, pressures to divert therapy resources to fulfil other priorities such mobility safety or a swift discharge home, physical/emotional support available) and the amount of tailoring required may all influence implementation and impact effectiveness further adding complexity (Craig *et al*. 2008; N. Kristensen *et al*. 2016; Pfadenhauer *et al*. 2017; Public Health England 2018b; Skivington *et al*. 2021). This complexity presents a special evaluation challenge (DeJong et al. 2004) as the lines between what constitutes (1) the intervention, (2) intervention implementation and (3) the context influencing intervention implementation are not immediately clear (Pfadenhauer *et al*. 2017). Acquiring knowledge of all three of these aspects in clinical trials of complex interventions, ideally co-designed with key stakeholders, is important to aid interpretation of outcome results and successful transfer of them to other settings to maximise research impact (Walker *et al*. 2017). However, complicated intervention research (Hoffmann *et al*. 2014; Skivington *et al*. 2021), including trials for stroke rehabilitation frequently fall short of assessing/documenting these elements (Bernhardt *et al*. 2016; Walker *et al*. 2017).

Consequently, the Medical Research Council (MRC) have produced guidance to help researchers make sound methodological choices when developing and evaluating complex interventions to maximise the efficiency, use, and impact of research (Craig *et al*. 2008; Skivington *et al*. 2021). The MRC guidance has been widely accepted in healthcare research (Datta and Petticrew 2013; Cathain *et al*. 2019).

The guidance presents a framework with four stages: Develop (or Identify) intervention, Feasibility, Evaluation and Implementation (Craig *et al*. 2008; Skivington *et al*. 2021) (Figure 14). All stages share a common set of core elements that should frequently be considered to help researchers decide

whether they should repeat a stage, proceed to the next stage or recede to a previous stage (Skivington *et al*. 2021) (Figure 14).

Figure 14: Framework for developing and evaluating complex interventions



Context=any feature of the circumstances in which an intervention is conceived, developed, evaluated, and implemented; Programme theory=describes how an intervention is expected to lead to its effects and under what conditions—the programme theory should be tested and refined at all stages and used to guide the identification of uncertainties and research questions; Stakeholders=those who are targeted by the intervention or policy, involved in its development or delivery, or more broadly those whose personal or professional interests are affected (that is, who have a stake in the topic)—this includes patients and members of the public as well as those linked in a professional capacity; Uncertainties=identifying the key uncertainties that exist, given what is already known and what the programme theory, research team, and stakeholders identify as being most important to discover—these judgments inform the framing of research questions, which in turn govern the choice of research perspective; Refinement=the process of fine tuning or making changes to the intervention once a preliminary version (prototype) has been developed; Economic considerations=determining the comparative resource and outcome consequences of the interventions for those people and organisations affected. Taken from Skivington, et al. (2021) 'A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance', *BMJ*, 374, n2061, available: http://dx.doi.org/10.1136/bmj.n2061. This is open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. Full Terms at: Creative Commons — Attribution 4.0 International — CC BY 4.0

The SUSHI trial aimed to progress the current evidence base on interventions involving non-robotic DHOs to improve upper limb recovery early after stroke (Alexander *et al*. 2021b) (Appendix A). The intervention studied is called the EMPOWER Help for Hands Programme and was designed in its original piloted version by the author prior to this doctorate (Appendix F). The intervention involves multiple components that may interact in their effectiveness making it a complex intervention. Consequently, its development and evaluation are informed by the MRC framework guidance for complex interventions (Craig *et al*. 2008; Skivington *et al*. 2021) (Figure 14).

3.3.1.1 Development of complex intervention

Chapter 1 of this thesis provides a detailed description of the rationale (evidence and theory, Figure 14) that informed the authors initial development, or identification, of the EMPOWER Help for Hands Programme. It highlighted that:

(i) Repetitive functional based and self-practice activities (Intercollegiate Stroke Working Party 2023), and increased training intensity (>100 movement repetitions) (Carey *et al*. 2002) may improve upper limb outcomes after stroke,

(ii) There is potential merit in offering strategies that increase early access to such activities (Nakayama *et al*. 1994; Malhotra *et al*. 2011; Veerbeek *et al*. 2014b), and

(iii) The inequitable provision of upper limb rehabilitation in people with severe upper limb deficits (less functional and strength based content and time dedicated to upper limb rehabilitation) (Stockley *et al*. 2019), including people lacking active digital extension (Kwakkel *et al*. 2003; Veerbeek *et al*. 2014b; Kwakkel *et al*. 2015a) may explain the poorer outcomes in this group (Nakayama *et al*. 1994; Kwakkel *et al*. 2003)

The modelling of the intervention was based on this evidence, along with the principles of stroke rehabilitation (assessment (or review)), problem solving and goal setting and a tailored/patient centred intervention with carer involvement (if needed) to assist in goal achievement) (Langhorne *et al*. 2011) and the perceived physical rehabilitation needs of stroke survivors (enhanced therapy provision, information and support, use of meaningful and progressive rehabilitation tasks, and empowerment) (McKevitt *et al*. 2011; Luker *et al*. 2015; Stroke Association 2016; Abrahamson and Wilson 2019), also presented in Chapter 1. Core components of the EMPOWER intervention are illustrated in Figure 15 (overleaf), several of which incorporate research evidence that stakeholders wish to prioritise implementing into clinical practice (improved

patient-centred interdisciplinary care, use of clinical practice guideline, increased physical rehabilitation intensity, caregiver support, early access to rehabilitation and equipment/technology to increase rehabilitation intensity, and the potential for improved care transition if the intervention delivery spans the rehabilitation gap between discharge home and it starting in the community) (Eng *et al*. 2019).

The specific design of the pilot version of the EMPOWER Help for Hands intervention, along with two research activities carried out by the author of this thesis prior to this doctorate commencing are described and justified in detail in Appendix F. Both activities included stakeholder involvement to increase the likelihood of creating a feasible, acceptable, and beneficial health intervention with optimal implementation impact (i.e. an intervention that could successfully engage the target population, maintenance of the integrity of core intervention components while incorporating flexibility needed in different individuals/settings) and a chance of bringing about changes in practise or policy (Figure 14) (Skivington *et al*. 2021).

The first activity was a single group, open pilot feasibility trial (The SaeboGlove Evaluation Trial (T-SET)) that assessed two progression criteria in the MRC framework, the feasibility of the EMPOWER Help for Hands Programme (Pilot version) (intervention adherence, safety, acceptability to stroke survivors, carers, occupational and physiotherapists, and glove laundering turnaround time and durability) and the feasibility of an evaluation trial (recruitment and outcome measure completion, and clinical upper limb data to inform sample size calculations) (Alexander and Dawson 2019) (Appendix F).

The second activity was a Patient and Public Involvement (PPI) activity that followed T-SET and captured the views of two stroke survivors from the target population on how future research should proceed to optimise relevance for this group (e.g. intervention timing, flexibility, duration of support provided, retention strategy for control group, appropriate/meaningful outcome) (Appendix F).

Figure 15: Core components of EMPOWER Help for Hands Programme



***EMPOWER principles: Equips patients with the tools needed (e.g. SaeboGlove, instructions) to carry out meaningful exercise involving everyday tasks (e.g. eating, drinking, self-care), Motivates patients by setting shared intensity goals, logging/monitoring daily self-practice activity and identifying and overcoming barriers to daily self-practice exercises, Provides a progress review every 1-2 weeks so that exercises remain challenging and progressive, Optimises self-management support at therapy reviews by coaching independence in exercises, progression, and tailoring, Weans from help provided for some/all exercises as able (e.g. reduce help provided by SaeboGlove bands and glove), Engages carer support whenever possible, and Reminds participants of the ultimate goal and need to transfer knowledge and skills gained into everyday life (e.g. increase use of affected hand in everyday tasks).**

The intervention and an evaluation trial were judged to be feasible (and acceptable) based on the findings in T-SET (Appendix F). Consistent with conclusions made in the Scoping review, and Systematic review (Appendix A) (Alexander et al. 2021a) in Chapter 2 conducted as part of this doctorate, T-SET also recommended an adequately powered, multi-site blinded randomised controlled evaluation trial with long term follow up to progress the evidence on the use of non-robotic DHOs after stroke (Appendix F). These recommendations were utilised in the design of the outcome and process evaluation in the SUSHI Trial (Chapters 4 and 5 respectively) to further optimise feasibility (and acceptability) of the EMPOWER intervention and of a future evaluation trial design.

3.3.1.2 Evaluation of complex interventions: The need to utilise evidence from multiple sources to improve the evidence base

Consistent with the MRC framework for developing and evaluating complex interventions (Craig *et al*. 2008; Skivington *et al*. 2021) (Figure 14), the SUSHI trial conducted in this doctorate (Chapters 4-5) utilised recommendations from the development work in Appendix F and the review chapter in this thesis (Chapter 2) to refine the EMPOWER Help for Hands Programme and inform the subsequent evaluation of it.

Additionally, when evaluating a complex intervention in order to obtain sufficient evidence base on it to support decision making and ensure usefulness of research in the real world, the MRC guidance (Craig *et al*. 2008; Skivington *et al*. 2021) and an international partnership of stroke recovery and rehabilitation experts (Walker *et al*. 2017) emphasises the need to utilise evidence from multiple sources that do not share the same weaknesses. Consequently, such guidance advocates the use of a process evaluation as well as an evaluation of an interventions outcomes (effectiveness) (Craig *et al*. 2008; Walker *et al*. 2017; Skivington *et al*. 2021).

Outcome evaluation

To improve upper limb outcomes it is essential that researchers develop accessible, evidence-based interventions. An outcome evaluation provides a mechanism to measure the change in health care outcomes of interest in

response to an intervention in order to assess if it is effective and by how much (Public Health England 2018a). Consistent with the MRC framework, the SUSHI trial conducted in this doctorate evaluated the outcomes of the EMPOWER Help for Hands Programme (Craig *et al*. 2008; Skivington *et al*. 2021).

Process evaluation

As previously described above, the effectiveness of complex interventions and their ability to reach their target population, are closely linked to the way the intervention is implemented and the contextual factors surrounding it (N. Kristensen *et al*. 2016; Pfadenhauer *et al*. 2017; Public Health England 2018b). However, outcome evaluations do not routinely collect information on the processes of implementation of complex interventions and are unable to capture information on the context surrounding an intervention (Craig *et al*. 2008; Moore *et al*. 2015).

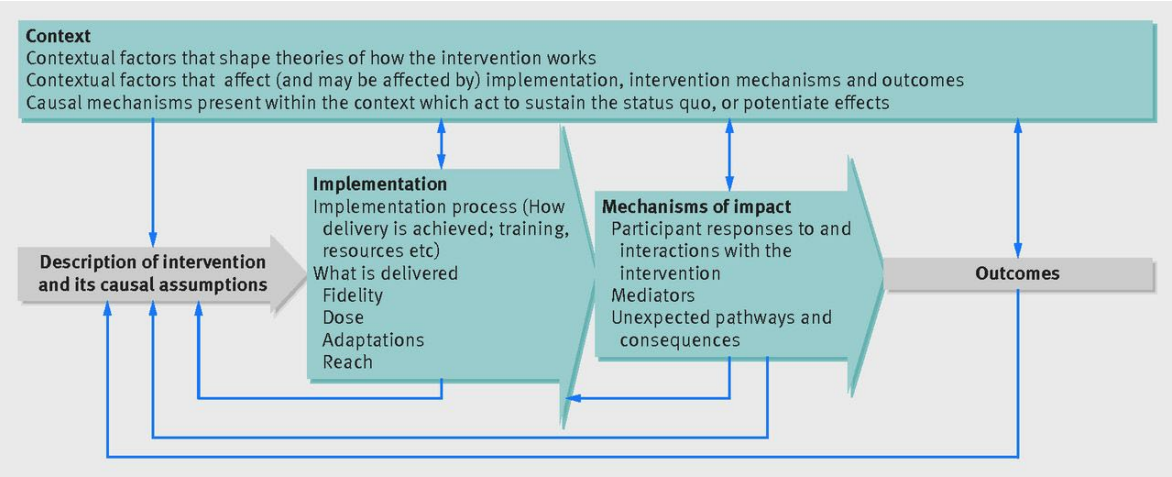
Failing to capture this information in an effectiveness study significantly impedes a researcher's ability to understand mechanisms of impact, variation in outcomes or ways to tailor therapy to optimise successful engagement (N. Kristensen *et al*. 2016; Pfadenhauer *et al*. 2017; Public Health England 2018b). Additionally, it limits their ability to replicate the intervention and apply the findings of a study to other contexts, thereby inhibiting the translation of evidence-based research into clinical practice, wasting resources allocated to clinical research and contributing to the existing healthcare gap between research and practice (N. Kristensen *et al*. 2016; Pfadenhauer *et al*. 2017).

Consequently, effectiveness trials must not only identify if a complex intervention "works", but must also identify why, how and in what circumstances outcomes work (Glasgow and Emmons 2007; Craig *et al*. 2008; Datta and Petticrew 2013; Moore *et al*. 2015; Luker *et al*. 2016; Walker *et al*. 2017; Rodgers *et al*. 2020; Skivington *et al*. 2021).

A process evaluation provides the mechanism to capture data on the implementation of an intervention and the environment it is contextualised in (Oakley *et al*. 2006; Clarke *et al*. 2013; Public Health England 2018b), thereby helping to answer these additional questions. It is defined by the MRC in the UK as:

> "a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors (Figure 16). Process evaluation is complementary to, but not a substitute for, high quality outcomes evaluation." (Moore *et al*. 2014, p.8)

Figure 16: Key functions of process evaluation and relations among them



Blue boxes are the key components of a process evaluation. Investigation of these components is shaped by a clear intervention description and informs interpretation of outcomes. Figure taken from guidance offered by the Medical Research Council (Moore *et al.* 2015). Taken from Moore, et al. (2015) 'Process evaluation of complex interventions: Medical Research Council guidance', *BMJ : British Medical Journal*, 350, h1258, available: http://dx.doi.org/10.1136/bmj.h1258. This is open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. Full Terms at: Creative Commons — Attribution 4.0 International — CC BY 4.0

The long-term objective of the SUSHI trial is to derive generalisable new knowledge on upper limb recovery after stroke in people with severe upper limb impairment and reduced upper limb function, thereby contributing to improved upper limb outcomes in this group. This study involved a complex stroke rehabilitation intervention with multiple components that may interact (Alexander *et al*. 2021b) (Figure 14). Consistent with the MRC framework for the evaluation of complex interventions (Craig *et al*. 2008; Skivington *et al*. 2021) and the need to derive generalisable knowledge (Department of Health 2005b), the outcome evaluation in this study was accompanied by a process evaluation.

3.3.2 Research objectives in the SUSHI Trial

The research objectives in the SUSHI trial were set to progress the existing evidence base on the use of non-robotic DHOs after stroke set out in Chapter 2. Conducting an outcome and process evaluation in the SUSHI trial meant that the study had multiple interconnected research objectives and involved confirmatory and exploratory research:

Primary objective (outcome evaluation):

- To evaluate the effects of six weeks of the EMPOWER Help for Hands Programme plus usual care improves upper limb function in comparison to usual care alone in people with reduced active digital extension, upper limb disability and severe hand impairment after recent stroke (confirmatory research)

Secondary complementary objectives (process evaluation):

- To explore factors relating to support that moderate, or influence, implementation of the EMPOWER Help for Hands Programme from a stroke survivor, carer, and therapist perspective (exploratory research)

3.3.2.1 Confirmatory research

The confirmatory research also required the collection of quantitative data (e.g. scores from measurement tools and questionnaires) and using statistical techniques to test a theory/hypothesis (deductive reasoning) (Bryman 2008).

3.3.2.2 Exploratory research

In contrast, the exploratory research involved the exploration of the human experience and contextual influences surrounding the intervention and therefore required using qualitative research methods, the collection of qualitative (i.e. non-numerical) data (e.g. text/audio from interviews), and the use of analytical methods to identify common themes (inductive reasoning) (Bryman 2008; Othman 2011; Kimmelman *et al.* 2014).

3.3.3 Theoretical assumptions underpinning methodology

In the quest for knowledge, research is influenced by different theoretical assumptions (beliefs or perspectives), about the world and the best way to acquire the knowledge sought (Creswell 2014).

Giving consideration to a researcher's theoretical assumptions is important as they may exert significant influence on a study's rationale and link the objectives of the research to the methodology and methods selected to fulfil them (Morgan 2007; Creswell 2014) (Figure 17), may lead to the selection of different research approaches involving the same phenomenon (Grix 2004) and therefore provide the foundation for establishing methodological congruence and credibility (Strudsholm *et al*. 2016).

Figure 17: The relationship between knowledge, a researcher's theoretical perspective on how best to obtain it and the chosen research methodology and methods

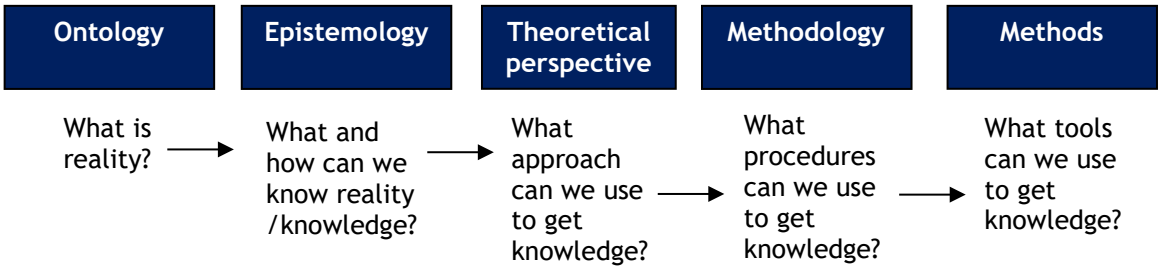


Figure reproduced by permission from Sage Publications. [Crotty, M. (1998) *The foundation of social research: Meaning and perspective in the research process.*, California: Thousand Oaks, Sage, 2023].

The concepts of ontology and epistemology will now be introduced (Sections 3.3.3.1 and 3.3.3.2 respectively) and then used to justify the theoretical perspective underpinning the multiple objectives in the SUSHI trial (Section 3.3.3.3).

3.3.3.1 Ontology

Ontology, or the study of the nature of reality, considers whether reality exists independently of the human mind i.e. if there is a single or multiple realities (Denzin and Lincoln 2005). Critical realists believe that reality, or the "real" world, cannot be observed as a whole and exists independent of the human mind (Letourneau and Allen 2006). Instead, a probabilistic truth must be achieved through the "observable" i.e. physical world using partial fragments and reasoning, to characterise the whole (Letourneau and Allen 2006; Clark *et al*.

2007; Bergin *et al*. 2010). In contrast to a probabilistic truth, relativists believe that reality is dependent on the mind i.e. socially derived (Denzin and Lincoln 2005) and not distinguishable from it (Guba and Lincoln 2005). Consequently, they believe that there are multiple truths (and multiple paths to it) as each individual, with their unique life experience (e.g. past and present experiences, education, values etc), does not simply interpret their external world differently, their worlds are different (Stajduhar *et al*. 2001).

3.3.3.2 Epistemology

Epistemology, or the study of what a discipline believes to be acceptable knowledge (Crotty 1998), considers the relationship between the knower (human subjectivity/bias) and the knowledge (truth/reality) i.e. if it is an objective or subjective source (Denzin and Lincoln 2005). While objectivists believe that truth is external and occurs independent of human subjectivity i.e. is objective (Crotty 1998), subjectivists believe that it is "always filtered through the lenses of language, gender, social class, race, and ethnicity" i.e. is subjective (Denzin and Lincoln 2005).

3.3.3.3 Chosen theoretical perspective (paradigm) to generate knowledge in the SUSHI trial

These different theoretical positions in research generate a number of perspectives, known as "paradigms" (Kuhn 1970) or worldviews (Creswell 2014).

Quantitative research involves collecting numerical data and has strong links with the postpositivist paradigm (a critical realist ontology and an objectivist epistemology), assuming that knowledge in their discipline is objective (Crossan 2003; Ma 2012), probabilistically true and acquired through observation and reasoning (Letourneau and Allen 2006). In contrast, qualitative research involves collecting non-numerical data (e.g. text/audio) and has links with the interpretivist paradigm (a relativist ontology and a subjectivist epistemology), assuming that knowledge is subjective (Ma 2012), socially constructed and acquired as representations of reality (Denzin and Lincoln 2005).

Selecting a suitable paradigm after a study's objectives have been determined is a crucial first step in creating a suitable research strategy. As well as being

influenced by the researcher's own personal assumptions/beliefs (Morgan 2007; Creswell 2014) paradigm decisions are also typically made using one of four stances when multiple research objectives are set involving research with different types of objectives (i.e. confirmatory and exploratory): selecting the 'best' single paradigm for all research objectives collectively; selecting different paradigms for different objectives; selecting a paradigm based on study context or one that is shaped by the relevant research community (Creswell and Plano Clark 2018).

A pragmatic paradigm adopts a reflexive, flexible, and empirical approach to research, rejects the view that reality (truth) can be accessed using a single scientific method alone (Maxcy 2003; Johnson and Onwuegbuzie 2004; Creswell *et al*. 2011). It believes that there is no single system of philosophy, and no single truth (Maxcy 2003; Creswell *et al*. 2011) and that knowledge may be objective or subjective and acquired in multiple ways (Johnson and Onwuegbuzie 2004). Additionally, it assumes that a single objective truth does exist, but is environment dependent and can only be encountered through human experience (Johnson and Onwuegbuzie 2004). Consequently, truth is not static, but always changing in response to changing events encountered (e.g. pain, illness, fatigue, emotions/beliefs, support), and an individual's knowledge is based on their unique beliefs and habits that are socially constructed (Johnson and Onwuegbuzie 2004). Knowledge can therefore be individually unique or socially shared depending on the degree of shared beliefs amongst those encountering a given situation.

Acceptable knowledge in a pragmatic paradigm requires the researcher to use a problem-solving approach to solve real world situations, selecting the study design and methodology that is most appropriate to fulfil the specific research objectives set (Johnson and Onwuegbuzie 2004). Different types of data can be used as the researcher critically evaluates different sources of evidence (e.g. quantitative and qualitative), and uses abductive reasoning, a form of logic used to overcome weaknesses associated with a deductive (quantitative) or inductive (qualitative) approach in order to explain events observed (Johnson and Onwuegbuzie 2004).

A pragmatic paradigm is well suited to the SUSHI trial and was adopted for it for two main reasons:

- It is considered by many to be the most favoured paradigm for complex i.e. multi-faceted research problems, common in healthcare research, which often have multiple objectives and require the use of different forms of data (quantitative and qualitative) in a single study (Doyle *et al*. 2009; Biddle and Schafft 2014; Dieronitou 2014; Gunasekare 2015; Fiorini *et al*. 2016; Kaushik and Walsh 2019). Additionally, it utilises abductive reasoning which is well placed to explain how the intervention worked (or not) and why. Consistent with this, it aligns with the pluralistic approach advocated by the medical research community set out in the MRC framework for the evaluation of complex interventions which advocates the use of multiple sources of evidence to obtain sufficient evidence base to support decision making and ensure usefulness of research involving such interventions in the real world (Craig *et al*. 2008; Skivington *et al*. 2021).

- It aligns well with the author's outlook which (i) accepts the presence of both the physical and social worlds, (ii) believes that knowledge can be both objective (e.g. a measure physically observed in an outcome evaluation) or subjective (e.g. a description of how human experience influences behaviour/engagement in a process evaluation) and (iii) believes that the method used to capture desired knowledge depends primarily on the nature and diversity of that knowledge i.e. the research objectives (confirmatory and exploratory) and to a lesser extent on the resources available to advance that knowledge.

3.3.4 Methodological approaches – strengths and weaknesses

As previously described, a sound methodological approach for a particular study depends on the nature of the research objectives (Denzin and Lincoln 2005) and the theoretical perspective underpinning it (Giddings and Grant 2007; Morgan 2007; Patel 2015) (Figure 17)). It may take one of three approaches, being quantitative, qualitative, or mixed i.e. utilising both qualitative and quantitative

components (Tashakkori and Teddlie 2003; Migiro and Magangi 2011; Gunasekare 2015).

Much variation exists in each of these three methodologies and the distinctions between quantitative and qualitative methods are often understood as endpoints on a continuum with some studies being more qualitative (data on individuals' own interpretations are sought), more quantitative (objective data sought), or in between i.e. mixed and incorporating both components (Creswell 2014). They are not rigid dichotomies (Creswell 2014). However, an overdrawn distinction of characteristics typically assumed in (i.e. associated with) quantitative and qualitative research methods are summarised in Table 10 (overleaf) (Bryman 2008; Othman 2011) for heuristic purposes (Kidder and Fine 1987; Creswell 2014).

Table 10: Characteristics typically assumed in quantitative and qualitative research methods

Quantitative research	RESEARCH ASPECTS	Qualitative research
Natural science: Typically confirmatory (top down) i.e. researcher sets a hypothesis based on existing theory then tests it using data (Deductive methodology) May be exploratory i.e. bottom up.	SCIENTIFIC METHOD	Social science: Typically exploratory (bottom up) i.e. researcher collects data and interprets it to generate a new hypothesis/theory (Inductive methodology)
Tests hypothesis, cause, and effect	PURPOSE	Understands and interprets human experience
Experimental: Measures and tests, assumes measurement accuracy and controlled setting	APPROACH	Interpretive: Observes and interprets, assumes natural setting
Quantitative data. Assumes truth requires a structured response with fixed, numerical values for precision	DATA COLLECTION APPROACH	**Qualitative data.** Assumes truth requires an unstructured response to varying degrees with free form, non-numerical data to generate depth
Identifies statistical relationships e.g. on who, what, when, where, how many	DATA ANALYSIS	Identifies patterns, themes e.g. on why and how
Assumes truth is objective i.e. external to human subjectivity and that the researcher is therefore uninvolved and takes steps to reduce bias (e.g. researchers may be blinded to participant characteristics/participants may be blinded to researcher's biases)	RESEARCHER INDEPENDENCE	Assumes there are multiple truths as truth is subjective (i.e. dependent on the human mind, filtered through the lenses of language, gender, social class, and ethnicity) and that human bias is therefore introduced as researcher is the primary data collection instrument
Assumes that knowledge is acquired through measurements made in large, random samples that provide statistical representation of the population to produce generalisable results regardless of context	SAMPLES	Assumes that knowledge is acquired through observation or interviews involving small, non-random purposeful samples that provide central themes and outliers with a rich and in-depth exploration of contextual understanding to permit a reader to judge the transferability of the results to individuals in a different context/setting

Reproduced and adapted with permission of Othman 2011, Available: http://shayaaresearch.blogspot.com/2011/04/qualitative-vs-quantitative-research-v.html

The roles of a quantitative and qualitative approach, and a mixed methods approach will now be considered (Sections 3.3.4.1 and 3.3.4.2 respectively) and then used to justify the chosen methodological approach in the SUSHI trial (Sections 3.3.4.3).

3.3.4.1 The roles of quantitative and qualitative approaches

Strengths assumed in quantitative research: While bias exists and is difficult to avoid completely in any research (Malone *et al*. 2014), quantitative research is typically assumed to be objective and have a lower risk of bias (Bryman 2008; Othman 2011). This is because this approach is amenable to researchers selecting highly structured methods and following systematic steps in a controlled setting that can minimise subjectivity and bias and positively influence the accurate and consistent measurement of variables of interest (Bryman 2008; Kimmelman *et al*. 2014). For example, a relationship between the researcher and participants is typically assumed to be absent to ensure that both parties act independently of each other to try to minimise bias and data collection methods (tools) are typically assumed to be accurate and objective (Bryman 2008; Kimmelman *et al*. 2014). Additionally, large, random samples of participants are often assumed to be utilised to enable the extension of the results from the study sample to the wider population (Bryman 2008; Kimmelman *et al*. 2014).

Thus, to ensure the usefulness and integrity of quantitative research findings, it is critical that a systematic, rigorous, and transparent scientific approach is utilised e.g. to determine if such assumptions (Table 10 above) hold. If conducted well, the findings should fulfil the criteria widely used to assure high methodological rigour in quantitative research (Table 11 overleaf), being objective (unbiased), a true reflection of the phenomenon studied (internal validity), generalizable to a larger population (external validity) and replicable by other researchers using a similar method (reliability) (Devers 1999). As research aims to obtain new generalisable knowledge, such an approach has obvious appeal.

Limitations assumed in quantitative research: The highly structured data collection techniques in quantitative research impose limits on participant

Table 11: Definitions for methodological rigour criteria used to judge the quality of a research study: Quantitative & qualitative terminology

Criteria for rigour**	Quantitative*	Qualitative**
Truth value Answers question asked truthfully	**Internal validity** 'The degree to which findings correctly map the phenomenon in question'.	**Credibility** The confidence that the research findings are 'truthful' i.e. represent the participants' original data/views and the context.
Applicability Findings can be applied in other situations	**External validity** 'The degree to which findings can be generalized to other settings similar to the one in which the study occurred.'	**Transferability** The degree to which the research findings can be transferred to other contexts/settings or with other groups of participants.
Consistency Same results obtained if study replicated in same conditions	**Reliability** 'The extent to which findings can be replicated or reproduced by another investigator.'	**Dependability** The stability of findings over time if the inquiry were replicated with the same participants in the same context.
Neutrality Absence of bias	**Objectivity** 'The extent to which findings are free from bias.'	**Confirmability** The degree to which the findings of an inquiry are determined by the participants and conditions of the inquiry and not by the biases, motivations, interests, or perspectives of the inquirer i.e. they are clearly derived/confirmed by the data.

***Definitions taken from Devers 1999, p.1157**
****Summarised from Lincoln and Guba 1985**

responses (e.g. questionnaires offer pre-set/closed responses) and have limited ability to accurately quantify topics e.g. where responses may be wide ranging or unanticipated, or where an in-depth explanation of the context (the how or why questions) surrounding a response is also sought (Fiorini *et al*. 2016).

Thus, when a research objective is exploratory in nature and aims to understand the human experience, the use of quantitative methods with such inherent limitations may prevent the study results representing the true views of participants (Bryman 2008; Fiorini *et al*. 2016). Consequently, in such cases, quantitative methods are not the preferred method of choice and other methods must be sought (Bryman 2008; Kimmelman *et al*. 2014).

Strengths assumed in qualitative research: In contrast to quantitative research, qualitative research does not seek to identify a single truth that can be generalised broadly to a population (Al-Busaidi 2008; Bryman 2008). Instead, it seeks an in-depth understanding of the human experience and the contextual factors that govern it to aid the transferability of finding to another setting (Al-Busaidi 2008; Bryman 2008). In order to obtain rich descriptive data, it requires a more dynamic research approach, often utilising open-ended questions that permit participants to lead their own response naturally i.e. without external constraints, and provide researchers with the opportunity to probe more deeply using follow-up questions (Table 10) (Al-Busaidi 2008) (Bryman 2008).

Indeed, a qualitative approach is favoured when the primary goal of research is to gain this in-depth human understanding (Table 10) (Al-Busaidi 2008; Bryman 2008; Bonell *et al*. 2012; Moore *et al*. 2015).

Limitations assumed in qualitative research: The findings of qualitative research are often assumed to be subjective and open to bias (Al-Busaidi 2008; Bryman 2008; Berger 2013). This is because the researcher is intimately involved in the research process and findings are often considered to be a product of the researcher's interpretation rather than a single accurate/trustworthy account of the truth (Al-Busaidi 2008; Bryman 2008; Berger 2013). Data collected is less structured as it depends on the particular questions the researcher asks or the observations he/she may or may not make, the data he/she selects for analysis, all of which are open to researcher and/or participant bias (Table 10) (Al-Busaidi 2008; Bryman 2008; Berger 2013). Similarly, data collected may vary depending on how a participant makes sense of and interprets their experiences at a given point in time based on the wider context. Consequently, subjectivity and the potential for bias are often assumed and felt to threaten readers confidence in qualitative research findings (Al-Busaidi 2008; Bryman 2008; Berger 2013).

Similarly, qualitative findings are often assumed by positivists to have limited usefulness as they utilise small samples which prevent generalisability of findings to a target population (Bryman 2008; Vasileiou *et al*. 2018). However, it is the depth of inquiry that predominates over generalisability in qualitative research (Bryman 2008; Vasileiou *et al*. 2018). Thus, the primary focus is on gathering

sufficient in-depth contextual information to understand the human experience with a secondary focus being to make a rich description of this information available to permit other researchers to make transferability judgements in relation to other contexts/settings, not the target population (Bryman 2008; Vasileiou *et al*. 2018).

Thus, to ensure the usefulness and integrity of qualitative research findings, it is critical that a systematic, rigorous and transparent scientific approach is utilised to instil confidence in the research process and transferability of findings (Sandelowski 1993; Korstjens and Moser 2018; Ramanadhan *et al*. 2021). Unlike quantitative research where scientific rigour is judged based on the internal and external validity, and reliability of findings based on objective measurements taken in a setting controlled by researchers (Devers 1999), scientific rigour in qualitative research is demonstrated by selecting methods that assure "trustworthiness" of findings (Lincoln and Guba 1985; Sandelowski 1993; Rolfe 2006; Korstjens and Moser 2018). Lincoln and Guba propose four criteria for establishing trustworthiness of findings that parallel internal and external validity, reliability and objectivity which have been widely adopted by the scientific community; credibility, transferability, dependability and confirmability (Lincoln and Guba 1985). These criteria are defined in Table 11 and efforts made to fulfil them will be provided in the chapters that follow on the SUSHI trial (Chapters 4: Outcome evaluation, Chapter 5: Process evaluation) to instil confidence in data and interpretation.

3.3.4.2 The role of a mixed methods approach – Emergence, definition & purpose

Emergence

The limitations of using a single quantitative or qualitative method were highlighted in the previous section. Such limitations have led to the emergence of mixed methods research as a third and relatively new methodological approach for answering complex research questions such as those often used in Healthcare research (Johnson and Turner 2003; Craig *et al*. 2008; Ma 2012; Biddle and Schafft 2014; Moore *et al*. 2015; Skivington *et al*. 2021). It has emerged through four key stages in its development.

In the formative period (1950s - early 1980s) quantitative methods were the dominant and more established approach but the foundations for utilising multiple methods were introduced and centred around the combining, or triangulation, of different research techniques to better understand a single phenomenon (e.g. upper limb recovery) (Campbell and Fiske 1959; Sieber 1973; Jick 1979). Quantitative, qualitative, or mixed approaches were combined in this early stage contributing to much variation in the methods reported (Campbell and Fiske 1959; Sieber 1973; Jick 1979).

A paradigm debate then followed (1970s – 1980s) between quantitative and qualitative researchers (Gunasekare 2015; Fiorini *et al*. 2016). Researchers from each specialism were racing to design rigorous research in their respective fields with many harbouring methodological resentments for contrasting methods (Gage 1989; Guba and Lincoln 2005). Heated debates ensued over whether these two differing approaches with contrasting theoretical, or philosophical, views could reasonably be integrated in a single study. Three perspectives were evident (Rossman and Wilson 1985):

- A purist view where qualitative and quantitative methods were not considered to be compatible in a single study as they shared different paradigms that were contradictory i.e. dichotomous and felt to be mutually exclusive,

- A situationists view where both methods were valued for different situations but kept separate i.e. were done in parallel but with little or no integration within the same study, and

- A pragmatist view, shared by the author (Section 3.3.3.3, above), where the dichotomy between both methods were perceived to be false (i.e. not so contrasting/opposing). One database or method may link or be integrated to the other within a single study at different stages or at single or multiple points e.g. through sampling, data collection and/or analysis as it is considered useful to make the most efficient use of both methods based on the strengths and weaknesses of each to better understand phenomena of interest (e.g. how desired outcomes can be optimised).

As the paradigm debate subsided (late 1980s – early twenty-first century), the focus shifted, from whether quantitative and qualitative methods should be mixed, to efforts to develop frameworks and strategies to guide researchers on how best to design studies that mixed both methods (Bryman 2008; Creswell and Plano Clark 2018). During this phase there was increased recognition of the potential value of expanding monomethod research into approaches that incorporate both (Craig *et al*. 2008; Moore *et al*. 2015; Skivington *et al*. 2021).

An advocacy period then followed (since early twenty first century) acknowledging mixed methods research as a distinct and accepted methodological approach with its own theoretical perspective and terminology (Creswell *et al*. 2003; Johnson *et al*. 2007; Bryman 2008; Doyle *et al*. 2009; Tashakkori and Teddlie 2010; Bowers *et al*. 2013). The publication of the first mixed methods specific textbook (Tashakkori and Teddlie 2003) and journal (Journal of Mixed Methods Research), providing evidence of this development (Bryman 2008). Additionally, the percentage of mixed methods studies commissioned by the Health Research and Development Programme in the United Kingdom nearly doubled from the mid-1990s to the early 2000s indicating its acceptance as a valid alternative over monomethod research within the health research community (O'Cathain *et al*. 2007).

Definition & purpose

Many definitions of mixed methods exist in the literature (Creswell *et al*. 2003; Johnson *et al*. 2007; Leech 2010; Wisdom and Creswell 2013). After examining definitions from 19 leaders in the field Johnson et al. (2007) defined mixed methods research as:

> "… the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g. use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration." (Johnson *et al*. 2007, p.123)

While the mixed methods literature has identified many compelling rationales for utilising mixed methods research (Doyle *et al*. 2009; Fiorini *et al*. 2016; Schoonenboom and Johnson 2017), a review by Gunasekare (2013) concludes

that these all fall into one of two main categories: confirmation or complementarity (Gunasekare 2015). Confirmation (or triangulation) being where findings from one data set are verified against a different data set involving the same phenomenon to gain confidence that findings from both sets are consistent (Creswell and Plano Clark 2007; Gunasekare 2015; Creswell and Plano Clark 2018). In contrast, complementarity is where the findings from one data set are complementary to another as they offsetting the weaknesses (i.e. knowledge limitations) inherent in using a single data set (Creswell and Plano Clark 2007; Gunasekare 2015; Creswell and Plano Clark 2018).

Strengths of mixed methods research: Thus, mixed methods research integrates both quantitative and qualitative approaches to capitalise on their combined strengths and minimise the weakness of using a single approach in isolation, the central purpose being to gain a more comprehensive understanding of the research problem (Doyle *et al*. 2009; Gunasekare 2015; Fiorini *et al*. 2016; Schoonenboom and Johnson 2017).

Limitations of mixed methods research: While the improved understanding offered by mixed methods research may be desirable, or even essential, to fulfil the objectives of a study, a dual approach does generate a considerable amount of diverse data which is more complex to interpret and requires additional expertise, time and expense (Craig *et al*. 2008; Ramanadhan *et al*. 2021). Thus, if utilised, sufficient resources and a clear rationale for its use are essential.

3.3.4.3 Chosen methodology to generate knowledge in the SUSHI Trial: A mixed methods approach

When considering which methodological approach to best address the multiple interconnected research objectives in the SUSHI trial (confirmatory and exploratory), it became clear that they could not be addressed collectively by a single method. The primary objective was confirmatory as it sought to evaluate the interventions effects, requiring the structured, objective and generalisable approach offered by quantitative methods.

However, the lack of flexibility inherent in a quantitative approach could not reasonably be utilised to address the exploratory objective i.e. to explore

factors that moderated implementation of the intervention (Bryman 2008; Kimmelman *et al*. 2014). The closed questions utilised in a quantitative approach would lack the depth of understanding required to explore the context (the how or why questions) surrounding the intervention and may not reflect a participant's true intervention experience (Bryman 2008). Consequently, a qualitative component was required to complement the quantitative component and offset this inherent limitation of a quantitative only approach (Gunasekare 2015).

Thus, a mixed methods research approach was chosen for the purpose of complementarity, thereby allowing all objectives to be addressed within a single study that provides a better overall understanding of the effects and experiences of non-robotic DHO for the recovery of upper limb function in people after stroke (Gunasekare 2015). Although resource intensive, a mixed methods study was possible because funding was secured to make this a fulltime project and the supervisory team included experts in quantitative, qualitative, and mixed methods research, as well as experts in the field of stroke rehabilitation.

3.3.4.4 Chosen quantitative component to generate knowledge in the SUSHI trial

As described in the systematic review of RCTs in Chapter 2, RCTs of interventions measure and compare the outcomes of one treatment with another, provide the highest level of evidence for an intervention from an individual study and are essential to drive positive change in healthcare (National Institute for Health and Care Excellence 2014; Hariton and Locascio 2018). They are the "gold standard" in intervention research as unlike other designs, the superior "controlled" and "randomised" methods used minimise research errors (also called bias), that threaten the validity of a study's findings and enable strong causal inferences to be made about the effect of the experimental intervention (Kendall 2003; Bondemark and Ruf 2015; Hariton and Locascio 2018; Aggarwal and Ranganathan 2019).

Trials that lack a control group (e.g. case series, case reports) generate a low quality of evidence as it is unclear if any change observed in an outcome is a

consequence of the experimental intervention or other influential factors (LoBiondo-Wood and Haber 2013; Bondemark and Ruf 2015). In contrast, the experimental treatment in a RCT is compared to a control treatment (e.g. usual care or placebo) in a similar group of participants to account for other influential factors, allowing superiority to be established (Kendall 2003; Bondemark and Ruf 2015; Hariton and Locascio 2018; Aggarwal and Ranganathan 2019). Similarly, unlike unrandomized trials (e.g. non-RCTs/quasi-experiments), a well-implemented randomisation procedure in RCTs can help to ensure that at baseline, comparator groups are as similar as possible (i.e. truly random and concealed to minimise selection and allocation bias) and balanced in terms of unknown prognostic factors (minimising confounding bias) (Kendall 2003; Bondemark and Ruf 2015; Hariton and Locascio 2018; Aggarwal and Ranganathan 2019). This is invaluable for the conclusions drawn as the two groups differ only in the intervention received meaning that any changes in the outcome must reflect true differences in the intervention, not differences between participant groups (Kendall 2003; Bondemark and Ruf 2015; Hariton and Locascio 2018; Aggarwal and Ranganathan 2019).

The current study set out to establish if a cause-effect relationship existed between the use of repetitive, functional-based practice using a non-robotic DHOs and upper limb recovery early after stroke. Consequently, a RCT design was selected for this study as this design provides the highest level of certainty on the effect of an intervention (Kendall 2003; Bondemark and Ruf 2015; Hariton and Locascio 2018; Aggarwal and Ranganathan 2019).

3.3.4.5 Chosen qualitative component to generate knowledge in the SUSHI trial

There are many methodological approaches utilised in qualitative research which can be selected depending on the research purpose, overall approach and resources available (Table 12) (Thomas 2006; Cooper and Endacott 2007).

Table 12: Qualitative methodologies & their distinguishing features

Qualitative methodologies	Distinguishing features
Grounded theory	Used where very little is known about the topic Theory is developed inductively through the data Hypotheses are generated and tested through further data collection Relies on iterative process of data collection and analysis
Ethnography	Focus on understanding cultural rules Observation is a central data collection method Observer role includes some degree of participation
Phenomenology	Focus on exploring a phenomenon in depth May include the participants "lived experience"
Action research	Aims to bring about change in practice during the research process Uses a spiral process of change and evaluation
Feminist research	Equal relationship between researcher and participants in order to: (1) Empower women (2) Raise consciousness of women's issues
Generic inductive approach	Focus on the core meanings, or describing the most important themes, evident in the text, relevant to evaluation or research objectives

Adapted by permission from BMJ Publishing Group Limited. [Cooper, S. and Endacott, R. (2007) 'Generic qualitative research: a design for qualitative research in emergency care?', Emergency Medicine Journal, 24(12), 816, available: http://dx.doi.org/10.1136/emj.2007.050641, 2023].

Broadly speaking, these are rooted within the interpretive paradigm (Cooper and Endacott 2007; Gichuru 2017) and follow strict methodological requirements which can make them complex and/or time-consuming (Ramanadhan et al. 2021) and limiting their applicability (Cooper and Endacott 2007).

The main purpose of a qualitative, or inductive, research approach is to allow the emergence of the findings from the frequent and noteworthy themes present in the raw data collected, without being constrained by structured methodologies (Thomas 2006). Thus, when there are no additional requirements

e.g. to examine cultural rules (ethnography) or develop a new theory (grounded theory), and the objective is to explore the perspectives of those experiencing a particular phenomenon, a pragmatic exploratory, or generic inductive descriptive, approach is often favoured (Thomas 2006; Cooper and Endacott 2007; Brkic *et al*. 2016; Luker *et al*. 2016; Ramanadhan *et al*. 2021). This can be particularly relevant in mixed methods studies where a pragmatic paradigm is often adopted and the practical requirements of the study's objectives govern the methods utilised (Cooper and Endacott 2007). For example, the use of a pragmatic approach is pertinent in implementation research where a time-bound approach is essential to ensure that a study's findings remain relevant at the time of implementation (Ramanadhan *et al*. 2021). Similarly, a pragmatic approach is relevant when capturing information on implementation processes is considered essential for future successful implementation but not considered possible in sufficient detail through quantitative research methods alone (Craig *et al*. 2008; Ramanadhan *et al*. 2021; Skivington *et al*. 2021).

The qualitative component of this study is rooted in the pragmatic paradigm. It supported an intervention trial and aimed to explore factors relating to self-management support that moderate, or influence, implementation of the EMPOWER Help for Hands Programme from a stroke survivor, carer, and therapist perspective.

Consequently, an approach aligned with a pragmatic inductive process that focuses on the participants'/users' perspectives on the intervention, not researchers, was essential. Given (1) these objectives, (2) the finite funding and staffing resources available for this secondary component of the project and (3) the need for a method that permitted the timely turnaround required for rapid implementation if found to be effective, a pragmatic exploratory, or generic inductive, approach was utilised.

3.3.5 Mixed methods design

Creswell and Plano Clark have produced guidance to help researchers select the best mixed methods approach for the research they conduct (Creswell and Plano Clark 2007; Creswell and Plano Clark 2018). They propose that a mixed methods approach must be underpinned by sound theoretical assumptions and give

careful consideration to the particular design and methods selected (Creswell and Plano Clark 2007; Creswell and Plano Clark 2018). Thus, in order to convey a systematic and rigorous scientific approach in mixed methods research, researchers must justify the specific approach they choose to fulfil their research objectives (Doyle *et al*. 2009). Mixed methods research designs serve as road maps to guide researchers in this process.

While there is variation in the classification of mixed methods designs in the literature (Creswell and Plano Clark 2007; Fetters *et al*. 2013; Bishop 2015; Gunasekare 2015; Fiorini *et al*. 2016; Schoonenboom and Johnson 2017; Creswell and Plano Clark 2018; Walker and Baxter 2019), there is agreement that designs are characterised according to how and why each data component is weighted, timed, and mixed during the study to best address the objectives (Creswell and Plano Clark 2007; Fetters *et al*. 2013; Bishop 2015; Gunasekare 2015; Fiorini *et al*. 2016; Schoonenboom and Johnson 2017; Creswell and Plano Clark 2018; Walker and Baxter 2019).

3.3.5.1 Four major mixed methods designs

Four major mixed methods designs are summarised below (Figure 18 overleaf) (Creswell and Plano Clark 2007). The distinguishing features of these mixed methods designs (the weighting, timing, and mixing of data sets) will now be discussed (Sections 3.3.5.2, 3.3.5.3 and 3.3.5.4 respectively) and then used to justify the concurrent (or convergent), embedded design utilised in the SUSHI trial (Section 3.3.5.5).

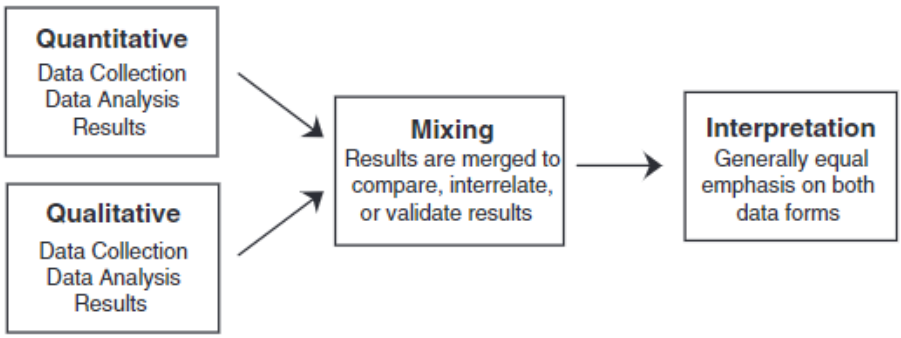
Figure 18: Four major mixed methods designs



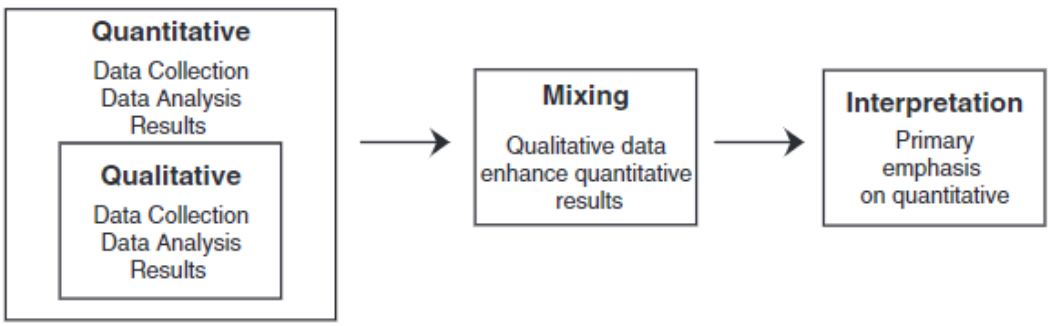
(a) Sequential exploratory design: Qualitative results are used to inform a subsequent quantitative phase e.g. to inform what outcome would be useful to measure. The latter data set is built using results from the former. Mixing is done for complementarity.



(b) Sequential explanatory design: Qualitative results are used to explain initial quantitative results. The latter data set is built using results from the former. Mixing is done for complementarity.



(c) Concurrent triangulation (parallel) design: Quantitative and qualitative results on the same phenomenon (e.g. measure outcomes) are directly compared to validate/confirm similarities and identify discrepancies). Both data sets are analysed independently and then merged. Mixing is done for confirmation.



(d) Concurrent embedded design: Results from one supportive data set are embedded within a predominant opposing data set (e.g. qualitative within a larger predominantly quantitative study) as the predominant data set alone cannot sufficiently address different aspects of a phenomenon that a researcher wishes to study (e.g. to measure outcomes and explore processes in-depth). Both data sets are typically linked at multiple points (e.g. sampling, data collection and analysis) but are analysed independently with further mixing (embedding) thereafter for complementarity.

Figure reproduced by permission from Sage Publications. [Creswell, J.W. and Plano Clark, V.L. (2007) 'Designing and Conducting Mixed Methods Research' in Creswell, J. W. and Plano, V. L., eds., London, UK: Sage, 2023].

3.3.5.2 Weighting of data components

The weighting given to the two data components in a mixed methods study is typically determined by the primary objective in a study (Andrew and Halcomb 2009; Morse and Niehaus 2009). If the study objective is exploratory and addressed using qualitative data, weighting is given to the qualitative component. If it is confirmatory in nature, and addressed using quantitative data, weighting is instead given to the quantitative component (Andrew and Halcomb 2009; Morse and Niehaus 2009). Alternatively, if a study has competing primary objectives, and both quantitative and qualitative methods are considered balanced (e.g. in theory, methodology and design) they may be reasoned to have equal-status (Greene 2015).

3.3.5.3 Timing of data components

The timing of the quantitative and qualitative data collection components should be guided by the study objectives and the rationale for collecting each data component (Creswell and Plano Clark 2007; Bishop 2015; Gunasekare 2015; Fiorini *et al*. 2016; Creswell and Plano Clark 2018; Walker and Baxter 2019). The two components may be collected either sequentially with the results of one being concluded and preceding the collection of the other (Figure 18a-b), or concurrently with both methods being deployed during the same approximate timeframe but using independent data collection and analysis (Figure 18c-d) (Creswell and Plano Clark 2007; Bishop 2015; Gunasekare 2015; Fiorini *et al*. 2016; Creswell and Plano Clark 2018; Walker and Baxter 2019). Additionally, more than two sequences (sequential, concurrent or both) may also be combined to form more complex, multiphase designs (Schoonenboom and Johnson 2017).

Typically, a sequential design is favourable when a qualitative component is required to (i) explore an understudied phenomenon in order to inform the design of a subsequent quantitative phase (e.g. inform responses to offer in a survey) (sequential exploratory design, mixing rationale for complementarity) (Figure 18a), or (ii) explain findings in a preceding quantitative phase (sequential explanatory design, mixing rationale for complementarity) (Figure 18b) (Creswell and Plano Clark 2007; Bishop 2015; Gunasekare 2015; Fiorini *et*

al. 2016; Creswell and Plano Clark 2018; Walker and Baxter 2019) i.e. to complement and build on results from the former.

Alternatively, a concurrent design involves the concurrent collection of both sets of data over a similar timeframe as there is no need to conclude the results from one component prior to commencing data collection for the other (Bishop 2015; Gunasekare 2015; Fiorini *et al*. 2016; Walker and Baxter 2019). This design is favourable to make direct comparisons between results from both data sets to offer a more complete understanding of the same phenomena (e.g. to validate/confirm similarities and identify discrepancies when measuring outcomes) (concurrent triangulated parallel design, mixing rationale for confirmation) (Figure 18c), or when a predominant data set alone cannot sufficiently address different aspects of a phenomenon that a researcher wishes to study (e.g. measure outcomes and explore processes) (concurrent embedded design, mixing rationale for complementarity) (Figure 18d) (Bishop 2015; Gunasekare 2015; Fiorini *et al*. 2016; Walker and Baxter 2019).

A concurrent design may be characterised as being parallel if both components are weighted equally (triangulated design) (Doyle *et al*. 2009), or embedded if one component has less weight than the other (Doyle *et al*. 2009; Gunasekare 2015) but is required in a study to complement and strengthen the overall design (embedded design) (Figure 18c and d respectively) (Creswell and Plano Clark 2007; Doyle *et al*. 2009; Creswell and Plano Clark 2018).

3.3.5.4 Mixing of data components

Central to all mixed methods research is the concept of "mixing" or combining qualitative and quantitative methods (Sandelowski 2000; Kroll *et al*. 2005; Creswell and Plano Clark 2007; Johnson *et al*. 2007; Doyle *et al*. 2009; Fetters *et al*. 2013; Gunasekare 2015; Schoonenboom and Johnson 2017; Creswell and Plano Clark 2018). Consequently, the "mixing" of methods in a mixed methods study, which may occur at different stages (sampling, data collection, analysis etc) and frequencies, should be evident and clearly articulated throughout the study including the study's rationale (e.g. confirmation or complementarity) and design (e.g. sequential, concurrent or both) (Sandelowski 2000; Kroll *et al*. 2005; Creswell and Plano Clark 2007; Fetters *et al*. 2013; Gunasekare 2015;

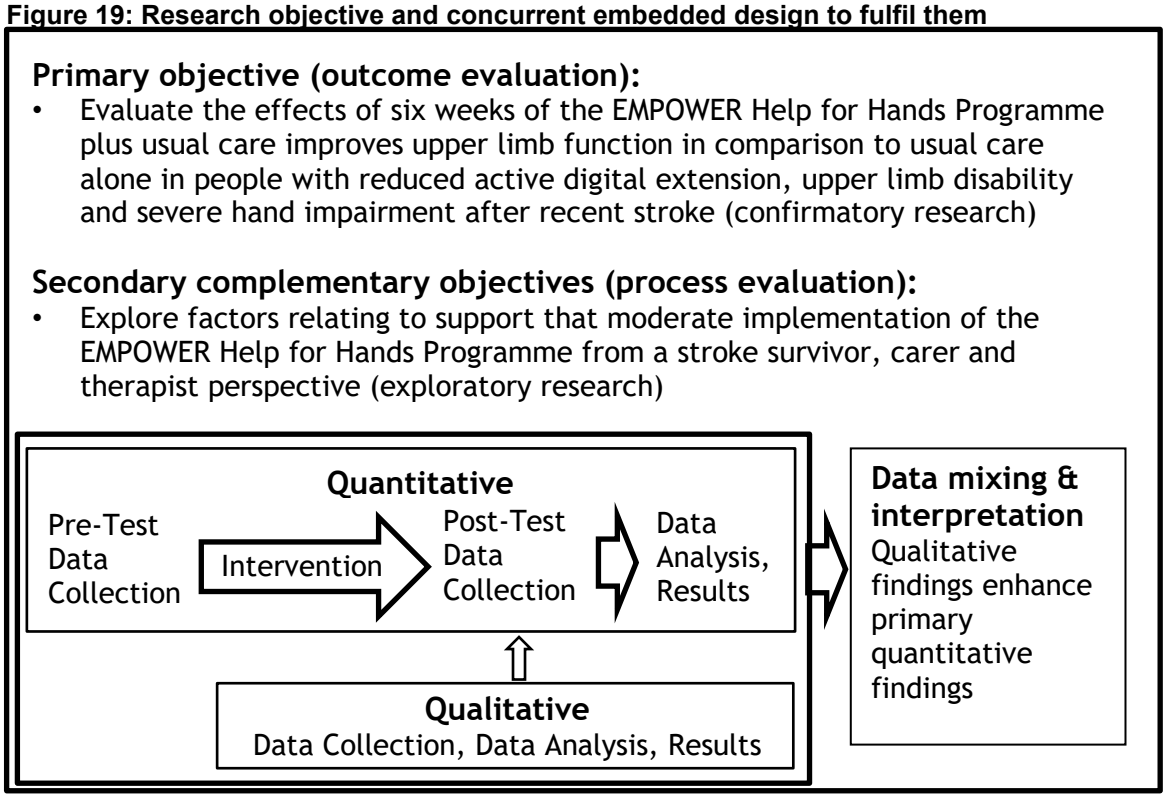
Schoonenboom and Johnson 2017; Creswell and Plano Clark 2018). Additionally, it should be clear in the interpretation and reporting phase that the "mixing" of both methods has led to a more complete understanding of the topic being investigated (Sandelowski 2000; Fetters *et al*. 2013; Schoonenboom and Johnson 2017; Creswell and Plano Clark 2018).

Three main approaches are typically used to mix (or integrate) quantitative and qualitative data collected in a mixed methods study; building, merging, and embedding (Fetters *et al*. 2013; Zhang and Creswell 2013). With building, common in sequential mixed methods designs (Figure 18a-b), data from one dataset is collected and analysed to inform the data that is subsequently collected in the other i.e. the results from one approach build upon the other (Fetters *et al*. 2013; Zhang and Creswell 2013). With merging, common in concurrent mixed method designs (Figure 18c), both datasets are collected and analysed independently then integrated to inform data interpretation (e.g. to validate one dataset against the other) (Fetters *et al*. 2013; Zhang and Creswell 2013). With embedding, data from both methods are typically linked at numerous points (e.g. sampling, data collection and analysis) with concurrent data collection and independent analysis with subsequent mixing to enhance, or complement, quantitative results (Figure 18d) (Creswell and Plano Clark 2007; Fetters *et al*. 2013) .

3.3.5.5 Chosen design to generate knowledge in the SUSHI trial

This research used a concurrent embedded design to fulfil the objectives in the SUSHI trial (Figure 19).

Figure 19: Research objective and concurrent embedded design to fulfil them



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The quantitative component was weighted as it was included to address the primary (confirmatory) research objective (i.e. to measure intervention outcomes) and therefore required the collection and analysis of quantitative data (Andrew and Halcomb 2009; Morse and Niehaus 2009). The qualitative component was included to address a secondary objective that aimed to explore intervention processes in-depth (e.g. human experiences and the context surrounding them). Consequently, it had less weighting and was embedded within a larger quantitative study for complementarity purposes i.e. as the weighted quantitative component could not sufficiently address the exploratory objective in isolation (Andrew and Halcomb 2009; Morse and Niehaus 2009).

Concurrent sequencing was selected in the SUSHI trial for two main reasons. Firstly, the study did not require the results from one data set to be concluded to build on, or inform, the other (mixing by building). Both data sets, each

addressing different aspects of the same phenomenon (e.g. quantitative data to measure intervention outcomes and qualitative data to explore processes i.e. human experience/context in response to the intervention), were concluded independently. Only then were the findings mixed i.e. during the analysis stage. Secondly, concurrent sequencing allowed the qualitative component to be conducted when the intervention had ended but without waiting until follow up measures from the quantitative component were completed or analysed. This was important as this design allowed the exploration of interviewees' experience of the intervention at the end of the intervention, but without introducing an unnecessary delay that may negatively influenced the interviewees' ability to accurately recollect the experience they had encountered.

Finally, consistent with an embedded approach both datasets were linked/mixed at numerous points (Fetters *et al*. 2013) e.g. shared sampling, similar data collection periods i.e. post intervention and pre-analysis, and analysed independently with subsequent mixing/linking made to enhance, or complement, the quantitative results.

3.4 Conclusions

As part of this program of research, this chapter entails a discussion of the rationale for the methodology selected to evaluate a complex intervention, the use of a DHO to improve upper limb recovery after stroke. Consistent with the MRC's guidance for the evaluation of complex interventions, a mixed methods intervention study was selected for SUSHI. The mixed methods approach involved a confirmatory quantitative blinded outcome evaluation involving a randomised controlled intervention trial and a process evaluation with a concurrent, embedded pragmatic exploratory (generic inductive) qualitative analysis of patient, carer, and therapist interviews after stroke.

This approach permitted an assessment of the clinical effectiveness of the intervention studied. It also enabled an exploration of patient, carer and therapist perceived self-management support needs, barriers and facilitators when using this intervention which will inform implementation in other settings. The outcome and process evaluation for SUSHI will be reported in Chapters 4 and 5 and will address Objectives 2a and 2b in Chapter 1 respectively.

Chapter 4

Outcome evaluation in the SUSHI Trial: A pragmatic, multicentre, parallel-group, randomised controlled intervention trial with blinded outcome assessment

4 Chapter 4: Outcome evaluation in the SUSHI Trial: A pragmatic, multicentre, parallel-group, randomised controlled trial with blinded outcome assessment

4.1 Introduction

Chapter 1 highlighted that upper limb recovery is likely to be best when rehabilitation includes intensive, repetitive, task specific training and strategies that facilitate this training type, such as self-management interventions. Accessing this type of rehabilitation was found to be a particular challenge for people with severe upper limb deficits, particularly those experiencing digital extensor weakness, and this may account for the poorer outcomes observed in this group. The optimal timing of upper limb rehabilitation was found to be uncertain. However, the potential merits of early versus late rehabilitation to instil healthy movement behaviours that minimize the development of maladaptive, habitual compensatory movements and learned non-use were highlighted.

Non-robotic dynamic hand orthoses (DHOs) were proposed as a rehabilitation aid that could increase access to intensive, repetitive, task specific training and related self-management interventions for the upper limb, regardless of extensor weakness severity (Franck *et al.* 2019; Saebo UK 2020). Thus, non-robotic DHOs offer the potential to reduce disability in a large and challenging group after stroke i.e. in people with severe hand impairment, including reduced active digital extension.

Chapter 2 provided a broad summary of the existing evidence available on the use of non-robotic DHOs after stroke and highlighted the need for good quality, adequately powered RCTs involving this intervention (Scoping review, Part 1). Chapter 2 also highlighted the current evidence-base on the effectiveness of non-robotic DHOs after stroke (Systematic review, Part 2). The systematic review conducted found a statistically significant difference in favour of the use of non-robotic DHOs for recovery of upper limb function and dexterity after stroke (Alexander *et al.* 2021a). However, the certainty that this positive effect was true was judged to be low due to the small number of studies included with

small sample sizes and poor methodological reporting. Thus, a good quality, adequately powered, multi-site RCT involving non-robotic DHOs was further justified to provide increased certainty on their effects after stroke.

Chapter 3 discussed the rationale for the methodology selected in SUSHI to evaluate a novel complex intervention involving self-directed, repetitive, functional-based practice using a non-robotic dynamic hand orthosis (DHO) called a SaeboGlove (The Help for Hands EMPOWER Programme) and to progress its evidence base. A mixed methods approach involving an outcome evaluation with a randomised controlled intervention trial design was justified as it offers the best method to control bias and therefore the greatest internal validity to allow causal inferences to be made on an experimental intervention. Consistent with the framework for developing and evaluating complex interventions (Skivington *et al.* 2021) the utilisation of learning from two activities conducted by the author of this thesis prior to it commencing was recommended in the RCT to further optimise feasibility (and acceptability) of the EMPOWER intervention and of a future evaluation trial design. These activities were a single site, open feasibility pilot trial (The SaeboGlove Evaluation Trial (T-SET)) for a novel intervention involving self-directed, repetitive, functional-based practice using a non-robotic DHO called a SaeboGlove (The Help for Hands EMPOWER Programme, Pilot version) and a subsequent related Patient and Public Involvement (PPI) activity that sought views from the target population on how T-SET should influence a subsequent trial.

This chapter reports the RCT designed and conducted in the SUSHI trial based on learning gained from Chapters 1-3. It aimed to assess the clinical effectiveness of two, six week interventions in people with upper limb disability and severe hand impairment, including reduced or absent active digital extension, wrist, elbow, or shoulder movement after recent stroke. These interventions were (1) usual care plus the EMPOWER Help for Hands Programme (self-directed, repetitive functional-based upper limb practice supported using a non-robotic DHO and four upper limb therapy progress reviews, version 1.0) (referred to in this work as the Intervention or SaeboGlove group), and (2) usual care plus additional upper limb usual care with frequency matched therapist reviews (i.e. therapy input based on National Clinical Guidelines: self-directed and repetitive

functional-based practice as able that was supported through the provision of four upper limb therapy progress reviews) (referred to in the work as the Control or Usual Care group). The RCT addresses objective 2a from Chapter 1.

The hypothesis of the RCT was that upper limb function measured by the Action Research Arm Test (ARAT) would be significantly greater in the SaeboGlove group at 6 weeks i.e. immediately post intervention.

4.2 Objectives

The primary objective of the RCT was to confirm whether upper limb function after a stroke was better immediately post intervention (6 week visit) in the group receiving SaeboGlove training (SaeboGlove group) or the group receiving usual care training with the same frequency of therapist contacts (Usual Care group).

The secondary objectives of the RCT were to confirm whether the following outcomes after stroke were better in the group receiving SaeboGlove training (SaeboGlove group) or usual care training with the same frequency of therapist contacts (Usual Care group):

- 6 and 14 week visits:
  - Upper limb and hand impairment
  - Upper limb pain intensity
  - Self-perceived habitual functional upper limb performance (quantity, quality and percentage of tasks involving the affected upper limb) in real-world activities
  - Self-reported performance in activities of daily living
  - Self-reported quality of life/health status after stroke
  - Degree of new disability after stroke

- 14 week visit:
  - Upper limb function

The specific measures selected for these outcomes will be justified in Section 4.3.2.4 below.

4.3 Methods

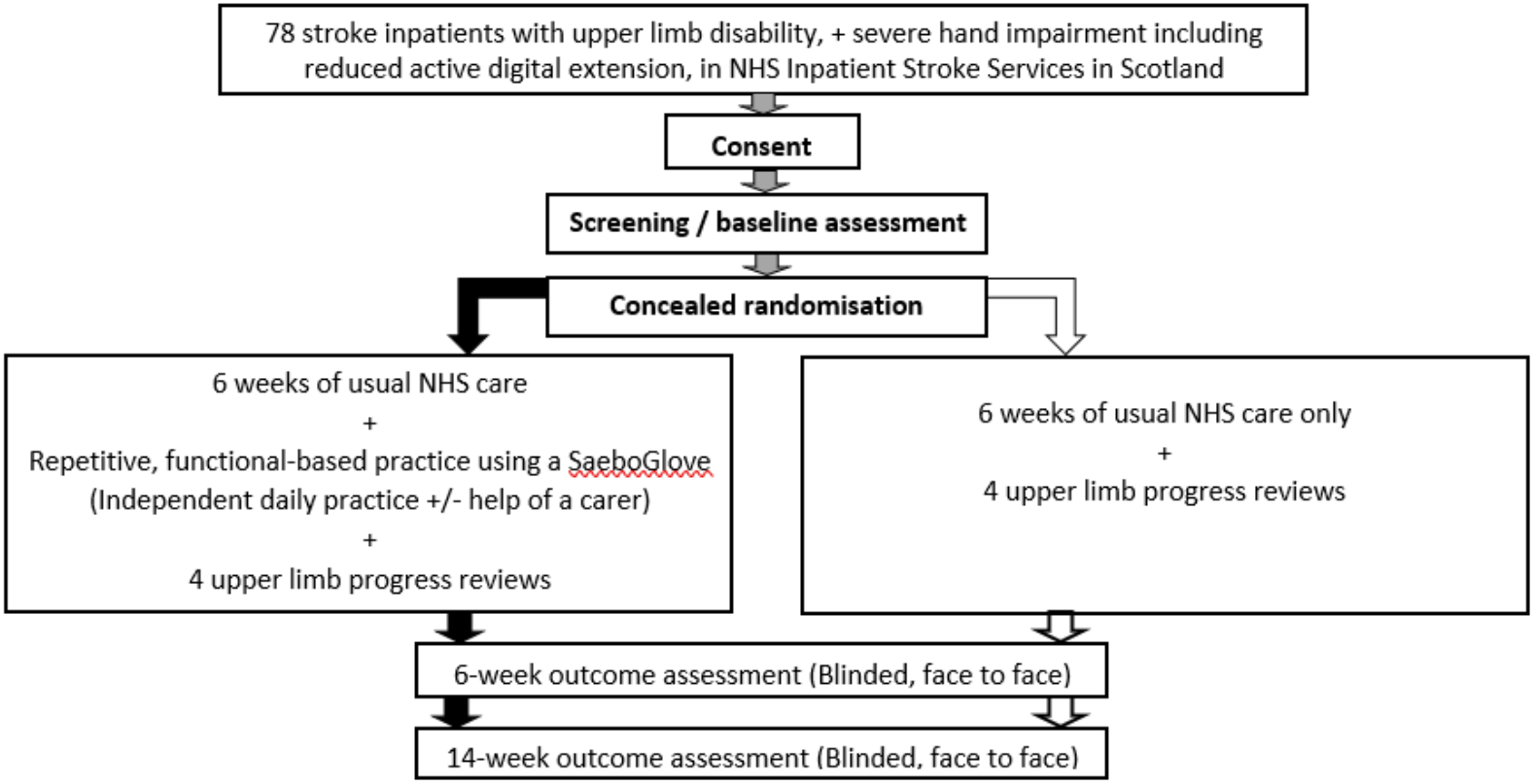
4.3.1 Design & regulatory approvals

The study was a pragmatic, parallel 1:1 allocation ratio randomised controlled intervention trial comparing usual care plus self-directed, repetitive, functional-based practice using a non-robotic DHO (the EMPOWER Help for Hands Programme), to usual care plus additional upper limb usual care with frequency matched therapist reviews.

As recommended by the pilot feasibility study preceding this programme of work and the scoping and systematic review that form part of it (Chapter 2), to generate enough recruitment to achieve adequate statistical power and ensure generalisability of study findings to a real-life population, multiple sites were involved. The trial included blinded outcome assessments. Follow-up for primary and secondary outcomes took place in the early to late subacute phase of recovery, at 6 and 14 weeks post randomisation. Figure 20 overleaf provides an overview of the RCT. All recommendations from T-SET and the PPI work that followed it (Appendix F) which encompassed stakeholder views, and the scoping and systematic reviews in Chapter 2 that preceded this RCT were adhered to where possible (Table 13 overleaf).

The study is presented according to the Consolidated Standards of Reporting Trials (CONSORT) for RCTs (Moher *et al*. 2012) and the Template for Intervention Description and Replication (TIDieR) Checklist (Hoffmann *et al*. 2014) to facilitate transparency, and completeness of reporting of the RCT design and experimental intervention.

Figure 20: RCT flow chart in SUSHI



After consent, successful screening and baseline assessment participating stroke survivors were randomised to receive either six weeks of usual NHS care plus repetitive, functional-based practice involving a SaeboGlove and four therapy reviews or usual NHS care plus additional upper limb usual care with frequency matched therapist reviews (i.e. therapy input based on National Clinical Guidelines: self-directed and repetitive functional-based practice as able involving four therapy reviews). The four upper limb therapy reviews were to assess progress and re-define treatment planning. Outcomes were measured at 6 and 14 weeks.

Table 13: Recommendations for future research from development work

Recommendations for future research	Source of recommendation				
	ScR	SysR	T-SET	PPI work	Method-ology
Intervention refinement	Ch 2		Ch 3, App F		Ch 3
Increases duration of SaeboGlove intervention if possible			✓	✓	
Continue to offer intervention early but with some flexibility			✓	✓	
Evaluation trial design					
Quality, multisite RCT with long term follow-up conducted	✓	✓	✓		
Minimises and records unblinding			✓		
Aims to be adequately powered (i.e. target population better represented e.g. in gender, age)	✓	✓	✓		
Primary outcome measure reflects a meaningful change in independence in life tasks (ARAT)			✓		
Uses a placebo or attention matched control group			✓		
Usual care therapy content and dose recorded			✓		
Offers SaeboGlove intervention later to control participants				✓	
Includes some flexibility for recruitment/trial activities, especially around discharge			✓	✓	
Efforts made to deliver the intervention via NHS staff			✓		
Research coordinator and adequate staffing			✓		
Provides central training and shares standardised assessment procedures			✓		
Access to two, 32 glove kits per three recruiting sites			✓		
Improves clarity over amount of active digital flexion required for eligibility – include ≥2 cm in thumb and ≥ one other digit			✓		
Excludes people with severe swelling if likely to cause discomfort when a DHO is worn			✓		
Evaluates in acute to subacute recovery period, ADL, extended ADL, AEs, ethnicity	✓	✓			
Uses equator guidelines, raw and descriptive statistics, improves reporting e.g. of setting, baseline characteristics, intended and actual intervention delivery	✓	✓	✓		
Stakeholder involvement	✓		✓		✓
Accompanied by a process evaluation (e.g. of intervention adherence & factors affecting it)					✓

ADL: Activities of Daily Living, AEs: Adverse Events, App: Appendix, ARAT: Action Research Arm Test, Ch: Chapter, PPI: Patient and Public Involvement, RCT: Randomised Controlled Trial, ScR: Scoping Review, SysR: Systematic Review, T-SET: The SaeboGlove Evaluation Trial

Participants were recruited from six NHS Inpatient Stroke Services in two Scottish Health Boards (Greater Glasgow and Clyde: Queen Elizabeth University Hospital, Glasgow Royal Infirmary, Stobhill Hospital, The Royal Alexandra Hospital, and Lanarkshire: University Hospitals Monklands and Hairmyers). Recruitment took place between 21st November 2019 and 4th October 2022. It was suspended from March to July 2020 due to restrictions related to Covid-19.

The study sponsor was the NHS Greater Glasgow and Clyde Health Board. The study was performed in line with the Declaration of Helsinki and General Data Protection Regulation. The SaeboGlove is CE marked for use as a rehabilitation device so prior regulatory approval from The Medicines and Healthcare products Regulatory Agency (MHRA) was not required. The study protocol was approved by the West of Scotland Research Ethics Committee (REC) 1 (19/WS/0097, protocol version 2.0). NHS Board approvals were granted by NHS Greater Glasgow and Clyde (GN19ST318) and NHS Lanarkshire (L19046) Health Boards in November 2019. The trial was registered on ClinicalTrials.gov (NCT04007315, 5 July 2019) and the protocol was published for transparency (Alexander *et al*. 2021b) (Appendix A).

After initial approvals were granted two substantial amendments were subsequently granted to try to boost recruitment (Table 14 overleaf).

The first was to broaden the inclusion criteria (rationale in Table 14 overleaf).

The second was arranged to offer a lower resource control group treatment option without a DHO and with less face-to-face reviews to try to support four Scottish Health Boards to become recruiting sites (Forth Valley, Lothian, Fife, and Tayside). These Health Boards expressed interest in the EMPOWER Help for Hands intervention and gaining experience using it by delivering it in the SUSHI trial. However, although these sites are all part of the Stroke Research Network none had a dedicated research therapy resource. This meant that without this amendment it was not feasible to identify therapy staff who could deliver trial interventions out with the inpatient environment as therapists in the clinical team did not have the staffing resource for it. Furthermore, training community therapists to use a DHO intervention would have been overly complex (many therapy teams to cover large geographic areas).

Table 14: Details of substantial amendments made in SUSHI after initial approval were granted

1. To change the eligibility criteria for upper limb disability from ARAT ≤28 to ARAT ≤46 and as a result add a third upper limb severity category to the minimisation algorithm (ARAT 0-10 and 11-28 as previously plus 29-46)*
As previously described, SUSHI aimed to target a group with more severe upper limb deficits after stroke. Initially a group with severe motor hand impairment (FMUE Hand ≤7/14) and also severe upper limb disability ARAT ≤28/57) was selected. An ARAT of ≤28 was initially selected to represent severe upper limb disability as it would mean that participants would score <50% over the 19 tasks it includes (score per task 0-3, total score 0-57 representing no to full upper limb function respectively). However, screening data revealed that some patients who fulfilled the criteria for severe hand impairment (FMUE Hand ≤7) failed screening as their upper limb disability was not severe i.e. ARAT score was >28 but ≤46 (ARAT 44, 46). It was felt that the relatively high functional use observed in these participants with severe distal impairment was possible due to proximal dominance that would likely encourage continued learned non-use of distal segments and therefore inhibit distal recovery without the enabling assistance of a SaeboGlove to train it. Analysis of pilot data also revealed that participants with an ARAT >28 but less than 46 who had significant hand weakness appeared to benefit (Alexander and Dawson 2019). Thus, *the eligibility criteria for upper limb disability were changed from ARAT ≤28 to ≤46* to make the intervention more widely accessible to people with upper limb disability who were likely to benefit from it.
2. To add an option for recruiting sites to continue to offer the intervention to control participants after the 14 week visit but without the use of a SaeboGlove and with only the first of the four therapy reviews done face-to-face**
The purpose of this amendment was to try to assist additional interested sites with more limited therapy research resources to get involved in SUSHI and to increase recruitment

ARAT: Action Research Arm Test, FMUE: Fugl Meyer Upper Extremity score, *Protocol 3.0 - Approval by the West of Scotland Research Ethics Committee 1 on 25/05/2020, Research and Development in NHS Greater Glasgow & Clyde on 17/07/2020 and Research and Development in NHS Lanarkshire on 04/06/2020, **Protocol 4.0 - Approval by the West of Scotland Research Ethics Committee 1 on 09/03/2021, Research and Development in NHS Greater Glasgow & Clyde on 05/07/2021 and Research and Development in NHS Lanarkshire on 13/4/2021

Unfortunately, despite arranging this amendment it was not used as other resource issues were encountered including difficulty identifying staff to conduct outcome measures (e.g. the FMUE score that requires baseline knowledge of anatomical movement assessment/interpretation) and clinic space to conduct trial visits after discharge. Additionally, even if outcome assessors could have been identified in these Boards it would have been challenging to maintain blinding as staff delivering trial interventions and outcomes would likely be based in the same clinical location.

Given these challenges, along with Covid-19 disruptions, the intended initial recruitment period was extended from two to three years to increase recruitment.

4.3.2 Population

4.3.2.1 Eligibility criteria

A full list of the inclusion and exclusion criteria which were informed by the T-SET trial (Appendix F) (Alexander and Dawson 2019) are listed in Table 15 overleaf. Like T-SET, participants aged 18 years or older who were inpatients with a new clinical stroke diagnosis were included in the study if they had reduced active digital and/or wrist extension (i.e. reduced active range of digital extension with wrist held passively in full extension) and capacity to consent to study participation without specific limitations imposed for language, cognition, or perception. Similarly, like T-SET participants needed to be able to don/doff the DHO and to carry out exercises provided daily with or without a supporting carer, be able to comply with the protocol and have no other upper limb impairments or diagnoses considered significant enough to interfere with study participation.

Detail added to improve the original criteria in T-SET based on recommendations made in T-SET (Appendix F) or for greater simplicity/clarity are highlighted (in italics with asterisks) and explained in the legend under Table 15 overleaf. New criteria subsequently added are highlighted in bold and explained in the main text that follows the table.

Table 15: Inclusion and exclusion criteria

Inclusion criteria
1. New clinical stroke diagnosis that occurred 7-60 days (inclusive) prior to randomisation
2. Age ≥18 years
3. ARAT ≤46 and FMUE Hand subscore ≤7 due to stroke
4. Capacity to consent to study participation - *with or without aphasia**
5. Identified during stroke index admission with consent, baseline assessment and randomisation occurring as an inpatient *or within 2 weeks of discharge home***
6. Considered eligible to use a SaeboGlove at consent/baseline assessment: *Reduced active range of digital extension with wrist held passively in full extension**** at consent/baseline *At least 5° passive wrist extension with fingers held passively in full extension***** Nil to minimal digital contractures (5-10° accommodated) Some initiation of gross active digital flexion (*crude estimate ≥2cm in thumb plus ≥1 other digit, using the tips of these digits as a reference)*** MAS ≤2 in wrist/fingers *and considered to have consistent hand opening/closing with SaeboGlove on to enable grasp/release despite tone present******
7. Considered able to don/doff a SaeboGlove and engage in independent rehabilitation with or without the help of a willing carer
8. Considered able to comply with the requirements of the protocol, *including questionnaires with or without help from proxy**
Exclusion criteria
1. *Swelling of the paretic hand considered severe enough to cause discomfort when glove is worn***
2. Other significant upper limb impairment e.g. fixed contracture, fracture within last 6 months, frozen shoulder, severe arthritis, amputation
3. Diagnosis likely to interfere with rehabilitation or outcome assessments e.g. registered blind or terminal illness
4. Participant in another intervention trial

ARAT: Action Research Arm Test; FMUE: Fugl Meyer Upper Extremity scale, MAS: Modified Ashworth Scale, *Equivalent to T-SET criteria but explicitly stated for clarity, **Detail added to original criteria in T-SET based on recommendations it made to improve feasibility of recruitment and the intervention in future research, ***Equivalent to T-SET criteria (reduced active range of digital and/or wrist extension) but is instead simpler as only one position with one possible outcome was assessed (either reduced or not) not two. Full passive wrist extension is a challenging position to generate digital extensor force in (active insufficiency) (Schoenfeld 2002) and immediately highlights any digital extensor weakness, ****Passive range of wrist extension typically well exceeds 5 degrees in recruitment timeline in SUSHI (57-62 degrees) (Horsley *et al.* 2007). >5 degrees is very similar to the original criteria in T-SET (at least 10° passive wrist extension) but as many wrist muscles cross finger and wrist joints and the SaeboGlove aims to assist people to regain full digital extension it makes much more sense clinically to reference passive wrist range with the fingers held in extension. Additionally, since T-SET another pilot trial involving the SaeboGlove utilised this criteria (Franck *et al.* 2019), *****Detail added to original criteria in T-SET to improve clarity and to ensure release can be established despite spasticity. This is because spasticity can fluctuate (e.g. with a change in mood, temperature) (Li and Francisco 2015) and while the MAS is quick to administer and widely accepted/utilised in clinical practice and research settings (van Wijck *et al.* 2001; Santisteban *et al.* 2016) it is subjective and open to an extent to interpretation (Salter *et al.* 2013). With permission table reprinted from Alexander, et al. (2021) 'SaeboGlove therapy for upper limb disability and severe hand impairment after stroke (SUSHI): Study protocol for a randomised controlled trial', European stroke journal, 23969873211036586, Copyright © [2021] (Sage Publications), available: http://dx.doi.org/10.1177/23969873211036586.

The chosen timeframe of 7-60 days post stroke was selected in SUSHI to capture a fairly homogenous acute to early subacute group (Bernhardt *et al*. 2017; Kwakkel *et al*. 2017) and due to the potential merits of early upper limb rehabilitation, including the potential for heightened recovery and reduced risk of secondary complications associated with poorer outcomes (e.g. spasticity, contractures, learned non-use) highlighted in Chapter 1. Importantly, consistent with the recommendations made in the PPI work that followed T-SET (Appendix F), it was felt to allow those with ability to participate early while also offering extra time to others who needed to consider if/when participation was right for them based on the other challenges they were experiencing. Additionally, this timeframe was felt to reduce the risk of either recruiting people who may have good spontaneous recovery in the first few days after stroke and do not need the intervention (e.g. possible restoration of active digital extension range) or waste research resources pursuing people who through time may have developed flexor spasticity significant enough to prevent study eligibility as spasticity may be too high for the glove bands to be able to assist hand opening.

A key aim of SUSHI was to study an intervention with the potential to improve recovery in a group with more severe upper limb movement problems who have a poorer upper limb prognosis/response to conventional therapy (Coupar *et al*. 2011) and lack the voluntary movement required to access/successfully engage in recommended functional-based rehabilitation activities (Barker and Brauer 2005; Galvin *et al*. 2009; Stockley *et al*. 2019). In T-SET people with severe and more modest upper limb functional impairment engaged with therapy. Thus, in order to target a more severe, homogeneous group and reduce the risk of including people with higher levels of upper limb function and negligible upper limb disability being recruited who may be more likely to respond to more conventional therapy, only participants with an ARAT ≤46 and FMUE Hand subscore ≤7 were recruited (see justification in Figure 21 overleaf and the Screening Assessment in Appendix H for the ARAT and FMUE outcome measures).

A FMUE Hand subscore of ≤7/14 (0 = greatest hand impairment) was selected to represent severe hand impairment as this meant that even people scoring a 7, representing less impairment in this chosen range, would still only be able to

Figure 21: Justification for including ARAT and FMUE criteria

To score 7/14 in the FMUE Hand sub-section (finger flexion and extension and Grasp A-E), participants could score partial i.e. a score of 1 out of 2 for each of the 7 test items.

In the first two test items (finger flexion and extension):

- At worst this could mean that a small amount of movement only is visible in one digit
- At best it could mean that the range of movement observed is almost normal and only a small amount of movement is missing in one digit

In the last five test items (Grasp A-E):

- At worst this could mean that a participant can achieve a desired grasp on 1 of 3 attempts and with great effort but are never able to maintain this control when the object is tugged slightly by an assessor, and they do not need to have any proximal control at their forearm, elbow, or shoulder, they can be held proximately by an assessor
- At best it could mean that they are able to achieve the desired grasp without effort on the first attempt, and may be able to keep that approximate grasp against a resistance offered by the assessor but the object slides very slightly in their grasp, and they may be able to hold the weight of their proximal arm without an assessors help

Consequently, while people with poor arm movement who score '1' in the hand movements (Hand Subsection a-g) in the FMUE scale will struggle to score many points in the ARAT, it is possible that people with lots of, albeit uncontrolled, arm movement who score 1s in all hand movement in the FMUE scale, could score 49/57 in the ARAT and have major compensation pattens:

- Score full marks (i.e. score of 3/3) using very abnormal grasp postures e.g. grasping objects with the pinky and palm only, if they do not take an abnormally long time or have great difficulty in many tasks
    - Grasp Section: 2.5, 5 and 7.5cm cubes
    - Grip Section: 2.25cm and 1cm tubes, and pour
    - Gross Section: all 3 tasks only involve proximal control, not grasp
- Score full marks in easily achieved grasp postures
    - Grasp Section: cricket ball, stone

Maximum total points 33/57

- Score 2/3 in the remaining tasks using very abnormal grasp postures
    - Grasp Section: 10cm cube
    - Grip Section: washer
    - Pinch Section: all 6 tasks permit objects to be picked up using **any** parts of the thumb

Maximum total points 16/57

complete 0-3 out of the seven tasks (i.e. <50%). An ARAT ≤46 was included as theoretically with good proximal movement and severe hand impairment (FMUE Hand subscore = 7) it would be possible to score an ARAT of 49/57 (Figure 21). As people with an ARAT of 47-49 represent people in the mid-high range of "notable" upper limb function (ARAT of 0-10, 11-21, 22-42, 43-53 and 54-57 represented "no", "poor", "limited", "notable" and "full" upper limb functional capacity respectively (Hoonhorst *et al*. 2015)) it was felt that this higher level of upper limb function may be more likely to respond to more conventional therapy.

Additionally, the cut off of 46/57 for the ARAT was chosen based on the screening data in T-SET, and also the screening data prior to the first substantial amendment in SUSHI that was processed to make the intervention more widely accessible to people with upper limb disability who were likely to benefit from it (Figure 21).

As SUSHI is a RCT that aims to measure the effectiveness of a non-robotic DHO and involvement in another interventional trial could theoretically influence (confound) the outcomes evaluated in it threatening the validity of the findings, people involved in other interventional research were excluded.

4.3.2.2 Recruitment

Potential participants were identified at each participating study site during their stroke inpatient stay by local clinicians and/or staff from the local Stroke Research Network (SRN) in two of the hospital sites. Following identification, and if they agreed, potential participants were approached in person by a local SRN staff member or a member of the SUSHI study team (research nurse, senior research physiotherapist, research assistant, investigator, or delegate) and asked whether they wished to consider taking part in the trial. Those who were willing to hear more were given a participant information sheet (PIS) (Appendix G) and a date (typically at least 24 hours later) arranged for further discussion with a local SRN staff member or a member of the study team. As well as the main PIS, an aphasia friendly version of the PIS, developed in conjunction with Chest Heart and Stroke Scotland, was available to aid understanding for

participants with capacity to consent and aphasia (Appendix G). A relative version of the main PIS was also available if participants felt they would also like a relative to receive one (Appendix G).

At this second meeting, staff checked stroke survivor's/carer's understanding of the study, made efforts to ensure that study expectations were realistic (e.g. therapy participation is hard work, study visits are required and a delay to receive the experimental intervention is possible). Any questions they had were answered. If they wished to participate and were able to give informed consent, they were asked to sign a consent form (Appendix G).

Consented participants were then assigned a unique five-digit study identification number (Appendix G). Minimal personal identifiable information was then collected on participants on a personal identification log (name, Community Health Index NHS number, contact details, GP contact details and ethnicity) (Appendix G).

One consent form was signed and kept in the study site file. One copy of the signed consent form was given to the patient and one copy was inserted into their case notes. A further copy was sent to the participant's General Practitioner (GP) with a PIS and a letter (Appendix G) informing them that their patient was participating in the SUSHI Trial. Consent to inform GPs was sought from participants on their consent form.

SUSHI posters (Appendix G) and study leaflets (Appendix G) with brief details of the SUSHI Trial and how to gain further information about it were made available to participating sites to use within their clinical environments.

During the consent process participants were made aware that randomisation and participation depended on subsequent successful screening. The schedule of enrolment, interventions, and assessments can be found in Table 16 overleaf.

Table 16: Schedule of enrolment, interventions, and assessments post randomisation

TRIAL ACTIVITY	STUDY PERIOD				
	Enrolment	Baseline Assessment (≤48hr after screening)*	Intervention	Outcome Assessments	
	Pre week 0	week 0	weeks 1-6	week 6	week 14
Written informed consent	X				
Contact details	X				
Demographics	X				
Stroke details	X				
Relevant comorbidities	X				
Hand + Wrist movement (Active, and passive (contractures + spasticity)	X				
Hand impairment (Hand subscore of Fugl Meyer upper extremity scale)	X	*			
Upper limb function (Action Research Arm Test)	X	*		X**	X
Screening check list	X				
Current upper limb treatment		X			
Upper limb impairment (Fugl Meyer upper extremity scale)		X		X	X
Self-perceived habitual functional use (Motor Activity Log)		X		X	X
Degree of new disability (Modified Rankin Scale)		X		X	X
Activities of daily living (Barthel Index)		X		X	X
Quality of life / health status (EQ-5D-5L) (Stroke Impact Scale)		X X		X X	X X
Upper limb pain intensity (Visual analogy scale)		X		X	X
Randomisation		X			
Adverse events			X	X	X
Usual care plus SaeboGlove therapy			X (Intervention group)		
Usual care***			X (Control group)		
Rehabilitation booklet completed weeks 1-14, weekly telephone reminder			X	X	X
Usual care recorded			X		

EQ-5D-5L: EuroQol with 5 Dimensions and 5 Levels, UL: Upper limb, *Screening and baseline were typically done at the same visit by same staff but a 48 hour gap was permitted in exceptional circumstances as assessments were lengthy and involved a severely affected group, often suffering from considerable fatigue, who are often unable to access research opportunities, *Hand subscore and ARAT only repeated if baseline assessment occurred >48 hours after the screening assessment or if it occurred <48 hours ago and assessor was concerned that eligibility may have changed. **represents the primary outcome. ***Optional six weeks of SaeboGlove therapy support offered after 14 week outcome visit was completed (Please see "Control group" in Section 4.3.3.3 below). With permission table reprinted from Alexander, et al. (2021) 'SaeboGlove therapy for upper limb disability and severe hand impairment after stroke (SUSHI): Study protocol for a randomised controlled trial', European stroke journal, 23969873211036586, Copyright © [2021] (Sage Publications), available: http://dx.doi.org/10.1177/23969873211036586.

4.3.2.3 Enrolment

After obtaining informed consent a local SRN staff member or a member of the study team carried out a screening assessment (Appendix H). This assessment involved checking if participating stroke survivors fulfilled the study inclusion and exclusion criteria. This included assessing wrist and hand movement (active and passive (contractures and spasticity)), the FMUE Hand subscore and the ARAT. Brief demographic, stroke and comorbidity details were also recorded for descriptive and comparative purposes (Table 16 above).

If eligibility criteria were met, participants' involvement in the trial continued (Table 15 above). If eligibility criteria were not met, participation in the study stopped and participants were thanked for their time. The recruitment/enrolment outcome of all potential participants identified was recorded on a screening log (Appendix G).

4.3.2.4 Baseline assessment

The baseline assessment was carried out by trained site personnel (Appendix H). Information was collected on current upper limb treatment (Table 16 above) and measures were selected to cover the impairment of body structures and functions, activity limitations, and participation restriction domains of the International Classification of Functioning, Disability and Health model (World Health Organisation 2001) (Table 17 overleaf):

Impairment of body structures and functions:

• Upper limb impairment (FMUE) and hand impairment (FMUE Hand subscore) (Fugl-Meyer *et al*. 1975)

• Upper limb pain intensity (Visual Analogue Scale (VAS)) (Pomeroy *et al*. 2000)

Activity limitations:

• Upper limb function (ARAT) (Lyle 1981)

• Self-perceived habitual functional upper limb use (Motor Activity Log (MAL)) (Uswatte *et al*. 2005)

Participation restriction:

• Degree of new disability after stroke (modified Rankin Scale (mRS)) (van

Swieten *et al*. 1988)

• Self-reported performance in activities of daily living (Barthel Index (BI) (Collin *et al*. 1988)

• Self-reported quality of life/health status (Stroke Impact Scale (version 3.0, UK) (SIS) (Duncan *et al*. 2003), EuroQol (EQ-5D-5L) (EuroQol Research Foundation 2017))

All measures selected have robust psychometric characteristics and are widely used in research studies in people with stroke (*FMUE* (Santisteban *et al*. 2016; Kwakkel *et al*. 2017), *ARAT* (Santisteban *et al*. 2016; Kwakkel *et al*. 2017), *MAL* (Santisteban *et al*. 2016), *SIS* (Wu *et al*. 2014), *BI* (Quinn *et al*. 2009), *EQ-5D-5L* (Quinn *et al*. 2009; Kwakkel *et al*. 2017), *mRS* (Quinn *et al*. 2009; Kwakkel *et al*. 2017), *VAS* (Price *et al*. 1999; University of Glasgow and NHS Quality Improvement Scotland 2011)) (*FMUE* (Gladstone *et al*. 2002; Platz *et al*. 2005b; Rabadi and Rabadi 2006; See *et al*. 2013; Pandian and Arya 2014), *ARAT* (Hsieh *et al*. 1998; Van der Lee *et al*. 2001; Platz *et al*. 2005b; Rabadi and Rabadi 2006; Pandian and Arya 2014), *MAL* (Uswatte *et al*. 2005; Hammer and Lindmark 2010), *SIS* (Duncan *et al*. 2003; Lin *et al*. 2010), *BI* (Quinn *et al*. 2011; Duffy *et al*. 2013), *EQ-5D-5L* (Dorman *et al*. 1998; Golicki *et al*. 2015), *mRS* (Banks and Marotta 2007), *VAS* (Price *et al*. 1999; Pomeroy *et al*. 2000; University of Glasgow and NHS Quality Improvement Scotland 2011)).

A description of each measure is provided in Table 17.

Table 17: Description of measures used at study assessments

Measure	Description
Fugl Meyer Upper Extremity (FMUE) - Motor Total, Hand and Sensory subscores (Fugl-Meyer *et al*. 1975)	The FMUE is a stroke-specific assessment which measures upper extremity impairment using three subscales (passive range of upper limb movement and pain during passive upper limb movement (24 items, 0-48), active movement impairment (33 items, 0-66) and sensory impairment (6 items, 0-12). Each item is rated on a 3-point ordinal scale (0=cannot perform, 1=performs partially and 2=performs fully) with a higher score representing a higher performance i.e. less impairment.
Action Research Arm Test (ARAT) (Lyle 1981)	The ARAT measures upper limb function and dexterity in people with hemiparesis. It scores 19 items grouped into four subscales (grasp, grip, pinch, and gross movements) using a 4-point ordinal scale (0-3). Items within each subscale are arranged hierarchically, such that some items may be skipped if earlier items score 0. The final score ranges from 0-57, with 57 representing the best function i.e. normal function. The revised, standardised (Platz *et al*. 2005a) and validated (Platz *et al*. 2005b) version of the original ARAT (Lyle 1981) without specific time limits was used.
Motor Activity Log (MAL-14) (Uswatte *et al*. 2005)	The MAL-14 is a structured interview used to assess self-perceived performance (Amount of use (i.e. Quantity) and Quality of use) in 14 real-world UE activities. Quantity and Quality scores are both rated using a 6-point scale (0-5). The mean for each scale is calculated and the final score ranges from 0-5 for each scale, with 5 indicating that the affected arm is used as much and as well as before the stroke. There are different versions of the MAL; MAL-14, MAL-30, MAL-28, MAL-14, MAL-45, LF-MAL, Grade 4/5 MAL and Turkish, Brazilian and German versions (Canadian Partnership for Stroke Recovery 2020). MAL-14 was used as it has been studied earlier after stroke, during the subacute phase (Hammer and Lindmark 2010), and has less items and therefore a smaller burden. While the MAL-14 has been found to be a reliable and valid post stroke measure (Uswatte *et al*. 2005; Hammer and Lindmark 2010), data on the MAL is limited during the acute phase after stroke (<1 month) (Uswatte *et al*. 2005; Hammer and Lindmark 2010). As SUSHI included acute and subacute stroke patients who are often likely to be inpatients with more limited opportunity to carry out everyday activities in a hospital environment, three additional upper limb activities (open a bottle/jar, tie lace, hobbies e.g. reading, cards etc) routinely accessible at a hospital beside were scored in addition to the MAL-14.

ARAT: Action Research Arm Test, FMUE: Fugl Meyer Upper Extremity score, MAL: Motor Activity Log

Measure	Description
Stroke Impact Scale (SIS) (Duncan *et al*. 2003)	The SIS is a two-part stroke-specific patient reported outcome measure that measures quality of life/health status after stroke. Part 1 scores 59 items grouped into eight subscales (strength, hand function, ADL/IADL, mobility, communication, emotion, memory and thinking, and participation/role function) using a 5-point Likert scale. Scores for each subscale range from 0-100, with the final total score for Part 1 ranging from 0-800 (expressed as a mean 0-100). The hand function and ADL/IADL are most useful for measuring the impact of stroke in relation to upper limb recovery. Part 2: An overall recovery score (0-100) is also included. A higher score reflects better health in both parts.
Barthel Index (BI) (Collin *et al*. 1988)	The BI is a patient reported outcome measure that measures performance in activities of daily living across 10 items of activities of daily living (feeding, bathing, grooming, dressing, bowel control, bladder control, toileting, chair transfer, ambulation and stair climbing). Items are rated in terms of whether individuals can perform activities independently, with some assistance, or are dependent. Scores for each item vary between 0-1, 0-2 or 0-3 with the overall score ranging from 0-20. A higher score represents a higher performance.
EuroQol 5 Dimensions and 5 levels (EQ-5D-5L™) (EuroQol Research Foundation 2017)	The EQ-5D-5L™ is a patient reported outcome measure for the generic measurement of quality of life/health status. It scores five health dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) using a five-level response (1-5, with 1 representing the best health). The responses from each dimension make a 5-digit health state profile which is combined into a single utility index value using population tariffs. An EQ-5D-5L index score of 1 represents full health.
Modified Rankin scale (mRS) (van Swieten *et al*. 1988)	The mRS is a stroke-specific tool that measures degree of new disability/dependence after stroke using a subjective 6-point ordinal global outcome scale. Disability/dependence is rated based on an individual's independence in relation to pre-stroke activities (0=no stroke symptoms at all, 5= Severe disability due to stroke: bedridden, incontinent, and requiring constant nursing care and attention). Higher scores reflect greater disability/dependence.

BI: Barthel Index, EQ-5D-5L: EuroQol 5 Dimensions and 5 Levels, mRS: modified Rankin Scale, SIS: Stroke Impact Scale 3.0

Measure	Description
Visual Analogue Scale (VAS) (Pomeroy *et al*. 2000)	The VAS for pain is a tool often used to measure pain intensity. Individuals are asked to rate their pain intensity at a specified time (in the SUSHI trial this is the average intensity of their pain over the previous week) using an 11-point scale displayed on a 10 cm line, ranging from 0=No Pain to 10=Unbearable Pain. Higher scores reflect greater pain intensity. While VAS is a reliable and valid measure in populations out with stroke (Wallenstein *et al*. 1980; Seymour 1982), and intra-rater reliability is good in a stroke population (Pomeroy *et al*. 2000), a large systematic bias has been found between raters (Pomeroy *et al*. 2000). Use of training and standardised assessment procedures have been recommended to overcome such differences (Pomeroy *et al*. 2000). Furthermore, stroke literature lacks a gold standard pain measure in patients with higher cortical (cognitive and visuospatial) deficits (Price *et al*. 1999). Data suggests that the validity in this group is improved using a vertical visual analogue scale (Benaim *et al*. 2007; University of Glasgow and NHS Quality Improvement Scotland 2011). Thus, like all measures used, training and standardised assessment procedures were utilised along with a training manual, a vertical scale was used to measure upper limb pain intensity and the same assessor assessed repeated outcomes whenever possible.

VAS: Visual Analogue Scale.

4.3.2.5 Randomisation

To prevent selection bias a central online randomisation service was used to ensure group allocation was a random process that was concealed prior to randomisation. The service was developed and maintained by the Clinical Trials Unit in the University of Glasgow (Robertson Centre for Biostatistics). Participating stroke survivors were allocated, on a 1:1 basis, to either the Intervention or Control group. Individuals were allocated using a minimisation algorithm designed to maintain balance with respect to study site (01-06), time since stroke (≤1 month, >1 month) and severity of upper limb function (ARAT 0-10, 11-28, 29-46). The online service was programmed to email nominated unblinded site personnel (research physiotherapist and study administrator) group allocation details. They then phoned or visited participants, typically later that day or the next working day, to advise them which group they were allocated to and plan for future study appointments (Appendix I) and completed a randomisation record (Appendix I).

4.3.2.6 Sample size calculation

The study protocol (Appendix A, (Alexander *et al.* 2021b)) states:

> 'A mean change in ARAT score of 10 points is assumed in the control group (Rabadi and Rabadi 2006). A mean difference between groups of 9 points is being used for our sample size calculation based on our pilot data where participants improved by 19 points (standard deviation 13.5 points) (Alexander and Dawson 2019). *A sample size of 49 per group will detect this difference with 90% power at a 5% significance level.* Allowing for 11% attrition, we will randomise up to 110 participants to achieve this number with a 6 week outcome measure…*Analysis will be performed on an intention to treat basis.'*

4.3.2.7 Interim analyses and stopping rules

There were no planned interim analyses or stopping rules in this trial. Given the time available for the project on the 21st of September 2022 it was agreed with the Trial Steering Committee and the funder that recruitment would continue until November 2022 with an aim to achieve 80% power (70 randomised participants).

4.3.3 Interventions

4.3.3.1 Usual care

All participating stroke survivors received usual NHS care. It was assumed that usual care involved an evidence-based approach that was tailored to each individual's needs (Langhorne *et al.* 2011; Pollock *et al.* 2014a), and was based on National Clinical Guidelines at the time of recruitment which recommended a minimum of 45 minutes of physiotherapy and occupational therapy, five days per week and support, where appropriate, to engage in self-management rehabilitation activities (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2016).

For the first 53/78 participating stroke survivors (68.0%) physiotherapy and occupational therapy teams were asked to use a study specific form to record if participants were in receipt of a therapist-directed upper limb therapy session or not on weekdays over the six week intervention period (Appendix J). This was to permit group comparisons and offer context. Reminders were provided to

therapists to record usual care (typically weekly). The recording of usual care by usual care therapists was stopped during the study as this was required to manage therapist trial burden during the Covid-19 pandemic.

4.3.3.2 Intervention group

Treatment began as soon as possible, with a target of within 48 hours, after randomisation and within one week of baseline assessment. The date of first use of the device was defined as the start of the intervention period.

Based on the positive findings in T-SET the intervention remained unchanged in SUSHI with two main exceptions. The intervention period was extended from four to six weeks as patient and carer feedback from both T-SET and the PPI work that followed it suggested that, if possible, future studies should consider increasing the intervention duration (Chapter 3, Appendix F). Additionally, the functional-based exercises utilised in T-SET that aimed to progress the hand in isolation as well as with the lower and upper arm and to wean participating stroke survivors from the SaeboGlove for some/all exercises given over this longer intervention period were categorised to reflect ability/progress made (ability levels 1–4) (Table 18, number 4).

The research physiotherapist from the study team and thesis author, self-trained in how to measure, fit and use the SaeboGlove and with over three years' experience in its use, trained stroke survivors and any assisting carers (informal or Health Care Worker) how to don/doff the glove and establish an individualised self-directed, repetitive, functional-based practice training programme involving grasping/releasing. The research physiotherapist encouraged stroke survivors to carry out their training programme daily and provided a total of four review sessions (approximately 60 minutes in duration) during the six week intervention period (i.e. every 1-2 weeks) to assess progress and re-define their individualised upper limb treatment plan (Appendix J). The research physiotherapist was reminded of scheduled reviews throughout the intervention period (Outlook calendar).

Stroke survivors started at the highest level according to their ability. The level and number of exercises performed was reduced/increased according to ability,

but all stroke survivors had to be able to carry out at least one exercise at ability level 1 with or without the help of a carer in order to participate in the trial.

If a participating stroke survivor was discharged during the intervention period, they travelled back to their local hospital to attend remaining review appointments with the research physiotherapist. If this was not possible then advice was provided by telephone or video call using a web-based platform called Attend Anywhere, depending on participant convenience.

To familiarise therapists in the clinical team with SaeboGlove use in therapy and to help with subsequent potential implementation physiotherapists and occupational therapists treating stroke survivors in the intervention group were advised of their patients' participation and offered basic training/observation involving the SaeboGlove. Consent to inform clinical physiotherapists and occupational therapists was sought from participating stroke survivors on their consent form (Appendix G).

A detailed description of the EMPOWER intervention along with changes made (underlined) since the pilot study and PPI that followed it is shown in Table 18 overleaf using the Template for Intervention Description and Replication (TIDieR) Checklist (Hoffmann *et al*. 2014).

Table 18: Template for Intervention Description and Replication (TIDieR) Checklist for the SUSHI trial intervention treatments

Item	Intervention
1. **Brief name:** Provide the name or a phrase that describes the intervention.	Help for Hands EMPOWER Programme (version 1.0)
2. **Why:** Describe any rationale, theory, or goal of the elements essential to the intervention.	The Help for Hands EMPOWER Programme involved SaeboGlove self-directed, repetitive, functional-based practice. Rationale for this therapy: National guidelines advocate repetitive, functional-based practice (i.e. practice of everyday life tasks that are goal-directed (i.e. desired) or non-goal directed movements that are likely to enhance the performance of functional-based goal-directed) and self-practice activities (i.e. activities practiced independently with/without a carer) (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2016; Intercollegiate Stroke Working Party 2023). Research shows that in order to improve brain function and regain the ability to perform every day movements after stroke, hundreds of challenging movement repetitions (Nudo and Milliken 1996; Carey *et al*. 2002; Kleim *et al*. 2002; Kleim *et al*. 2003; Luke *et al*. 2004; Monfils and Teskey 2004), specific to a given every day task (Perez *et al*. 2004; Boyd *et al*. 2010) must be practised per session. Systematic review evidence shows that after stroke (1) increased intensity of repetitive, functional-based rehabilitation is known to improve functional outcomes (dose >20 hours) (Pollock *et al*. 2014b) and (2) self-directed interventions that involve repetitive functional-based practice can improve upper limb function and independence in activities of daily living (Da-Silva *et al*. 2018). Research on dynamic hand orthoses after stroke (including the SaeboGlove (Alexander and Dawson 2019; Franck *et al*. 2019)) consists of small feasibility studies involving between 1-20 participants with moderate and severe upper limb impairment using RCT (Barry *et al*. 2012; Jeon *et al*. 2012; Lannin *et al*. 2016; Huang *et al*. 2019) and non-RCT (Davenport 2005; Barry *et al*. 2006; Butler *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Davenport *et al*. 2011; Gollega *et al*. 2012; Franck *et al*. 2013; Woo *et al*. 2013; Prange *et al*. 2014; Rickards *et al*. 2014; Stuck *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Semenko 2017; Doucet 2018; Alexander and Dawson 2019; Franck *et al*. 2019; Pooyania and Semenko 2014) designs). This preliminary evidence suggests that such devices are safe, feasible and acceptable, and enable this group to perform higher numbers of functional-based movement repetitions (Stuck *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Alexander and Dawson 2019), even when self-directed (Stuck *et al*. 2014; Chang and Lai 2015; Chen *et al*. 2017; Alexander and Dawson 2019). Positive trends in upper limb recovery are observed in the acute-subacute (Davenport *et al*. 2011;

Item	Intervention
	Rickards *et al*. 2014; Stuck *et al*. 2014; Semenko 2017; Alexander and Dawson 2019; Franck *et al*. 2019) and subacute-chronic (Davenport 2005; Barry *et al*. 2006; Butler *et al*. 2006; Farrell *et al*. 2007; Heise *et al*. 2010; Barry *et al*. 2012; Gollega *et al*. 2012; Jeon *et al*. 2012; Franck *et al*. 2013; Woo *et al*. 2013; Prange *et al*. 2014; Chang and Lai 2015; Lannin *et al*. 2016; Chen *et al*. 2017; Doucet 2018; Huang *et al*. 2019; Pooyania and Semenko 2014) phases of recovery. Essential elements of this intervention included: • SaeboGlove device • Increased access to repetitive, functional-based practice • Increased access to self-practice opportunities • Increased intensity of training (aim >100 movement repetitions daily where possible) (Carey *et al*. 2002)
3. **What - Materials:** Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The **SaeboGlove** was used (Saebo UK 2020). It consists of a glove velcroed inside a wrist splint and tensioner bands of different size/strength which span between hooks, on the SaeboGlove, over weak joints to enable variable hand opening support, essential for self-directed, repetitive, functional-based practice (Figure 7, Chapter 1). **A Hand and Arm self-management rehabilitation exercise booklet** (Appendix J) adapted by the author from another study (Rodgers *et al*. 2019) with permission was used to encourage self-management (de Iongh *et al*. 2015; Parke *et al*. 2015). Booklets included a paragraph highlighting the need for intensive (>100 movement repetitions daily (Carey *et al*. 2002)), repetitive functional-based practice to optimise recovery, and were used to record intensity goals agreed at each review, and encourage participating stroke survivors to record the number of hand opening movements they performed daily during their individualised self-directed, repetitive, functional-based training programme along with their active upper limb therapy time spent with and without a therapist. A **written copy of all exercises** was provided to participating stroke survivors. If stroke survivors wished, their exercises were **videoed** on their/their carers mobile phone to refer to later. Additional materials used included a **form to record usual care** (completed by clinical occupational and physiotherapists on weekdays over the intervention period) and **forms to record/monitor treatment interruptions and safety** (completed by therapist delivering the intervention and/or research team respectively) (Appendix J). A one **hour training video** for therapists was also created to help standardise intervention implementation/therapy support (Video may be accessed by NHS/NHS partners via request to author).

Item	Intervention
4. **What - Procedures:** Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	**Self-practice:** Intervention group participants received a SaeboGlove for 6 weeks to carry out self-directed, functional-based hand and arm exercises daily, independently with or without support of a carer. They aimed to fulfil a daily intensity goal agreed with their therapist (number of hand opening movements to aim to perform), typically 50 repetitions daily the first few days and increasing gradually towards 100 at the end of the first week if there was no reason not to (e.g. new hand pain or limiting fatigue). Participating stroke survivors were encouraged to count repetitions by recording tally marks using paper and a pen. **Progress reviews:** A physiotherapist supervised and supported stroke survivors (and carers) by providing a progress review during 4 of the 6 weeks to: i) Assess/reassess their ability, define/redefine their treatment plan and set shared intensity goals for their daily practice ii) Administer them with an individualised self-directed, repetitive, functional-based practice training programme where all exercises provided involve grasping /releasing (where possible grasping should involve an object, alternatively it should involve opposition) iii) Train them on the intervention, specifically on how to don/doff the SaeboGlove, and on how to perform any exercises given and log daily self-practice activity (number of hand opening repetitions) against their agreed goal in their booklet along with their active upper limb therapy time spent with and without a therapist iv) Remind them of the ultimate goal and need to increase use of their affected hand, out with therapy exercises, in everyday tasks between each review **Rehabilitation booklet**: Site personnel tried to phone stroke survivors each week to remind them to complete their rehabilitation booklet daily. **The EMPOWER principles were followed (Alexander *et al*. 2021b):** Equips patients with the tools needed to carry out meaningful exercise involving everyday tasks (e.g. eating, drinking, self-care). Examples: SaeboGlove, written/video instructions. Motivates patients by setting shared intensity goals, logging/monitoring daily self-practice activity and identifying and overcoming barriers to daily self-practice exercises. Provides a progress review every 1-2 weeks so that exercises remain challenging and progressive. Optimises self-management support at therapy reviews by coaching independence in exercises, progression, and tailoring. Weans from help provided for some/all exercises as able. Examples: reduce help provided by

Item	Intervention
	SaeboGlove bands and glove. *First: wean bands* - reduce band support incrementally when full active (assisted) digital extension wished/needed in gross grasp/release exercises is accessed with some consistency e.g. three times consecutively. Simultaneously, if ability allows, do similar for more complex selective grasp/release exercises (i.e. reduce extensor band support as soon as it is not needed e.g. when 3rd-5th digits can remain extended while 1st and 2nd digits pinch an object (wide progressing to narrow) the band support provided to the 3rd-5th digits may be reduced/removed, similarly when the distal interphalangeal joints of the 1st and 2nd digits have adequate extension control for pinch contact stability band support provided over these joints can be reduced/removed). *Second: wean glove* - remove glove for gross grasp/release exercises when full active gross digital extension wished/needed is accessed wearing glove without bands with some consistency e.g. three times consecutively. Do similar for more complex selective grasp/release exercises (wide progressing to narrow objects). In this second stage, without the glove the ultimate target in therapy is to provide functional-based tasks that 'make' stroke survivors move further and further into active wrist extension as possible while simultaneously maintaining the newly regained and desired active digital extension control with a sustained hold (i.e. 3, 5 or 10 seconds depending on ability) between grasp/pinch efforts i.e. to regain wrist and digital extension range/strength/endurance needed for desired gross and selective function. Engages carer support whenever possible, and Reminds stroke survivors of the ultimate goal and need to transfer knowledge and skills gained into everyday life. Example: increase use of the stroke affected hand in everyday tasks.
5. **Who provided:** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	The intervention was carried out by stroke survivors with support from (1) a trained physiotherapist and (2) a trained carer if needed. The physiotherapist was a clinical specialist in stroke care who followed manufacturer's instructions on how to measure and fit a SaeboGlove, had 3+ years' experience in the delivery of SaeboGlove therapy and developed the EMPOWER Help for Hand intervention. All supporting carers were encouraged to attend review sessions with participating stroke survivors where they received training on the intervention, specifically on how to don/doff the glove, assist with the performance of any exercises and record self-practice activity. Stroke survivors and carers were encouraged to contact their therapist for further advice if they had questions/concerns.

Item	Intervention
6. **How:** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Therapy reviews: Typically, 1:1 i.e. face-to-face delivery, though on occasion, for stroke survivor convenience after discharge by telephone or video call using an NHS web-based platform called Attend Anywhere. Self-practice: At bedside, at home.
7. **Where:** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Therapy reviews: 1:1: At bedside or clinic room in NHS hospital facilities, by telephone or video call: stroke survivor/carer - in NHS hospital facilities if inpatient, or at home if discharged, therapist - in private room for blinding purposes/confidentiality. Self-practice: At bedside, at home.
8. **When and how much:** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Over the six week intervention period: • Stroke survivors were encouraged to fulfil their individualised, shared intensity goal daily. • A progress review with a physiotherapist was provided every 1-2 weeks (four occasions) at a mutually suitable time that also allowed flexibility depending on anticipated rate of progress. • SaeboGlove self-directed, repetitive, functional-based practice was delivered in addition to usual NHS care. It was assumed that usual care was based on current National Clinical Guidelines (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2016). Consequently, therapy teams were asked to ensure that participating stroke survivors received 45 minutes of physiotherapy and occupational therapy daily for as long as required and were asked to record the usual care they provide on a study specific form (Appendix J).
9. **Tailoring:** If the intervention was planned to be personalised, titrated, or adapted, then describe what, why, when, and how.	Programmes were set at 1 of 4 levels: **Level 1:** 1-2 exercises involving grasping/releasing (with or without wrist movement). **Level 2:** Level 1 **plus** a lower arm movement (supination/pronation or elbow flexion/extension) involving grasping/releasing. **Level 3:** Level 2 **plus** an upper arm movement (any shoulder movement) involving grasping/releasing. **Level 4**: If the therapist felt that the **SaeboGlove was no longer needed for some/all of the exercises**, stroke survivors continued to carry out an individualised self-directed, repetitive, functional-based practice training programme involving grasping/releasing **based on level 3** exercises with/without a SaeboGlove according to their changing ability (see Weaning in no. 4 above).

Item	Intervention
	Stroke survivors started at the highest level according to their ability. The difficulty level and number of exercises performed was reduced/increased according to ability, but all stroke survivors had to be able to carry out at least one level 1 exercise with or without the help of a carer to participate in the trial. As stroke survivors moved from levels 1 to 3, exercises became progressively more difficult because each increment involved movement of more upper limb segments and joints, and this required greater strength to lift the weight of an increased number of body segments up against gravity (Eng 2004), the ability to coordinate movement over increasing numbers of joints, and the generation of higher torque as the length of the moment arm (i.e. perpendicular distance between the joint (axis) e.g. wrist, elbow, shoulder and the hand carrying a given object or force in a task) is gradually increased (Swanson 2011). Progression from level 3 to 4 was more difficult again as help from the glove was no longer needed for some/all the exercises performed. Exercises selected were functional-based movements identified through stroke survivors/physiotherapist discussion as being meaningful to participants. Stroke survivors were encouraged to learn the best way for them to achieve their daily intensity goal e.g. doing exercises all at once, or spreading exercises out separated by breaks, doing more challenging exercises first before tiring, or last after warming up. They were also encouraged to increase the use of their affected hand in a varying number and type of everyday tasks between each review depending on ability and preference. The design of the SaeboGlove enabled assistance from tensioners to be increased/decreased according to individual ability. Please see information on weaning in Item 4 above.
10. **Modifications:** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	On occasion (only 2/39; 5% of stroke survivors) inpatient reviews were done in two halves to manage fatigue and progress while ensuring positivity/coping. In some cases, people with a Modified Ashworth Score = 2 and no active digital extension were unable to access full digital extension wearing a SaeboGlove. Thus, while the band sizing/placement guideline chart provided by Saebo Ltd was utilised, on occasion in this situation, a second band (size c) was attached between the distal proximal interphalangeal joint hook and a proximal metacarpophalangeal hook to help these stroke survivors better access full digital extension. In this

Item	Intervention
	case, stroke survivors/carers were advised of the importance of monitoring closely for new/worsening hand pain and asked to report any new/worsening hand pain to the research team without delay. Additionally, to gain confidence that joint pain did not occur/accumulate due to the addition of the extra band stroke survivors/carers were asked strictly not to exceed 50 daily repetitions for the first 3 – 4 days even if they felt comfortable. Repetitions were ramped up towards 100 by 10-20 repetitions every few days with vigilant self-monitoring thereafter if no concerns developed.
11. **How well - Planned:** If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	The physiotherapist completed a Case Report Form after each review to document adherence at planned sessions (i.e. attendance and timing of reviews) (Appendix J). Stroke survivors completed a Hand and Arm rehabilitation booklet to record the number of hand opening movements they carried out daily (i.e. actual number of planned self-practice sessions and repetitions performed daily) (Appendix J). Data from booklets were studied by the physiotherapist at reviews to monitor intervention adherence and take steps to optimise it.
12. **How well - Actual:** If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Details provided in the Interventions section in the results in this chapter (Section 4.4.4) and in the fidelity results in Chapter 5, Part 1.

Underlined text highlights changes made between the Pilot version of the Help for Hands EMPOWER programme in T-SET to version 1.0 in SUSHI. Reproduced from Hoffmann, T.C., Glasziou, P.P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D.G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S.E., Dixon-Woods, M., McCulloch, P., Wyatt, J.C., Chan, A.W. and Michie, S. (2014) 'Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide', *BMJ*, 348, g1687, available: http://dx.doi.org/10.1136/bmj.g1687, (copyright notice year: 2023) with permission from BMJ Publishing Group Ltd.

4.3.3.3 Control group

The date of randomisation was defined as the start of the intervention in control group participants. To balance therapist contact/expertise between groups physiotherapists/occupational therapists from the clinical team were asked to provide control participants with four usual care based upper limb therapy review sessions in addition to usual care therapy during the six week intervention period (Appendix J). The purpose of these reviews was to assess upper limb progress and re-define individualised upper limb treatment plans. While the study aimed to match therapist attention in both groups in terms of the number of contacts (reviews), the duration of each review was not recorded to minimise research burden on clinical teams. Clinical therapists were reminded of the need to schedule reviews throughout the intervention period by the research physiotherapist (typically at recruitment and at one to two week intervals thereafter).

A placebo intervention (wearing the device without exercising/exercise support) was considered for the control group but was not utilised for three reasons; (1) it was not feasible to provide it within the resources available for the study (e.g. insufficient number of gloves, transport budget, therapy staff/time) and, (2) it was felt it would introduce a high probability of control participants being inadvertently exposed to the active SaeboGlove intervention due to the understanding they gained about it at recruitment and their wish to use it or influences from clinicians/other SaeboGlove group participants who had gained knowledge of the intervention (contamination bias) (Robinson *et al*. 2020) and (3) it would change the question from is the experimental intervention better than usual care.

Consistent with recommendations offered in earlier PPI work (Appendix F) to help manage attrition in the control group, after the 14 week outcome assessments were completed usual care participants were offered six weeks of the EMPOWER intervention. Data collected during this six week period were not included in the formal efficacy analysis.

4.3.3.4 Hand and Arm Rehabilitation Booklets

To encourage self-management, to permit group comparison and offer context and to record treatment interruptions for fidelity purposes (Appendix J) stroke survivors/carers in both groups were given a Hand and Arm rehabilitation exercise booklet to record and monitor their active upper limb therapy time (minutes) with and without a therapist during the intervention period (weeks 1-6) and for eight weeks afterwards (weeks 7-14) (Table 16 above) (Appendix J).

Additionally, like T-SET, booklets provided to SaeboGlove group participants highlighted the need for intensive, repetitive functional based practice to optimise recovery, recorded intensity goals agreed at each review and encouraged participants to record the number of hand opening movements they performed daily during their individualised functional-based grasping/releasing training programme over the intervention period.

Site personnel explained the booklets to participating stroke survivors after randomisation and phoned them weekly to remind them to complete their rehabilitation booklet and to attend any upcoming scheduled trial visits.

4.3.4 Outcome assessments

Assessments were completed at 6 and 14 weeks (range 5-9 weeks and 13-17 weeks respectively) after randomisation (Table 16 above) (Appendix H) by two trained site personnel.

4.3.4.1 Outcome assessor training and consistency

All outcome assessors received training on the assessments before conducting any assessments. To optimise reliable and repeatable scoring, this included the provision of a training manual with standardised assessment procedures (Appendix H), and face to face training and independent co-scoring of each outcome measure a minimum of three times with the research physiotherapist who had over five years' scoring experience.

To optimise reliability of scoring the same assessor scored outcomes at all time points for each participating stroke survivor wherever possible. In exceptional

situations (e.g. safety) the 6 and 14 week assessments were performed at stroke survivors' homes.

4.3.4.2 Primary outcome

The ARAT (Lyle 1981) was selected to be the primary outcome measure in SUSHI. As it has been historically described as a measure of upper limb function, a term that aligns with upper limb activity limitations within The International Classification of Functioning, Disability and Health model, this thesis will continue to use this terminology. The ARAT was selected to be the primary outcome measure as it is an objective measure, it is recommended as a measure of activity limitation in all stroke recovery trials involving the upper limb (Kwakkel *et al.* 2017) and improving upper limb function is a recognised research priority for stroke survivors (Pollock *et al.* 2014b). Additionally, a significant improvement in it should represent a change in independence in life tasks, aligning well with a meaningful change for the target population according to the PPI activity that followed T-SET (Chapter 3, Appendix F). It was also responsive to change in T-SET, improving by nearly double that observed in historical controls (mean (SD) of 18.8 (13.5) point (Alexander and Dawson 2019) compared to 10 (15) points (Rabadi and Rabadi 2006)). Furthermore, it was scored by a blinded assessor to improve objectivity and internal validity (Hariton and Locascio 2018) (See Blinding section below - Section 4.3.4.4).

4.3.4.3 Secondary outcomes

The secondary outcomes were upper limb function (ARAT) (Lyle 1981) at 14 weeks post randomisation, all remaining baseline measures at 6 and 14 weeks and therapy participation (attendance at therapy reviews, stroke survivor-reported total number minutes of upper limb therapy with and without a therapist (weeks 1-6, 7-14 and 1-14) and physiotherapist and occupational therapist-reported total number of days and % of weekdays they delivered upper limb therapy (weeks 1-6) (Table 16 above).

4.3.4.4 Blinding and masking of treatment allocation

To minimise the risk of group allocation knowledge influencing outcome data (detection bias), outcome assessments were conducted by a blinded assessor.

Stroke survivors, carers, therapists, and the clinical team were asked not to let outcome assessors know which treatment group stroke survivors had been allocated to and were provided with reminders of this prior to scheduled outcome visits. Additionally, the trial physiotherapist did not share a base with outcome assessors in the research team and all therapy visits/activities and therapy equipment storage took place in a different building.

At the baseline assessment all stroke survivors were given an identical small therapy box with a cardboard insert weighing the same as a SaeboGlove and a Hand and Arm rehabilitation booklet specific for control participants (Table 16 above). The box had a note in it thanking them for their participation in the SUSHI trial, asking them to bring the box with their Hand and Arm Therapy Booklets to their future study visits and to not discuss the contents of the box or the treatment group they were placed in with outcome assessors (Appendix I).

When stroke survivors in the intervention group were given a SaeboGlove, it was left in their therapy box in exchange for the cardboard insert which their therapist removed. The Hand and Arm rehabilitation booklet previously provided was also swapped for a booklet specific for the intervention group (Table 16 above). All therapy booklets looked identical from the outside and would need to be opened and studied to reveal group allocation. Regardless of group allocation, therapy booklets, and all case report forms used for the recording of usual care and upper limb therapy reviews appeared identical externally and would not reveal group allocation unless opened and studied. These measures helped keep outcome assessors blinded. Assessors were asked to record if they had been unblinded at each outcome visit to enable potential bias to be reported.

Given the interventions involved, it was not possible to conceal group allocation from stroke survivors/carers, their therapist, or their clinical team. Thus, it was not possible to minimise the risk of group allocation knowledge influencing outcome data purely due to behavioural alterations in response to this knowledge (performance bias) (e.g. less usual care upper limb therapy may have been delivered to SaeboGlove group participants as they were already receiving support or more usual upper limb therapy may have been delivered in all participants as usual care therapy was being recorded, more self-practice

therapy may have been performed in control participants as they were aware they were being monitored). To counter this, an objective, not subjective, primary outcome measure was selected for blinded assessment, the research physiotherapist was asked to try not to impart any group superiority bias and participants and usual care therapists were asked not to feel any pressure to change their practice/usual upper limb rehabilitation behaviour due to study monitoring procedures.

After the week 14 visit, SaeboGlove therapy was offered to control participants who remained suitable to use the SaeboGlove (Table 16 above).

4.3.4.5 Safety monitoring

Predicted adverse device effects included discomfort in the upper limb considered to be device related. The safety of the EMPOWER programme and usual care were evaluated by examining the occurrence of all adverse device events (ADEs), serious adverse events (SAEs), serious adverse device events (SADEs) and unexpected serious adverse device events (USADEs) until the 14 week visit (NHS Health Research Authority 2019) (Table 19) (Appendix J). Site personnel were asked to assume that all participating stroke survivors were using a SaeboGlove when reporting potential ADEs.

Table 19: Definitions of adverse events

Type of adverse event	Definition
Adverse Event (AE)*	Any untoward medical occurrence experienced by a trial participant.
Serious adverse Event (SAE)*	Any Adverse Event that: • results in death; • is life-threatening (an event in which the participant was at risk of death at the time of the event; not an event which hypothetically might have caused death if it were more severe); • requires inpatient hospitalisation or prolongation of an existing hospitalisation; • results in persistent or significant disability or incapacity; • consists of a congenital anomaly or birth defect. • includes other 'important medical events' that jeopardise the participant or require an intervention to prevent one of the above consequences e.g. fall with significant upper limb injury/fracture that interrupts rehabilitation or requires referral, tests/scans or intervention
Adverse Device Event (ADE)**	Any AE that is judged to be probably or definitely related to the use of SaeboGlove therapy.
Serious Adverse Device Event (SADE)**	Any SAE that is judged to be probably or definitely related to the use of SaeboGlove therapy.
Unexpected serious Adverse Event (USADE)**	An USADE that was not predicted.

***(Global Pharmacovigilance 2023), **(Medical Device Coordination Group 2022)**

The occurrence of all such events were checked at each study visit and participating stroke survivors were encouraged to report them between visits. Stroke survivors undergoing SaeboGlove therapy who had upper limb discomfort of a degree sufficient to compromise function had study therapy stopped. Such individuals were allowed to resume therapy should they wish and if their upper limb discomfort improved, provided this was within the planned six week intervention period. Any treatment interruptions or terminations were recorded (Appendix J) and follow-up assessments were carried out according to protocol.

4.3.5 Data management, clinical monitoring, and dissemination

4.3.5.1 Data management

All personal information was collected, stored, and processed in accordance with the General Data Protection Regulation (2018). Each person was identified on case report forms only by their study number. Site personnel recorded data on paper source forms and entered data into an electronic database. Anonymised data was stored on a research repository called Enlighten for 10 years from the time of last data access and will be shared with other organisations or universities to carry out research to improve scientific understanding.

4.3.5.2 Clinical monitoring

A trial steering committee and a patient and carer research advisory group were convened and met annually. The trial steering committee comprised an independent chair, two other independent members, the Chief Investigator, the co-investigator/lead physiotherapist and two other investigators. The committee shared the overall scientific responsibility of the study with the Chief Investigator and Sponsor, contributing expertise, oversight, and guidance for the study duration.

The patient and carer research advisory group comprised two stroke survivors, two carers and the research physiotherapist. The role of this group was to offer advice/feedback on any issues that arose throughout the trial including any publications, represent the wider views of people affected by reduced upper

limb function after stroke and contribute to decision making and clinical implementation planning where relevant.

A Data Monitoring Committee was not convened due to limited resources and additional Covid-19 challenges. However completeness of data recorded by stroke survivors/carers was reviewed at therapy reviews and at the end of the six and 14 week data collection periods. Additionally, completion of all data was reviewed at the point of data entry and any queries were passed to research staff to review and addressed them, seeking information from stroke survivors/carers/ therapists where needed. Finally, this review/query process was repeated for the full study database every one to two months to optimise data completion where this was possible. Additionally, all adverse events were reviewed by the relevant PI and the CI to ensure monitoring and oversight of safety outcomes.

The study was audited by designated representatives of the Sponsor, NHS GG&C, according to their audit processes.

4.3.6 Statistical Analysis Plan

The Robertson Centre for Biostatistics within the Glasgow Clinical Trials Unit provided statistical support to the RCT. The Statistical Analysis Plan (SAP) that follows in this section was agreed with them before completion of enrolment.

4.3.6.1 General principles

Primary and secondary outcome measures were summarised at baseline and at each follow up. All summaries include the number of observed values and the number of missing values. Continuous variables were summarised by the mean, standard deviation, median, interquartile range, minimum and maximum. Categorical variables were summarised as the number and percentage of participants in each group.

The primary and continuous secondary efficacy outcomes are compared between intervention groups using linear regression analyses, adjusting for baseline value of the outcome, study site, time since stroke (≤1 month, >1 month) and severity of upper limb function (ARAT 0-10, 11-28, 29-46). The distribution of the

residuals of each linear regression analysis were reviewed and transformations were applied to the outcome variable as appropriate.

Regression results were reported as adjusted mean differences between intervention groups with 95% confidence intervals and p-value.

Safety outcomes were reported in a descriptive fashion.

Missing values were not imputed in main analyses.

4.3.6.2 Protocol deviations

The SAP contained no deviations from analyses planned in the study protocol. Deviations are summarised in a descriptive fashion by each group and both groups combined.

4.3.6.3 Additional analyses to those specified in the study protocol

The SAP contained no additional analyses to those planned in the study protocol.

4.3.6.4 Software

Data were analysed using R version 3.6.2 or higher.

4.3.6.5 Populations

The Analysis Population included all randomised participants.

Efficacy analyses were carried out according to randomised group, regardless of compliance with the intervention. Safety analyses were carried out if the intervention was commenced.

4.3.6.6 Statistical analysis

Participant disposition

The number of participants in the analysis population are tabulated as a whole and by randomised group. The number and percentage who completed each study assessment and reasons for not completing each assessment are reported (death, withdrawal, loss to follow-up).

Baseline characteristics

The following baseline characteristics are summarised in the analysis population:

- Age
- Gender
- Ethnic group
- Study site
- Fugl Meyer Upper Extremity Total Motor score
- Fugl Meyer Upper Extremity Hand Motor score
- Fugl Meyer Upper Extremity Sensory score
- Action Research Arm Test subscores (Grasp, Grip, Pinch, Gross)
- Action Research Arm Test score (total continuous, and categorised 0-10, 11-28, 29-46)
- Modified Rankin scale score
- Motor Activity Log scores (Quantity, Quality, % of tasks)
- Barthel Index
- EuroQol five dimension and five levels Health Utility Score
- EuroQol five dimension and five levels VAS
- Pain above elbow VAS
- Pain below elbow VAS
- SIS Hand subscore
- SIS Total score
- SIS Recovery
- Current upper limb rehab therapy
    - Physiotherapy/occupational therapy
    - Splints
    - Shoulder sling
    - TENS
    - Antispasticity medication (e.g. Dantrolene, Baclofen, Tizanidine)
    - Botulinum toxin
- Ischaemic stroke
- Haemorrhagic stroke
- Time from stroke (≤1 months, >1 month)
- Handedness
- Affected arm

Scores relating to left and right arms are summarised for the affected arm only.

Treatment

The following measures are summarised for both randomised groups:

- Attendance at therapy reviews – % in each group who had review 1,2,3,4 and all reviews.
- Stroke survivor-reported total number minutes of upper limb therapy with a therapist (reported for weeks 1-6, 7-14, weeks 1-14)
- Stroke survivor -reported total minutes of upper limb therapy without a therapist (reported for weeks 1-6, 7-14, weeks 1-14)

The following measures were collected up to September 2021, and are summarised for both randomised groups:

- Physiotherapist-reported upper limb therapy (total number of days and % of weekdays for weeks 1-6)
- Occupational therapist-reported upper limb therapy (total number of days and % of weekdays for weeks 1-6)

Collection of therapist-reported upper limb therapy was stopped in September 2021 due to the need to reduce recording burden in the clinical team during the Covid-19 pandemic.

Efficacy outcomes

Primary outcome: The primary outcome, upper limb function (ARAT) at 6 weeks post randomisation (Table 16 above), was analysed in a linear regression analysis with predictor variables for randomised intervention group, baseline ARAT as a continuous measure, study site, and time since stroke (≤1 month, >1 month). Only data concerning the affected upper limb is reported for upper limb outcome scales.

Secondary outcomes: The secondary outcomes (Table 16 above) were:

- Upper limb function
  - ARAT Total score at 14 weeks post randomisation
- Upper limb impairment
  - Fugl Meyer Upper Extremity (FMUE) Motor Total Score at 6 and 14 weeks
  - Fugl Meyer Upper Extremity (FMUE) Hand Score at 6 and 14 weeks
- Upper and lower arm pain intensity
  - Visual Analogue Scale (VAS) at 6 and 14 weeks
- Stroke survivor-reported SaeboGlove therapy participation
- Perceived habitual functional upper limb use
  - Motor Activity Log (MAL) at 6 and 14 weeks
- Degree of disability/dependence
  - modified Rankin Scale (mRS) at 6 and 14 weeks
- Activities of daily living
  - Barthel Index (BI) at 6 and 14 weeks
- Quality of life and health status
  - Stroke Impact Scale (SIS) (Total score and Hand score) at 6 and 14 weeks
  - EuroQol (EQ-5D-5L) Health Utility Score and VAS, at 6 and 14 weeks

Each continuous secondary outcome measure was analysed in a linear regression analysis with predictor variables for randomised intervention group, the baseline value of the outcome measure, baseline upper limb function (ARAT 0-10, 11-28, 29-46), study site, and time since stroke (≤1 month, >1 month).

Blinding and masking of treatment allocation

Outcome assessors were asked to record if they have been unblinded at each outcome visit to enable potential bias to be reported and blinding success in assessors was analysed descriptively.

Safety outcomes

Premature withdrawal: Withdrawals and withdrawal reasons are summarised overall and by intervention group.

Adverse events: The number of participants experiencing at least one SAE, ADE, SADE, and USADE were summarised overall and by intervention group up to 14 weeks for those who received at least one session of SaeboGlove therapy and all control group participants to help establish the relative safety of the SaeboGlove group versus Usual Care group interventions. SAEs, ADEs, SADEs, and USADEs characteristics (seriousness criteria, severity, expectedness, relation to intervention, outcome, and duration) are summarised descriptively overall and by study group.

4.3.7 Rigour & reporting

A detailed checklist of information to include when reporting a randomised trial according to the Consolidated Standards of Reporting Trials (CONSORT) (Moher *et al*. 2012) and a summary of methods adopted to improve rigour based on the criteria set out in the Methodology chapter (Chapter 3) to judge the quality of a quantitative research study are presented in Appendix K and Table 20 overleaf respectively.

Table 20: Summary of methods used to enhance rigour

Criteria for rigour *	Summary of methods used to enhance rigour
Internal validity 'The degree to which findings correctly map the phenomenon in question'.	Randomisation, use of a control group, a sample with adequate power and an intention to treat analysis help to improve the likelihood that both groups were similar in baseline & confounding factors Outcome measures with robust psychometric characteristics were used The primary outcome is pre-specified and objective The same blinded assessor was used at all time points The success of assessor blinding was recorded and reported for transparency
External validity 'The degree to which findings can be generalized to other settings similar to the one in which the study occurred.'	The study population included patients from six hospitals over two health boards A process evaluation was performed to explore and understand the self-management support needs, barriers, and facilitators to implement clinically/in real-life setting (Reported in Chapter 5)
Reliability 'The extent to which findings can be replicated or reproduced by another investigator.'	A RCT design is the most reliable design to obtain a true result as it enhances the likelihood of both groups being similar in baseline and confounding factors A sample size calculation was used to identify the sample size needed to accurately determine a relationship between the dependent & independent variables Both outcome assessors were trained by the same person, used standardised assessment procedures/resources, and worked across all sites The same assessor was used at different time points Outcome measures with robust psychometric characteristics were used A CONSORT checklist was used
Objectivity 'The extent to which findings are free from bias.'	Random group allocation used and concealed The success of assessor blinding was recorded and are report for transparency The primary outcome is prespecified and objective All outcomes measured are reported An intention to treat analysis was used The trial was registered Ethical approval was gained

***Definitions taken from Devers 1999, p.1157**

4.4 Results

4.4.1 Recruitment

Between November 2019, and October 2022 (35 months) a total of 275 stroke survivors were identified; 188 were excluded without consent or formal screening based on information gained by identifiers (clinical/Stroke Research Network staff), 9 were consented and excluded and 78 were consented and randomised (Table 21 and Figure 22 overleaf).

Table 21: Monthly recruitment

Month	Recruitment	
	Per Month	Cumulative
Nov 2019	2	2
Dec 2019	2	4
Jan 2020	5	9
Feb 2020	4	13
Mar 2020	3	16
Apr 2020*	0	16
May 2020*	0	16
Jun 2020*	0	16
Jul 2020*	1	17
Aug 2020	2	19
Sep 2020	1	20
Oct 2020	4	24
Nov 2020	5	29
Dec 2020	2	31
Jan 2021	1	32
Feb 2021	3	35
Mar 2021	3	38
Apr 2021	1	39
May 2021	5	44
Jun 2021	4	48
Jul 2021	2	50
Aug 2021	4	54
Sep 2021	1	55
Oct 2021	4	59
Nov 2021	2	61
Dec 2021**	1	62
Jan 2022**	1	63
Feb 2022**	1	64
Mar 2022	4	68
Apr 2022	3	71
May 2022	2	73
Jun 2022	2	75
Jul 2022***	0	75
Aug 2022***	1	76
Sep 2022***	1	77
Oct 2022***	1	78

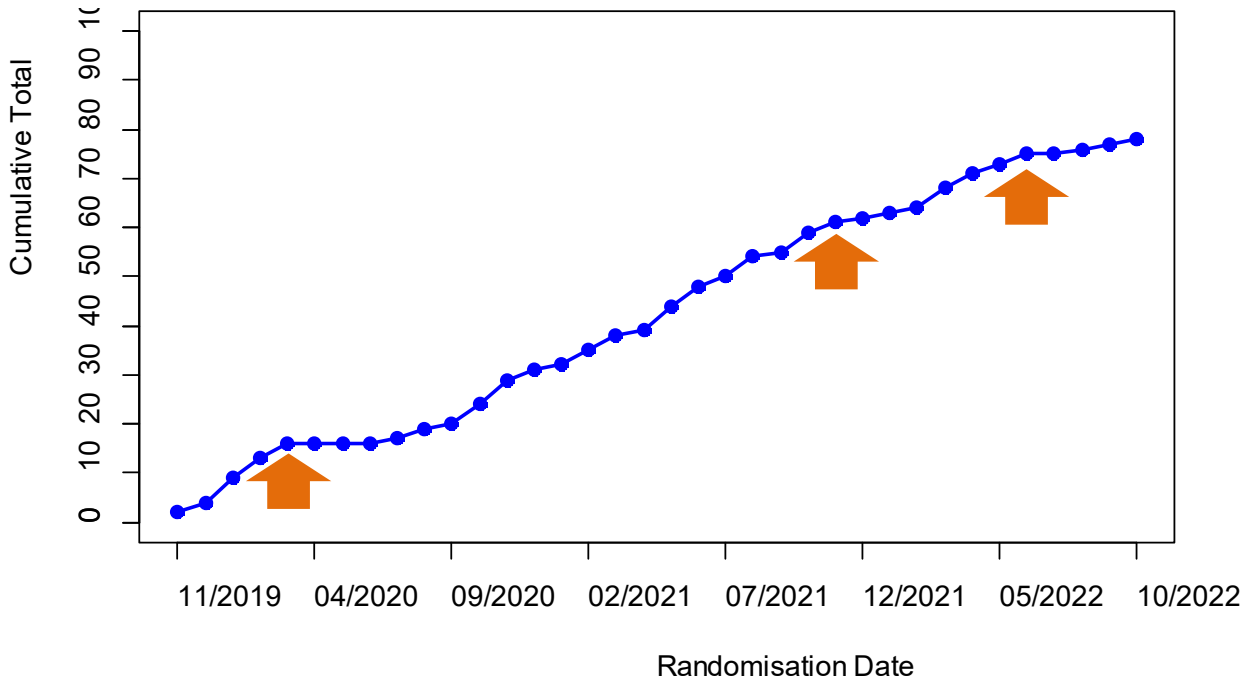
***Initial COVID-19 lockdown: all research activities ceased, **Clinic/staff availability challenges, ***Change in target population**

As 78 stroke survivors randomised the target aim of achieve 80% power (i.e. 70 stroke survivors split randomly into two groups) by November 2022 was fulfilled.

The mean (SD, range) overall recruitment rate over the 35 months was 2.2 (1.5, 0-5) participating stroke survivors per month.

Three periods of particular recruitment challenge were encountered (i) the initial lockdown when all research activities ceased for around 4 months (recruitment rate: 0.25/month), (ii) clinic/staff availability challenges (recruitment rate: 1/month) and (iii) a change in the target population due to Covid-19 morbidity (recruitment rate: 0.75/month) (Table 21, Figure 22).

Figure 22: Recruitment to the SUSHI Trial

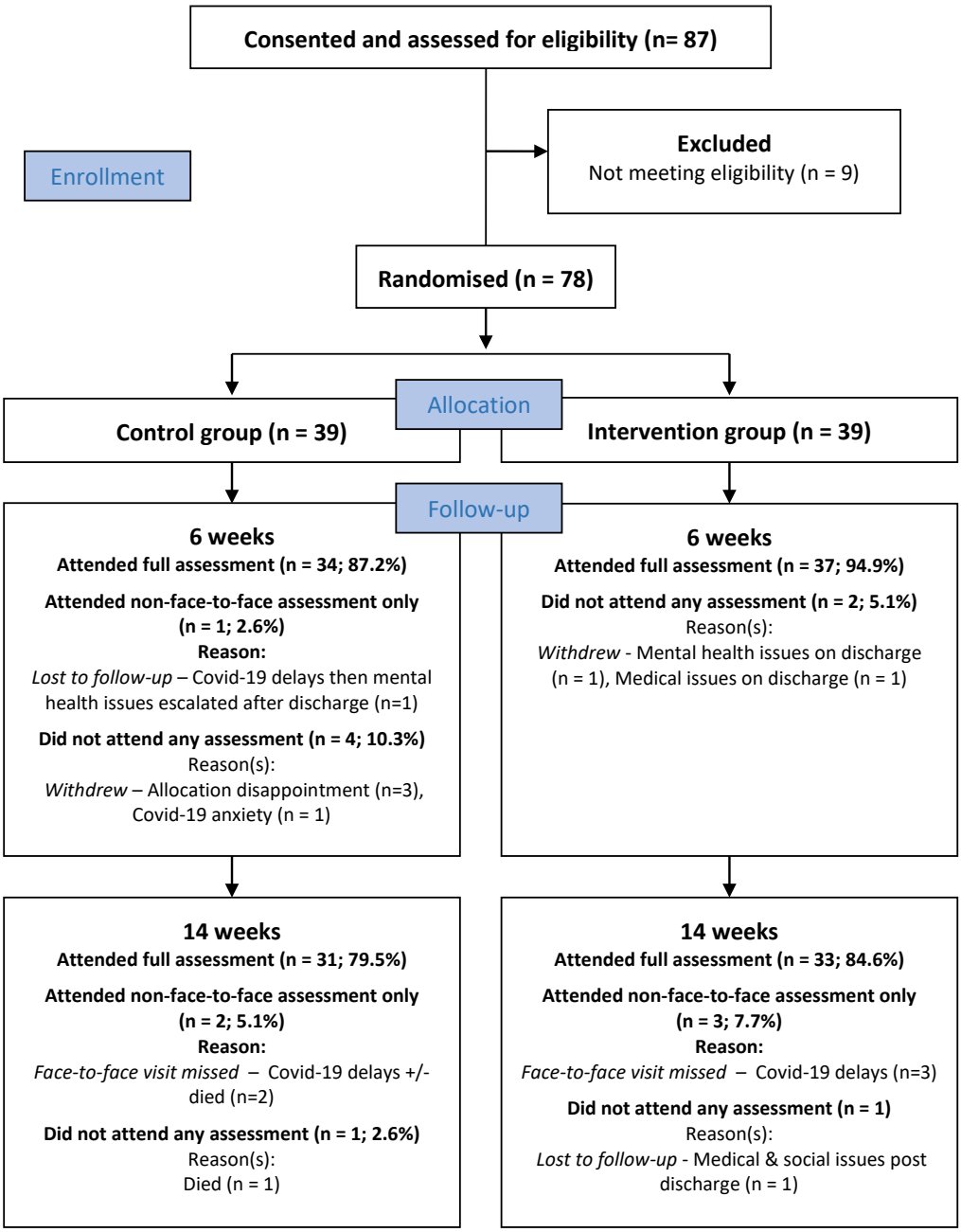


Recruitment to the SUSHI Trial. The start of periods of particular recruitment challenge over and above more consistent challenges are highlighted using orange arrows: From left to right: Initial lockdown - all research activities ceased for 4 months, clinic/staff availability challenges and change in target population due to Covid-19 morbidity.

4.4.2 Participant disposition

Recruits were randomly assigned to receive SaeboGlove therapy (n = 39) or usual care (n= 39) (Figure 23). Of the 78 participating stroke survivors, 71 (34+37; 91.0%) and 1 (1.3%) attended the 6 weeks assessment in full, or partially (non-face-to-face measures only) respectively. The equivalent figures for the 14 week assessment were 64 (31+33; 82.1%) and 5 (6.4%) respectively. Reasons for partial and non-attendance at visits are shown in Figure 23.

Figure 23: Trial visit attendance



The progress of randomised stroke survivors through trial phases along with reasons why assessments were partially or not attended. Non-face-to-face measures: all measures except the Action Research Arm Test and the Fugl Meyer Upper Extremity score, data from all follow-up visits were analyses on an intention to treat basis.

Withdrawals were slightly higher in the Control group as the nature of the intervention meant that treatment allocation could not be masked from participating stroke survivors leading to allocation disappointment.

The availability of outcome data at each assessment visit is show in Table 22.

Table 22: Availability of outcome data at assessment visits by intervention group

Outcome data	Availability by intervention group		
	All (N_{OBS}/N_{MISS} = 78/0)	**Usual Care** (N_{OBS}/N_{MISS} = 39/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 39/0)
Baseline			
Provide any baseline data	78 (100.0%)	39 (100.0%)	39 (100.0%)
Provide baseline data for:			
All measures	78 (100.0%)	39 (100.0%)	39 (100.0%)
Non-face-to-face measures	78 (100.0%)	39 (100.0%)	39 (100.0%)
6 week assessments			
Provide any follow-up data	72 (92.3%)	35 (89.7%)	37 (94.9%)
Provide follow-up data for:			
All measures	71 (91.0%)	34 (87.2%)	37 (94.9%)
Non-face-to-face measures*	72 (92.3%)	35 (89.7%)	37 (94.9%)
14 week assessments			
Provide any follow-up data	69 (88.5%)	33 (84.6%)	36 (92.3%)
Provide follow-up data for:			
All measures	64 (82.1%)	31 (79.5%)	33 (84.6%)
Non-face-to-face measures	69 (88.5%)	33 (84.6%)	36 (92.3%)

Categorical variables are no. of stroke survivors in group (N (%))
Face-to-face measures: Action Research Arm Test and Fugl Meyer Upper Extremity score, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, Non-face-to-face measures: Modified Rankin Scale, Visual Analogue Scale for Pain, Motor Activity Log, Barthel Index, Stroke Impact Scale, EuroQol five dimensions and five levels, *The EQ-5D-5L Visual Analogue Scale was missed in a usual care participant as he was too unwell

All intended measures were available for analysis from the 78 scheduled baseline participant visits (100.0%). Of the 78 participating stroke survivors, all measures

were available in 71 (91.0%) and 64 (82.1%) of 6 week and 14 week visits respectively. The equivalent figures for non-face-to-face measures were 72 (92.3%) and 69 (88.5%) respectively. All missing outcome data occurred due to partially or not attended visits with the exception of two data points missed at 6 week visits due to human error, one in the MAL Quality in a SaeboGlove participant and one in the EQ-5D-5L (Health scale today) in a usual care participant (Table 22 above).

4.4.3 Sample

Baseline demographics, stroke characteristics, upper limb clinical measures, other (non-upper limb) clinical measures and upper limb rehabilitation are summarised in Tables 23, 24, 25, 26 and 27 respectively. There were more males and less right-hand dominant stroke survivors in the Usual Care group (Males: 29 (74.4%) versus 21 (53.8%), Right handedness: 32 (82.1%) versus 37 (94.9%)) but these differences were not thought sufficient to bias results Table 23).

Table 23 shows that at baseline the mean age of participating stroke survivors was 63.3 (13.2) years, and the majority of participating stroke survivors were male (50; 64.1%), white (73; 93.6%), enrolled at the Queen Elizabeth University Hospital in the Greater Glasgow and Clyde Health Board (37; 47.4%) and right hand dominant (69; 88.5%).

Table 23: Baseline characteristics in the intention-to-treat population - demographics

Demographics	Baseline characteristics by intervention group		
	All (N_{OBS}/N_{MISS} = 78/0)	**Usual Care** (N_{OBS}/N_{MISS} = 39/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 39/0)
Age (years)	63.3 (13.2), 64.0 (54.2, 73.0), [29.0, 88.0]	61.6 (13.7), 64.0 (53.5, 70.5), [29.0, 87.0]	64.9 (12.5), 64.0 (57.0, 73.5), [39.0, 88.0]
Gender			
Male	50 (64.1%)	29 (74.4%)	21 (53.8%)
Female	28 (35.9%)	10 (25.6%)	18 (46.2%)
Ethnic group			
White	73 (93.6%)	37 (94.9%)	36 (92.3%)
Non-White	5 (6.4%)	2 (5.1%)	3 (7.7%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)
Study site			
QEUH	37 (47.4%)	19 (48.7%)	18 (46.2%)
RAH	15 (19.2%)	8 (20.5%)	7 (17.9%)
STO	12 (15.4%)	6 (15.4%)	6 (15.4%)
MON	7 (9.0%)	4 (10.3%)	3 (7.7%)
GRI	4 (5.1%)	1 (2.6%)	3 (7.7%)
HAI	3 (3.8%)	1 (2.6%)	2 (5.1%)
Handedness			
Right	69 (88.5%)	32 (82.1%)	37 (94.9%)
Left	9 (11.5%)	7 (17.9%)	2 (5.1%)

Categorical variables are no. of stroke survivors in group (N (%)), continuous variables are mean (SD), median (IQR), [range]
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set

Table 24 shows that the majority of stroke survivors experienced a stroke due to cerebral infarction (63; 80.8%) and were recruited within 1 month of it occurring (44; 56.4%). The mean time from stroke to randomisation was 28.6 (15.1) days and the left upper limb was affected in just over half of participating stroke survivors (41; 52.6%) (Table 24).

Table 24: Baseline characteristics in the intention-to-treat population - stroke details

Stroke details	Baseline characteristics by intervention group		
	All (N_{OBS}/N_{MISS} = 78/0)	**Usual Care** (N_{OBS}/N_{MISS} = 39/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 39/0)
Stroke Reason			
Infarction	63 (80.8%)	32 (82.1%)	31 (79.5%)
Haemorrhage	14 (17.9%)	7 (17.9%)	7 (17.9%)
Unknown	1 (1.3%)	0 (0.0%)	1 (2.6%)
Time since stroke (binary)			
≤1 month	44 (56.4%)	21 (53.8%)	23 (59.0%)
>1 month	34 (43.6%)	18 (46.2%)	16 (41.0%)
Time since stroke (days)	28.6 (15.1), 25.0 (17.0, 39.0), [7.0, 66.0]	29.9 (15.7), 25.0 (16.5, 41.0), [8.0, 66.0]	27.4 (14.6), 25.0 (17.0, 38.0), [7.0, 59.0]
Affected arm			
Right	37 (47.4%)	20 (51.3%)	17 (43.6%)
Left	41 (52.6%)	19 (48.7%)	22 (56.4%)

Categorical variables are no. of stroke survivors in group (N (%)), continuous variables are mean (SD), median (IQR), [range]
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set

At baseline the mean (SD) ARAT Total score of all stroke survivors was 13.3 (11.8) points and on average stroke survivors in all groups had poor upper limb functional capacity (ARAT: 11-21, (Hoonhorst *et al*. 2015), mean (SD) ARAT Total - All: 13.3 (11.8), Usual Care group: 12.8 (12.2), SaeboGlove group: 13.7 (11.6)) (Table 25 overleaf). However, the majority of recruits were in the lowest ARAT subcategory (ARAT: 0-10, 43 (55.1%)) and therefore had no upper limb functional capacity (Hoonhorst *et al*. 2015) (Table 25 overleaf).

At baseline the mean (SD) FMUE Motor Total and Hand scores of all recruits were 23.0 (10.3) and 2.8 (1.4) respectively (Table 25). The mean (SD) FMUE Sensory score was 7.1 (2.1) (Table 25 overleaf).

At baseline the mean (SD) MAL Quantity and Quality scores for all stroke survivors were 0.3 (0.3) and 0.2 (0.2) respectively. On average stroke survivors in all groups reported use of their affected upper limb in a mean of 2 out of the 17 MAL ADL tasks (mean (SD) MAL % of tasks - All: 12.3 (12.8)% i.e. 2.1 tasks (12.3%/5.9%; 2.1 tasks), Usual Care group: 11.6 (13.3)% i.e. 2.0 tasks (11.6%/5.9%; 2.0), SaeboGlove group: 13.0 (12.5) i.e. 2.2 tasks (13.0%/5.9%; 2.2) (Table 25 overleaf).

The mean (SD) VAS pain score above the elbow and in/below the elbow were 0.9 (1.4) and 0.6 (1.3) respectively (Table 25 overleaf).

Table 25: Baseline characteristics in the intention-to-treat population – Upper limb clinical measures

Upper limb clinical measures	Baseline characteristics in the intention-to-treat population		
	All (N_{OBS}/N_{MISS} = 78/0)	**Usual Care** (N_{OBS}/N_{MISS} = 39/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 39/0)
ARAT Grasp (0-18)*	4.8 (5.4) 2.0 (0.0, 9.0) [0.0, 18.0]	4.8 (5.6) 2.0 (0.0, 9.0) [0.0, 17.0]	4.9 (5.3), 3.0 (0.5, 8.5), [0.0, 18.0]
ARAT Grip (0-12)*	2.7 (2.7) 2.0 (0.0, 4.0) [0.0, 10.0]	2.5 (2.7) 2.0 (0.0, 4.0) [0.0, 9.0]	2.9 (2.8), 3.0 (0.0, 4.5), [0.0, 10.0]
ARAT Pinch (0-18)*	1.2 (2.1) 0.0 (0.0, 2.0) [0.0, 9.0]	1.2 (2.4) 0.0 (0.0, 0.5) [0.0, 9.0]	1.1 (1.7), 0.0 (0.0, 2.0), [0.0, 6.0]
ARAT Gross (0-9)*	4.5 (2.6) 4.0 (3.0, 6.0) [0.0, 9.0]	4.3 (2.6) 3.0 (3.0, 6.0) [0.0, 9.0]	4.8 (2.7), 4.0 (3.0, 6.5), [0.0, 9.0]
ARAT Total (0-57)*	13.3 (11.8) 9.0 (3.2, 20.8) [0.0, 42.0]	12.8 (12.2) 7.0 (3.0, 20.5) [0.0, 42.0]	13.7 (11.6), 9.0 (4.5, 21.0), [0.0, 40.0]
ARAT Total by upper limb functional capacity (Hoonhorst *et al*. 2015): 1) No capacity (0-10) 2) Poor to limited capacity (11-28) 3) Limited to notable capacity (29-46)	1) 43 (55.1%) 2) 23 (29.5%) 3) 12 (15.4%)	1) 22 (56.4%) 2) 12 (30.8%) 3) 5 (12.8%)	1) 21 (53.8%) 2) 11 (28.2%) 3) (17.9%)
FMUE Motor Total score (0-66)*	23.0 (10.3), 21.0 (16.2, 26.0), [6.0, 55.0]	21.8 (10.4), 21.0 (15.0, 26.0), [6.0, 51.0]	24.1 (10.1), 22.0 (19.0, 7.0), [7.0, 55.0]
FMUE Motor Hand score (0-14)*	2.8 (1.4), 2.0 (2.0, 3.0), [1.0, 7.0]	2.7 (1.5), 2.0 (2.0, 3.0), [1.0, 7.0]	2.8 (1.4), 2.0 (2.0, 4.0), [1.0, 7.0]
FMUE Sensory score (0-12)*	7.1 (2.1), 8.0 (8.0, 8.0), [0.0, 8.0]	7.2 (2.0), 8.0 (8.0, 8.0), [0.0, 8.0]	7.0 (2.3), 8.0 (8.0, 8.0), [0.0, 8.0]

Categorical variables are no. of stroke survivors in group (N (%)), continuous variables are mean (SD), median (IQR), [range]
ARAT: Action Research Arm Test, FMUE: Fugl Meyer Upper Extremity score, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, *higher represents better function

Upper limb clinical measures	Baseline characteristics in the intention-to-treat population		
	All (N_{OBS}/N_{MISS} = 78/0)	**Usual Care** (N_{OBS}/N_{MISS} = 39/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 39/0)
MAL Quantity (0-5)*	0.3 (0.3), 0.1 (0.0, 0.4), [0.0, 1.4]	0.2 (0.3), 0.1 (0.0, 0.3), [0.0, 1.4]	0.3 (0.3), 0.2 (0.1, 0.4), [0.0, 1.3]
MAL Quality (0-5)*	0.2 (0.2), 0.1 (0.0, 0.4), [0.0, 1.0]	0.2 (0.2), 0.1 (0.0, 0.4), [0.0, 0.8]	0.2 (0.2), 0.1 (0.1, 0.3), [0.0, 1.0]
MAL % of Tasks (0-100%, 1 task = 5.9%)*	12.3 (12.8), 5.9 (0.0, 17.6), [0.0, 47.1]	11.6 (13.3), 5.9 (0.0, 17.6), [0.0, 47.1]	13.0 (12.5), 11.8 (5.9, 7.6), [0.0, 47.1]
VAS pain above elbow (0-10)**	0.9 (1.4), 0.0 (0.0, 1.0), [0.0, 7.0]	0.8 (1.3), 0.0 (0.0, 1.0), [0.0, 5.0]	0.9 (1.4), 0.0 (0.0, 1.8), [0.0, 7.0]
VAS pain elbow/ below elbow (0-10)**	0.6 (1.3), 0.0 (0.0, 1.0), [0.0, 8.0]	0.8 (1.6), 0.0 (0.0, 1.0), [0.0, 8.0]	0.5 (0.8), 0.0 (0.0, 1.0), [0.0, 3.0]

Continuous variables are mean (SD), median (IQR), [range]
MAL: Motor Activity Log, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, VAS: Visual Analogue Scale, */higher/lower represents better outcome**

Table 26 shows that at baseline the mean (SD) mRS and BI scores of all recruits were 3.6 (0.7) and 10.9 (4.8) respectively. The mean (SD) SIS Hand, SIS Total and SIS Recovery scores were 2.4 (7.8), 51.7 (10.3) and 42.4 (18.0) respectively. The mean EQ-5D-5L Total and EQ-5D-5L Visual Analogue Scale scores were 15.2 (3.7) and 58.4 (19.3) respectively (Table 26).

Table 26: Baseline characteristics in the intention-to-treat population – other clinical measures

Other clinical measures	Baseline characteristics in the intention-to-treat population		
	All (N_{OBS}/N_{MISS} = 78/0)	**Usual Care** (N_{OBS}/N_{MISS} = 39/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 39/0)
mRS (0-5)**	3.6 (0.7), 4.0 (3.0, 4.0), [2.0, 5.0]	3.7 (0.7), 4.0 (3.5, 4.0), [2.0, 5.0]	3.5 (0.7), 4.0 (3.0, 4.0), [2.0, 5.0]
BI (0-20)*	10.9 (4.8), 10.0 (7.0, 16.0), [3.0, 19.0]	10.6 (4.4), 10.0 (7.0, 14.5), [4.0, 18.0]	11.1 (5.1), 10.0 (7.0, 17.0), [3.0, 19.0]
SIS Hand score (0-100)*	2.4 (7.8), 0.0 (0.0, 0.0), [0.0, 45.0]	1.8 (6.7), 0.0 (0.0, 0.0), [0.0, 40.0]	2.9 (8.9), 0.0 (0.0, 0.0), [0.0, 45.0]
SIS Total score (0-100)*	51.7 (10.3), 50.3 (43.6, 58.7), [27.4, 76.9]	51.9 (9.8), 50.3 (43.2, 58.8), [27.4, 68.2]	51.5 (11.0), 49.7 (44.4, 58.4), [32.7, 76.9]
SIS Recovery (0-100)*	42.4 (18.0), 40.0 (30.0, 53.8), [5.0, 80.0]	41.7 (17.8), 40.0 (30.0, 50.0), [10.0, 80.0]	43.1 (18.3), 50.0 (30.0, 60.0), [5.0, 75.0]
EQ-5D-5L Total (0-25)**	15.2 (3.7), 15.0 (13.0, 18.0), [5.0, 22.0]	15.4 (3.6), 15.0 (13.5, 18.0), [7.0, 22.0]	15.1 (3.9), 15.0 (13.0, 18.0), [5.0, 22.0]
EQ-5D-5L VAS (0-100)*	58.4 (19.3), 60.0 (45.0, 73.8), [10.0, 100.0]	59.2 (18.5), 60.0 (47.5, 77.5), [20.0, 90.0]	57.5 (20.3), 60.0 (45.0, 70.0), [10.0, 100.0]

Continuous variables are mean (SD), median (IQR), [range]
BI: Barthel Index, EQ-5D-5L: EuroQol with 5 Dimensions and 5 Levels, mRS: modified Rankin Scale, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, SIS: Stroke Impact Scale, VAS: Visual Analogue Scale, */higher/lower represents better outcome**

The majority of stroke survivors reported taking part in physical rehabilitation (69; 88.5%) but not receiving an upper limb splint (77; 98.7%), shoulder sling (74; 94.9%) or Transcranial Electrical Nerve Stimulation (TENS) (76; 97.4%) (Table 27). No stroke survivors reported receiving anti-spasticity medication for their upper limb (78; 100.0%) (Table 27). Baseline upper limb physical rehabilitation appeared balanced between groups (Table 27).

Table 27: Baseline upper limb rehabilitation in the intention-to-treat population

Current upper limb rehabilitation	Intervention group		
	All (N_{OBS}/N_{MISS} = 78/0)	**Usual Care** (N_{OBS}/N_{MISS} = 39/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 39/0)
Physical rehabilitation			
No	7 (9.0%)	4 (10.3%)	3 (7.7%)
Yes	69 (88.5%)	35 (89.7%)	34 (87.2%)
Unknown	2 (2.6%)	0 (0.0%)	2 (5.1%)
Splints			
No	77 (98.7%)	38 (97.4%)	39 (100.0%)
Yes	1 (1.3%)	1 (2.6%)	0 (0.0%)
Shoulder sling			
No	74 (94.9%)	37 (94.9%)	37 (94.9%)
Yes	4 (5.1%)	2 (5.1%)	2 (5.1%)
TENS			
No	76 (97.4%)	38 (97.4%)	38 (97.4%)
Yes	2 (2.6%)	1 (2.6%)	1 (2.6%)
Anti-spasticity medication			
No	78 (100.0%)	39 (100.0%)	39 (100.0%)
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)

Categorical variables are no. of stroke survivors in group (N (%))
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set,
TENS: Transcutaneous Electrical Nerve Stimulation,

4.4.4 Interventions

4.4.4.1 Usual care upper limb therapy weekdays delivered by group during the six week intervention period – Therapist-reported

Table 28 summarises the therapist-reported usual care upper limb therapy delivered by therapists on weekdays during the six week intervention period. Data was collected until September 2021 (53rd participating stroke survivor) and then stopped due to the need to reduce recording burden in the clinical team during the Covid-19 pandemic. This data was available for 53 (53/53; 100.0%) and 52 (52/53; 98.1%) of these participants for physiotherapy and occupational therapy respectively (Table 28).

Table 28: Mean number (proportion) of therapy-reported usual care upper limb therapy weekdays (max: 30 days) they delivered by intervention group

Therapy discipline	**Mean number (proportion) of therapist reported usual care upper limb therapy weekdays they delivered over six week intervention period by intervention group (max: 30 days)**		
Physiotherapy	**All** (N_{OBS}/N_{MISS} = 53/0)	**Usual Care** (N_{OBS}/N_{MISS} = 26/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 27/0)
	11.2 (37.3%)	11.7 (39.0%)	10.7 (35.7%)
Occupational therapy	**All** (N_{OBS}/N_{MISS} = 53/1)	**Usual Care** (N_{OBS}/N_{MISS} = 26/1)	**SaeboGlove** (N_{OBS}/N_{MISS} = 27/0)
	8.2 (27.3%)	8.2 (27.3%)	8.3 (27.7%)

Categorical variables are no. of stroke survivors in group (N (%))
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set.
Data in table collected until September 2021 (53rd participating stroke survivor) and then stopped due to the need to reduce recording burden in the clinical team during the Covid-19 pandemic.

Physiotherapists

The mean number (%) of weekdays that *physiotherapists* reported delivering upper limb therapy over the six week intervention period (max 30 days) was 11.7 (39.0%) days in stroke survivors in the Usual Care group (Table 28). The equivalent figure for the SaeboGlove group was 10.7 (35.7%) (Table 28).

Occupational therapists

The mean number (%) of weekdays that *occupational therapists* reported delivering upper limb therapy over the six week intervention period (max 30 days) was 8.2 (27.3%) days in stroke survivors in the Usual Care group (Table 28). The equivalent figure for the SaeboGlove group was 8.3 (27.7%) (Table 28).

Thus, therapist-reported delivery of usual care upper limb therapy on weekdays was slightly higher in physiotherapists than occupational therapists but was balanced by discipline between groups.

4.4.4.2 Stroke survivor-reported upper limb therapy time by group spent with and without a therapist

Table 29 summarises the stroke survivor-reported upper limb therapy time spend with and without a therapist by intervention group. This data was available for 69 (69/78; 88.5%) of the participating stroke survivors for weeks 1-6 (Usual Care = 31 (31/39; 79.5%), SaeboGlove = 38 (38/39; 97.4%)) and 59 (59/78; 75.6%) of the stroke survivors for weeks 7-14 (Usual Care = 27 (27/39; 69.2%), SaeboGlove = 32 (32/39; 82.1%)) (Table 29).

Table 29: Stroke survivor-reported upper limb therapy time spent with and without a therapist by intervention group

Timeline	Stroke survivor-reported upper limb therapy time by intervention group (minutes)		
	All (N_{OBS}/N_{MISS}: 6 weeks = 78/9, 14 weeks = 78/19)	**Usual Care** (N_{OBS}/N_{MISS}: 6 weeks = 39/8, 14 weeks = 39/12)	**SaeboGlove** (N_{OBS}/N_{MISS}: 6 weeks = 39/1, 14 weeks = 39/7)
With a therapist			
Weeks 1-6	284 (243), 230 (110, 390), [0, 1200]	309 (264), 236 (132, 456), [0, 1200]	264 (227), 200 (105, 358), [0, 950]
Weeks 7-14	160 (178), 90 (19, 240), [0, 690]	146 (186), 70 (0, 192), [0, 600]	171 (174), 120 (40, 240), [0, 690]
Weeks 1-14	441 (335), 360 (186, 594), [0, 1490]	442 (364), 332 (172, 741), [0, 1370]	440 (316), 397 (205, 560), [25, 1490]
Without a therapist			
Weeks 1-6	1461 (1163), 1200 (633, 1895), [38, 4950]	1149 (1327), 700 (332, 1128), [38, 4950]	1716 (953), 1456 (1147, 2152), [180, 4695]
Weeks 7-14	1465 (1538), 960 (328, 1860), [0, 6785]	1513 (1734), 875 (272, 1610), [0, 6785]	1426 (1383), 1010 (360, 1860), [0, 5345]
Weeks 1-14	2966 (2356), 2150 (1378, 4030), [153, 10730]	2736 (2949), 1515 (1178, 2524), [153, 10730]	3147 (1786), 2985 (1828, 4170), [250, 7500]

Continuous variables are mean (SD), median (IQR), [range]
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set

Weeks 1-6

During the six week intervention period Usual Care group stroke survivors

reported spending slightly *more* upper limb therapy contact time with a therapist (Table 29 - Usual Care group: mean 45 (309-264; 45) minutes and median 36 (236-200; 36) minutes more) but *less* upper limb therapy time in a self-directed format than SaeboGlove group participants (Table 29 - Usual Care group: *mean* 567 (1716-1149; 567) minutes and *median* 750 (1450-700; 750) minutes less i.e. *mean* 9.5 (567/60; 9.5) and *median* 12.5 (750/60; 12.5) hours less). Overall SaeboGlove group participants reported engaged in a *mean* and *median* total of 8.7 hours and 12.0 hours more upper limb therapy respectively (Table 29 – *mean* 522 ((264+1716; 1980) – (309+1149; 1458)); 522 minutes i.e. 8.7 (522 minutes/60 minutes; 8.7 hours) and a *median* of 720 ((236+700; 936) – (200+1456; 1656)); 720 minutes i.e. 12.0 (720 minutes/60 minutes; 12.0 hours)).

Weeks 7-14

During the 7-14 week follow up period Usual Care group stroke survivors reported receiving slightly *less* upper limb therapy contact time with a therapist than SaeboGlove group participants (Usual Care group: mean 25 (171-146) and median 50 (120-70) minutes less). Usual Care group stroke survivors also reported spending slightly *more* mean upper limb therapy time (Usual Care group: mean 87 (1513-1426) i.e. 1.5 hours more) but less median upper limb therapy time in a self-directed format than the SaeboGlove group (median 135 (1010-875) minutes i.e. median 2.3 hours less). Overall SaeboGlove group participants reported engaged in a *mean* and *median* total of 1.0 hours and 3.1 hours more upper limb therapy respectively (Table 29 – *mean* 62 ((1513+146; 1659) – (1426+171; 1597)); 62) minutes i.e. 1.0 (62 minutes/60 minutes; 1.0 hours) and a *median* of 185 ((70+875; 945) – (120+1010; 1130)); 185) minutes i.e. 3.1 (185 minutes/60 minutes; 3.1 hours)).

Weeks 1-14

Over the entire 14 week intervention and follow-up period stroke survivor-reported upper limb therapy contact time with a therapist appeared balanced between groups (mean 2 (442-440) minutes more and median 65 (397-332) minutes less in the Usual Care group). However, the SaeboGlove group stroke survivor-reported spending much more upper limb therapy time in a stroke survivor-directed format (mean 411 (3147-2736) and median 1470 (2985-1515) minutes i.e. mean 6.9 and median 24.5 hours more). Overall SaeboGlove group

participants reported engaged in a *mean* and *median* total of 6.8 hours and 18.9 hours more upper limb therapy respectively (Table 29 – *mean* 409 ((442+2736; 3178) – (440+3147; 3587)); 409) minutes i.e. 1.0 (409 minutes/60 minutes; 6.8 hours) and a *median* of 1135 ((332+1515; 1847) – (397+2985; 2982)); 1135) minutes i.e. 18.9 (1135 minutes/60 minutes; 18.9 hours)).

4.4.4.3 Receipt of additional four therapy reviews by group

Table 30 summarises the number (proportion) of therapy reviews attended by intervention group. This data was available for all 78 participating stroke survivors (100.0%).

Table 30: Number (proportion) of therapy reviews attended by intervention group

Reviews attended	Reviews attended by intervention group		
	All (N_{OBS}/N_{MISS} = 78/0)	**Usual Care** (N_{OBS}/N_{MISS} = 39/0)	**SaeboGlove** (N_{OBS}/N_{MISS} = 39/0)
1	77 (98.7%)	38 (97.4%)	39 (100.0%)
2	74 (94.9%)	35 (89.7%)	39 (100.0%)
3	71 (91.0%)	33 (84.6%)	38 (97.4%)
4	68 (87.2%)	30 (76.9%)	38 (97.4%)
All	68 (87.2%)	30 (76.9%)	38 (97.4%)

Categorical variables are no. of stroke survivors in group (N (%))
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set.

The number (%) of stroke survivors receiving all four therapy reviews in the Usual Care and SaeboGlove groups were 30 (30/39; 76.9%) and 38 (38/39; 97.4%) respectively (Table 30). Missed reviews in the Usual Care group involved nine stroke survivors (9/39; 23.1%) and 20 reviews (20/156; 12.8%) (Table 30). The reasons for missed reviews were that stroke survivors withdrew due to group allocation disappointment (3/9; 33.3%), a gap occurred in stroke survivors usual NHS care delivery after discharge home i.e. community therapy input had yet to start (3/9; 33.3%), NHS therapists forgot when staffing short over holidays (2/9; 22.2%) and one stroke survivor developed a chest infection and was too unwell (1/9; 11.1%).

The number (%) of stroke survivors receiving all four therapy reviews in the SaeboGlove group was 38 (38/39; 97.4%) (Reviews 1, 2, 3 and 4: 39 (39/39;

100.0%), 39 (39/39; 100.0%), 38 (38/39; 97.4%), 38 (38/39; 97.4%) respectively) (Table 30). Missed reviews in the SaeboGlove group involved one stroke survivors (1/39; 2.6%) and two reviews (2/156; 1.3%) (Table 30). The reason for the missed reviews was that this stroke survivor withdrew due to mental health issues that occurred on discharge (1/1; 100.0%).

Thus, around 20% fewer stroke survivors in the Usual Care group received all four reviews than the SaeboGlove group. Furthermore, this difference primarily occurred due to group allocation disappointment (inevitable unblinding of participating stroke survivors) and challenges conducting trial activities as per protocol within a clinical service in the Usual Care group stroke survivors (e.g. service gaps and staff shortages).

4.4.5 Outcomes

4.4.5.1 Continuity of outcome assessors

The number (%) of stroke survivors with same assessor as baseline visit is shown in Table 31. The number (%) of stroke survivors who had the same assessor at their baseline and 6 week assessment was 66 (66/72; 91.7%). The equivalent number (%) for the 14 week assessment was 62 (62/69; 89.9%). The number (%) of stroke survivors who had the same assessor at their baseline, 6 week and 14 week assessments was 61 (61/69; 88.4%).

Table 31: Number (proportion) of stroke survivors with the same assessor as baseline visit

No. (%) of attending stroke survivors with the same assessor as baseline		
6 weeks (N=72)	**14 weeks** (N=69)	**6 + 14 weeks** (N=69)
66 (91.7%)	62 (89.9%)	61 (88.4%)

Categorical variables are no. of stroke survivors in group (N (%))

4.4.5.2 Blinding success in outcome assessors

Outcome assessors reported being unblinded for 2 (2/71; 2.8%) and 5 (5/68; 7.4%) of the outcome visits at 6 and 14 weeks respectively. Thus, masking of group allocation at the 6 and 14 week visits was maintained in 69 (69/71; 97.2%) and 63 (63/68; 92.6%) of the visits respectively.

4.4.5.3 Outcome analysis

Table 32 overleaf shows the linear regression analysis predicting scores for upper limb clinical measures 6 and 14 weeks after randomisation adjusting for baseline ARAT, study site and time since stroke (≤1 month, >1 month).

Table 32: Outcome analysis in the intention-to-treat population – Change in primary and secondary upper limb clinical measures at the 6 and 14 week assessments

Outcomes (min-max)	**Change in Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/5, 14 weeks = 39/8)	**Change in SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/6)	**Adjusted mean between group difference**	**95% Confidence interval**	**p-value**
Primary outcomes					
ARAT Total (0-57)* week 6, mean (SD)	15.8 (14.8)	23.8 (15.6)	7.11	0.22, 14.00****	0.047
ARAT Grasp (0-18)* week 6, mean (SD)	5.1 (4.6)	7.4 (5.4)	2.23	0.04, 4.42***	0.050
ARAT Grip (0-12)* week 6, mean (SD)	3.4 (3.2)	5.2 (3.7)	1.68	0.25, 3.10***	0.024
ARAT Pinch (0-18)* week 6, mean (SD)	6.0 (6.8)	9.6 (6.7)	2.89	0.23, 5.56***	0.037
ARAT Gross (0-9)* week 6, mean (SD)	1.2 (2.0)	1.6 (1.8)	0.62	-0.10, 1.34***	0.097
Secondary outcomes					
ARAT Total (0-57)* week 14, mean (SD)	20.1 (15.0)	25.2 (17.2)	4.61	-3.01, 12.23****	0.241
ARAT Grasp (0-18)* week 14, mean (SD)	6.2 (5.4)	7.6 (6.3)	1.37	-1.38, 4.11***	0.333
ARAT Grip (0-12)* week 14, mean (SD)	4.7 (3.4)	5.5 (3.9)	0.93	-0.78, 2.65***	0.292
ARAT Pinch (0-18)* week 14, mean (SD)	7.8 (6.6)	10.5 (7.2)	2.27	-0.89, 5.43***	0.165
ARAT Gross (0-9)* week 14, mean (SD)	1.5 (2.2)	1.5 (1.9)	0.21	-0.58, 0.99***	0.612
FMUE Motor Total (0-66)* week 6, mean (SD)	9.4 (11.0)	14.5 (10.4)	5.01	0.86, 9.16*****	0.021
FMUE Motor Total (0-66)* week 14, mean (SD)	11.9 (9.8)	15.3 (13.1)	3.76	-1.67, 9.20*****	0.181
FMUE Motor Hand (0-14)* week 6, mean (SD)	3.8 (3.7)	5.6 (3.6)	1.73	0.29, 3.17***	0.022
FMUE Motor Hand (0-14)* week 14, mean (SD)	4.8 (3.4)	5.8 (4.4)	1.05	-0.81, 2.91***	0.275
FMUE Sensory Total (0-12)* week 6, mean (SD)	0.1 (1.7)	0.6 (1.7)	0.42	-0.16, 1.00***	0.162
FMUE Sensory Total (0-12)* week 14, mean (SD)	0.4 (1.0)	0.5 (1.5)	0.19	-0.11, 0.49***	0.228

ARAT: Action Research Arm Test, FMUE: Fugl Meyer Upper Extremity score, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found, ****MCID: chronic phase ≥5.7 points (Van der Lee *et al.* 2001), acute phase ≥12 points (dominant) and ≥17 points (non-dominant) (Lang *et al.* 2008), *****MCID: acute/ subacute phase 4 points (Lundquist and Maribo 2017) and chronic phase 5.25 (Page *et al.* 2012)

Outcomes (min-max)	**Change in Usual Care group** N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6	**Change in SaeboGlove group** N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3	**Adjusted mean between group difference**	**95% Confidence interval**	**p-value**
Secondary outcomes					
MAL Quality (0-5)* week 6, mean (SD)	0.8 (0.8)	1.1 (1.0)	0.26	-0.08, 0.61****	0.143
MAL Quality (0-5)* week 14, mean (SD)	1.0 (1.0)	1.5 (1.3)	0.45	-0.04, 0.93****	0.075
MAL Quantity (0-5)* week 6, mean (SD)	0.9 (0.9)	1.2 (1.1)	0.19	-0.20, 0.57***	0.350
MAL Quantity (0-5)* week 14, mean (SD)	1.2 (1.2)	1.7 (1.4)	0.40	-0.12, 0.92***	0.133
MAL % of tasks (0-100%, 1 task = 5.9%) week 6, mean (SD)	24.2 (21.5)	31.6 (22.9)	6.71	-2.29, 15.70***	0.149
MAL % of tasks (0-100%, 1 task = 5.9%)* week 14, mean (SD)	28.2 (25.2)	39.4 (27.2)	9.90	-1.67, 21.48***	0.099
VAS upper arm pain (0-10)** week 6, mean (SD)	0.9 (1.6)	0.5 (1.5)	-0.39	-1.09, 0.32***	0.287
VAS upper arm pain (0-10)** week 14, mean (SD)	1.0 (2.4)	0.8 (2.1)	0.03	-0.84, 0.91***	0.942
VAS lower arm pain (0-10)** week 6, mean (SD)	0.6 (2.1)	0.4 (1.6)	-0.43	-1.23, 0.37***	0.299
VAS lower arm pain (0-10)** week 14, mean (SD)	0.2 (2.5)	0.7 (1.9)	0.02	-0.89, 0.92***	0.969

MAL: Motor Activity Log, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, VAS: Visual Analogue Scale, */higher/lower represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found, ****MCID: 1-1.1 (Simpson and Eng 2012)**

Primary outcome analysis

All mean ARAT scores improved in both groups between the baseline and 6 week visit (i.e. immediately post intervention period) (Table 32 above).

The change in the ARAT Total score and ARAT Grasp, Grip and Pinch subscores at the 6 week visit from baseline were all statistically significantly improved in the SaeboGlove versus Usual Care group (adjusted mean difference (95% CI) *Total*: 7.11 (0.22, 14.00), p-value 0.047, *Grasp*: 2.23 (0.04, 4.42), p-value 0.050, *Grip*: 1.68 (0.25, 3.10), p-value 0.024, *Pinch*: 2.89 (0.23, 5.56), p-value 0.037. Additionally, the mean improvement observed in upper limb function (ARAT Total) was over 1.5 times higher in the SaeboGlove group (23.8 points, SD 15.6) compared to the Usual Care group (15.8 points, SD 14.8).

The change in the ARAT Gross subscore, which requires no dextrous ability, was not significantly different between groups (adjusted mean difference (95% CI) 0.62 (-0.10, 1.34), p-value 0.097) (Table 32 above).

Secondary outcome analysis – upper limb clinical measures

Mean upper limb pain scores increased very slightly and similarly at the 6 week and 14 week visits in both groups in comparison to the baseline visit (Table 32 above).

Mean scores for all other secondary upper limb measures improved in both groups between baseline and the 6 week visit and between the 6 and 14 week visits except for the ARAT Gross subscore in the SaeboGlove group which largely remained unchanged from 6 to 14 weeks (Table 32 above, dropped by a mean of 0.1 points).

ARAT

Table 32 above shows the linear regression analysis predicting ARAT scores at 14 weeks from randomisation adjusting for baseline ARAT, study site and time since stroke (≤1 month, >1 month).

At the 14 week visit the change in the ARAT Total score and ARAT Grasp, Grip and Pinch subscores from baseline were no longer significantly different between the two intervention groups (adjusted mean difference (95% CI) *Total*:

4.61 (-3.01, 12.23), p-value 0.241, *Grasp:* 1.37 (-1.38, 4.11), p-value 0.333, *Grip*: 0.93 (-0.78, 2.65), p-value 0.292, *Pinch*: 2.27 (-0.89, 5.43), p-value 0.165 (Table 32 above).

The ARAT Gross subscore remained non-significant (adjusted mean difference (95% CI), *Gross*: 0.21 (-0.58, 0.99), p-value 0.612) (Table 32 above).

FMUE

The change in the FMUE Motor Total and hand scores at the 6 week visit from baseline were both statistically significantly improved in the SaeboGlove versus Usual Care group (adjusted mean difference (95% CI) *Total*: 5.01 (0.86, 9.16), p-value 0.021, *Hand*: 1.73 (0.29, 3.17), p-value 0.022) (Table 32 above).

However, at 14 weeks the change in the FMUE Motor Total and Hand scores from baseline were no longer significantly different between the two intervention groups (adjusted mean difference (95% CI) *Total*: 3.76 (-1.67, 9.20), p-value 0.181, *Hand*: 1.73 (0.29, 3.17), p-value 0.022) (Table 32 above).

The change in the FMUE Sensory subscore was not significantly different between groups at the 6 or 14 week visits (adjusted mean difference (95% CI) *6 week*: 0.42 (-0.16, 1.00), p-value 0.162, *14 weeks*: 0.19 (-0.11, 0.49), p-value 0.228) (Table 32 above).

MAL and VAS pain scores

There were no significant differences between groups at the 6 or 14 week visits for the other upper limb measures i.e. the MAL, or VAS pain scores (Table 32 above).

Secondary outcome analysis – other (non-upper limb) clinical measures

Table 33 overleaf shows the linear regression analysis predicting scores for other (non-upper limb) clinical measures at the 6 and 14 week visits from randomisation adjusting for baseline ARAT, study site and time since stroke (≤1 month, >1 month). Mean scores for all these measures improved in both groups between baseline and the 6 week visit, and between the 6 and 14 week visits with the exception of the EQ-5D-5L Total between 6 and 14 weeks in the Usual Care group (Table 33, mean of 0.7 points worse) (Table 33). However, none of

these measures were significantly different between groups at the 6 or 14 week visits (Table 33 overleaf).

Table 33: Outcome analysis in the intention-to-treat population – Change in other (non-upper limb) secondary clinical measures at the 6 and 14 week assessments

Outcomes (min-max)	**Change in Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**Change in SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean between group difference**	**95% Confidence interval**	**p-value**
Secondary outcomes					
mRS (0-5)** week 6, mean (SD)	-0.5 (0.9)	-0.5 (0.7)	-0.07	-0.39, 0.24***	0.647
mRS (0-5)** week 14, mean (SD)	-0.7 (0.9)	-0.8 (0.8)	-0.09	-0.44, 0.26***	0.611
BI (0-20)* week 6, mean (SD)	3.6 (3.6)	3.5 (3.7)	0.05	-1.54, 1.64****	0.950
BI (0-20)* week 14, mean (SD)	4.9 (4.1)	4.4 (4.6)	-0.52	-2.48, 1.44****	0.604
SIS Total (0-100)* week 6, mean (SD)	8.0 (13.1)	12.1 (11.8)	2.95	-2.41, 8.31***	0.284
SIS Total (0-100)* week 14, mean (SD)	11.4 (13.2)	15.5 (14.2)	2.43	-3.94, 8.81***	0.457
SIS Hand (0-100)* week 6, mean (SD)	21.7 (26.7)	29.5 (30.8)	6.41	-3.22, 16.03*****	0.197
SIS Hand (0-100)* week 14, mean (SD)	29.7 (32.0)	40.6 (35.1)	8.92	-3.83, 21.68*****	0.176
EQ-5D-5L Total (0-25)** week 6, mean (SD)	-2.3 (2.5)	-2.3 (3.1)	0.14	-0.97, 1.26******	0.802
EQ-5D-5L Total (0-25)** week 14, mean (SD)	-1.6 (3.6)	-2.4 (3.5)	-0.52	-2.15, 1.10******	0.531
EQ-5D-5L VAS (0-100)* week 6, mean (SD)	4.6 (25.1)[1]	3.6 (19.8)	-1.73	-9.71, 6.24***	0.671
EQ-5D-5L VAS (0-100)* week 14, mean (SD)	5.3 (26.5)	5.6 (19.8)	-0.63	-9.44, 8.19***	0.890

BI: Barthel Index, EQ-5D-5L: EuroQol Five Dimensions and Five Levels, mRS: modified Rankin Scale, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, SIS: Stroke Impact Scale, VAS: Visual Analogue Scale, */higher/lower represents better outcome, [1]: N_{OBS}/N_{MISS} is 39/5 as VAS was missed in one usual care participant who was too unwell to score it, ***Minimal Clinically Important Difference (MCID): Not found, ****MCID: 1·85 points in the early subacute recovery phase (Hsieh *et al.* 2007), *****MCID: ≥8.44 points from acute to subacute (Kao and Pai 2023), ******MCID: 0.18 (range 0.03-0.54) (Coretti *et al.* 2014)**

For completeness data on the change in outcomes in the above two tables (Table 32 and 33) are reproduced below in Tables 34 and 35 along with their corresponding median, interquartile range (IQR) and range values for change. The corresponding mean (SD), median, interquartile range (IQR) and range values for baseline, 6 and 14 week outcome visits are also summarised.

The ARAT Total scores in Table 34 highlight that on average upper limb functional capacity was 'poor' at baseline but improved being in the mid and upper range of 'limited' in the usual care and SaeboGlove groups respectively at both the 6 and 14 week visits (Table 34 overleaf) (ARAT Total/functional capacity – none: 0-10, poor: 11-21, limited: 22-42, notable: 43-53 and full: 54-57 (Hoonhorst *et al*. 2015)).

Table 34 also highlights that the mean (SD) % of MAL ADL tasks that stroke survivors reported using their affected upper limb in in the Usual Care and SaeboGlove group at the baseline visit was 2.0 tasks (11.6 (13.3)% i.e. 11.6%/5.9%; 2.0 tasks) and 2.2 tasks (13.0 (12.5)% i.e. 13.0%/5.9%; 2.2 tasks) respectively out of 17 ADL tasks. The equivalent figures at the 6 week visit were 6.1 tasks (36.1 (28.7)% i.e. 36.1%/5.9%; 6.1 tasks) and 7.5 tasks (44.5 (27.7)% i.e. 44.5%/5.9%; 7.5 tasks) respectively out of 17 ADL tasks. The equivalent figures at the 14 week visit were 6.8 tasks (39.9 (31.0)% i.e. 39.9%/5.9%; 6.8 tasks) and 8.9 tasks (52.6 (31.7)% i.e. 52.6%/5.9%; 8.9 tasks) respectively out of 17 ADL tasks.

Thus, even after the six week intervention had stopped habitual upper limb use in ADL continued to improve in both groups from the 6 to 14 week visits, albeit with a recovery rate in the SaeboGlove group of more than twice that reported in the Usual Care group (1.4 tasks (52.6 – 44.5%; 8.1%, 8.1%/5.9%; 1.4 tasks) versus 0.6 tasks (39.9-36.1; 3.8%, 3.8%/5.9%; 0.6 tasks) between the 6 and 14 week visits (Table 34).

Table 34: Outcome analysis in the intention-to-treat population – Change in primary and secondary upper limb clinical measures at the 6 and 14 week assessments

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS} = 78/7)	**Usual Care group** (N_{OBS}/N_{MISS} = 39/5)	**SaeboGlove group** (N_{OBS}/N_{MISS} = 39/2)	**Adjusted mean difference (95% CI)**	**p-value**
Primary outcomes					
ARAT Total (0-57)*					
Baseline	13.3 (11.8), 9.0 (3.2, 20.8), [0.0, 42.0]	12.8 (12.2), 7.0 (3.0, 20.5), [0.0, 42.0]	13.7 (11.6), 9.0 (4.5, 21.0), [0.0, 40.0]		
6 weeks	33.9 (21.3), 40.0 (12.0, 54.5), [0.0, 57.0]	29.5 (22.7), 27.0 (7.8, 54.8), [0.0, 57.0]	37.9 (19.3), 46.0 (16.0, 54.0), [3.0, 57.0]		
Change from baseline	19.9 (15.6), 17.0 (6.0, 33.5), [-3.0, 52.0]	15.8 (14.8), 13.5 (2.2, 27.2), [-3.0, 44.0]	23.8 (15.6), 24.0 (10.0, 36.0), [1.0, 52.0]	7.11 (0.22, 14.00)***	0.047

Continuous variables are mean (SD), median (IQR), [range],
ARAT: Action Research Arm Test, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): ≥5.7 points in the chronic recovery phase (Van der Lee *et al.* 2001) and ≥12 and ≥17 points in the acute recovery phase in the dominant and non-dominant affected upper limb (Lang *et al.* 2008) respectively

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS} = 78/7)	**Usual Care group** (N_{OBS}/N_{MISS} = 39/5)	**SaeboGlove group** (N_{OBS}/N_{MISS} = 39/2)	**Adjusted mean difference (95% CI)**	**p-value**
Primary outcomes					
ARAT Grasp (0-18)*					
Baseline	4.8 (5.4), 2.0 (0.0, 9.0), [0.0, 18.0]	4.8 (5.6), 2.0 (0.0, 9.0), [0.0, 17.0]	4.9 (5.3), 3.0 (0.5, 8.5), [0.0, 18.0]		
6 weeks	11.4 (7.1), 15.0 (4.0, 18.0), [0.0, 18.0]	10.2 (7.7), 13.0 (2.0, 18.0), [0.0, 18.0]	12.5 (6.4), 15.0 (6.0, 18.0), [0.0, 18.0]		
Change from baseline	6.3 (5.1), 5.0 (2.0, 10.0), [0.0, 17.0]	5.1 (4.6), 4.0 (1.0, 9.0), [0.0, 14.0]	7.4 (5.4), 6.0 (3.0, 12.0), [0.0, 17.0]	2.23 (0.04, 4.42)***	0.050
ARAT Grip (0-12)*					
Baseline	2.7 (2.7), 2.0 (0.0, 4.0), [0.0, 10.0]	2.5 (2.7), 2.0 (0.0, 4.0), [0.0, 9.0]	2.9 (2.8), 3.0 (0.0, 4.5), [0.0, 10.0]		
6 weeks	7.2 (4.7), 9.0 (3.0, 12.0), [0.0, 12.0]	6.1 (4.8), 5.5 (1.2, 11.0), [0.0, 12.0]	8.2 (4.4), 11.0 (4.0, 12.0), [0.0, 12.0]		
Change from baseline	4.3 (3.6), 4.0 (1.0, 7.0), [-2.0, 12.0]	3.4 (3.2), 3.0 (0.2, 5.0), [-1.0, 10.0]	5.2 (3.7), 5.0 (2.0, 8.0), [-2.0, 12.0]	1.68 (0.25, 3.10)***	0.024

Continuous variables are mean (SD), median (IQR), [range]
ARAT: Action Research Arm Test, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS} = 78/7)	**Usual Care group** (N_{OBS}/N_{MISS} = 39/5)	**SaeboGlove group** (N_{OBS}/N_{MISS} = 39/2)	**Adjusted mean difference (95% CI)**	**p-value**
Primary outcomes					
ARAT Pinch (0-18)*					
Baseline	1.2 (2.1), 0.0 (0.0, 2.0), [0.0, 9.0]	1.2 (2.4), 0.0 (0.0, 0.5), [0.0, 9.0]	1.1 (1.7), 0.0 (0.0, 2.0), [0.0, 6.0]		
6 weeks	9.2 (7.7), 10.0 (0.5, 17.5), [0.0, 18.0]	7.5 (8.0), 3.5 (0.0, 16.0), [0.0, 18.0]	10.7 (7.1), 13.0 (4.0, 18.0), [0.0, 18.0]		
Change from baseline	7.9 (6.9), 7.0 (0.0, 14.5), [-1.0, 18.0]	6.0 (6.8), 1.5 (0.0, 13.0), [-1.0, 18.0]	9.6 (6.7), 12.0 (3.0, 16.0), [0.0, 18.0]	2.89 (0.23, 5.56)***	0.037
ARAT Gross (0-9)*					
Baseline	4.5 (2.6), 4.0 (3.0, 6.0), [0.0, 9.0]	4.3 (2.6), 3.0 (3.0, 6.0), [0.0, 9.0]	4.8 (2.7), 4.0 (3.0, 6.5), [0.0, 9.0]		
6 weeks	6.1 (2.9), 6.0 (3.0, 9.0), [0.0, 9.0]	5.6 (3.2), 5.5 (3.0, 9.0), [0.0, 9.0]	6.5 (2.5), 7.0 (4.0, 9.0), [0.0, 9.0]		
Change from baseline	1.4 (1.9), 1.0 (0.0, 3.0), [-3.0, 6.0]	1.2 (2.0), 0.0 (0.0, 2.8), [-3.0, 6.0]	1.6 (1.8), 1.0 (0.0, 3.0), [0.0, 6.0]	0.62 (-0.10, 1.34)***	0.097

Continuous variables are mean (SD), median (IQR), [range]
ARAT: Action Research Arm Test, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS} = 78/14)	**Usual Care group** (N_{OBS}/N_{MISS} = 39/8)	**SaeboGlove group** (N_{OBS}/N_{MISS} = 39/6)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
ARAT Total (0-57)*					
Baseline	13.3 (11.8), 9.0 (3.2, 20.8), [0.0, 42.0]	12.8 (12.2), 7.0 (3.0, 20.5), [0.0, 42.0]	13.7 (11.6), 9.0 (4.5, 21.0), [0.0, 40.0]		
14 weeks	37.3 (20.2), 43.5 (20.0, 57.0), [0.0, 57.0]	34.6 (20.4), 38.0 (17.5, 56.5), [0.0, 57.0]	39.8 (19.9), 50.0 (22.0, 57.0), [0.0, 57.0]		
Change from baseline	22.8 (16.3), 19.5 (10.0, 36.0), [-3.0, 54.0]	20.1 (15.0), 18.0 (10.0, 32.0), [-1.0, 54.0]	25.2 (17.2), 28.0 (10.0, 44.0), [-3.0, 53.0]	4.61 (-3.01, 12.23)***	0.241

Continuous variables are mean (SD), median (IQR), [range]
ARAT: Action Research Arm Test, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, continuous variables are mean (SD), median (IQR), [range], ***Minimal Clinically Important Difference (MCID): ≥5.7 points in the chronic recovery phase (Van der Lee *et al.* 2001) and ≥12 and ≥17 points in the acute recovery phase in the dominant and non-dominant affected upper limb (Lang *et al.* 2008) respectively

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS} = 78/14)	**Usual Care group** (N_{OBS}/N_{MISS} = 39/8)	**SaeboGlove group** (N_{OBS}/N_{MISS} = 39/6)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
ARAT Grasp (0-18)*					
Baseline	4.8 (5.4), 2.0 (0.0, 9.0), [0.0, 18.0]	4.8 (5.6), 2.0 (0.0, 9.0), [0.0, 17.0]	4.9 (5.3), 3.0 (0.5, 8.5), [0.0, 18.0]		
14 weeks	12.3 (6.8), 16.0 (5.0, 18.0), [0.0, 18.0]	11.6 (6.9), 15.0 (5.0, 18.0), [0.0, 18.0]	12.9 (6.8), 17.0 (6.0, 18.0), [0.0, 18.0]		
Change from baseline	6.9 (5.9), 6.5 (1.8, 11.0), [-2.0, 18.0]	6.2 (5.4), 6.0 (1.0, 9.5), [-1.0, 18.0]	7.6 (6.3), 8.0 (2.0, 14.0), [-2.0, 17.0]	1.37 (-1.38, 4.11)***	0.333
ARAT Grip (0-12)*					
Baseline	2.7 (2.7), 2.0 (0.0, 4.0), [0.0, 10.0]	2.5 (2.7), 2.0 (0.0, 4.0), [0.0, 9.0]	2.9 (2.8), 3.0 (0.0, 4.5), [0.0, 10.0]		
14 weeks	8.2 (4.4), 11.0 (4.8, 12.0), [0.0, 12.0]	7.5 (4.5), 9.0 (4.0, 12.0), [0.0, 12.0]	8.7 (4.4), 11.0 (6.0, 12.0), [0.0, 12.0]		
Change from baseline	5.1 (3.7) 5.0 (3.0, 8.0) [-2.0, 12.0]	4.7 (3.4) 4.0 (3.0, 7.0) [-2.0, 12.0]	5.5 (3.9) 5.0 (3.0, 8.0) [-1.0, 12.0]	0.93 (-0.78, 2.65)***	0.292

Continuous variables are mean (SD), median (IQR), [range]
ARAT: Action Research Arm Test, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS} = 78/14)	**Usual Care group** (N_{OBS}/N_{MISS} = 39/8)	**SaeboGlove group** (N_{OBS}/N_{MISS} = 39/6)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
ARAT Pinch (0-18)*					
Baseline	1.2 (2.1), 0.0 (0.0, 2.0), [0.0, 9.0]	1.2 (2.4), 0.0 (0.0, 0.5), [0.0, 9.0]	1.1 (1.7), 0.0 (0.0, 2.0), [0.0, 6.0]		
14 weeks	10.6 (7.5), 12.5 (3.8, 18.0), [0.0, 18.0]	9.4 (7.5), 9.0 (2.0, 18.0), [0.0, 18.0]	11.7 (7.4), 16.0 (4.0, 18.0), [0.0, 18.0]		
Change from baseline	9.2 (7.0), 10.0 (2.0, 16.0), [0.0, 18.0]	7.8 (6.6), 6.0 (1.5, 14.5), [0.0, 18.0]	10.5 (7.2), 14.0 (2.0, 17.0), [0.0, 18.0]	2.27 (-0.89, 5.43)***	0.165
ARAT Gross (0-9)*					
Baseline	4.5 (2.6), 4.0 (3.0, 6.0), [0.0, 9.0]	4.3 (2.6), 3.0 (3.0, 6.0), [0.0, 9.0]	4.8 (2.7), 4.0 (3.0, 6.5), [0.0, 9.0]		
14 weeks	6.3 (2.6), 6.0 (4.8, 9.0), [0.0, 9.0]	6.0 (2.7), 6.0 (3.0, 9.0), [0.0, 9.0]	6.5 (2.5), 7.0 (5.0, 9.0), [0.0, 9.0]		
Change from baseline	1.5 (2.0), 1.0 (0.0, 3.0), [-3.0, 7.0]	1.5 (2.2), 1.0 (0.0, 2.5), [-3.0, 6.0]	1.5 (1.9), 1.0 (0.0, 3.0), [-2.0, 7.0]	0.21 (-0.58, 0.99)***	0.612

Continuous variables are mean (SD), median (IQR), [range]
ARAT: Action Research Arm Test, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/7, 14 weeks = 78/14)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/5, 14 weeks = 39/8)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/6)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
FMUE Motor Total (0-66)*					
Baseline	23.0 (10.3), 21.0 (16.2, 26.0), [6.0, 55.0]	21.8 (10.4), 21.0 (15.0, 26.0), [6.0, 51.0]	24.1 (10.1), 22.0 (19.0, 27.0), [7.0, 55.0]		
6 weeks	35.5 (16.2), 31.0 (25.0, 49.0), [2.0, 64.0]	31.7 (16.3), 27.5 (19.2, 46.5), [2.0, 62.0]	38.9 (15.4), 36.0 (26.0, 51.0), [11.0, 64.0]		
14 weeks	37.7 (16.3), 35.0 (25.8, 51.0), [7.0, 66.0]	34.9 (14.7), 30.0 (24.0, 46.0), [8.0, 62.0]	40.4 (17.5), 40.0 (26.0, 55.0), [7.0, 66.0]		
Change at 6 weeks	12.0 (10.9), 10.0 (5.5, 20.0), [-19.0, 37.0]	9.4 (11.0), 8.5 (3.0, 14.2), [-19.0, 36.0]	14.5 (10.4), 11.0 (6.0, 23.0), [0.0, 37.0]	5.01 (0.86, 9.16)***	0.021
Change at 14 weeks	13.7 (11.7), 11.5 (6.0, 21.2), [-15.0, 39.0]	11.9 (9.8), 11.0 (5.5, 17.5), [-4.0, 33.0]	15.3 (13.1), 14.0 (6.0, 26.0), [-15.0, 39.0]	3.76 (-1.67, 9.20)***	0.181

Continuous variables are mean (SD), median (IQR), [range]
FMUE: Fugl Meyer Upper Extremity score, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): 4 and 5.25 points in the acute/subacute (Lundquist and Maribo 2017) and chronic (Page *et al.* 2012) recovery phase respectively

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/7, 14 weeks = 78/14)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/5, 14 weeks = 39/8)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/6)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
FMUE Hand (0-14)*					
Baseline	2.8 (1.4), 2.0 (2.0, 3.0), [1.0, 7.0]	2.7 (1.5), 2.0 (2.0, 3.0), [1.0, 7.0]	2.8 (1.4), 2.0 (2.0, 4.0), [1.0, 7.0]		
6 weeks	7.6 (4.5), 9.0 (3.0, 11.5), [0.0, 14.0]	6.5 (4.7), 5.5 (2.0, 11.0), [0.0, 14.0]	8.5 (4.1), 10.0 (5.0, 12.0), [1.0, 14.0]		
14 weeks	8.2 (4.5), 8.5 (4.0, 12.0), [1.0, 14.0]	7.5 (4.3), 7.0 (4.5, 10.5), [1.0, 14.0]	8.7 (4.7), 10.0 (4.0, 14.0), [1.0, 14.0]		
Change at 6 weeks	4.8 (3.7), 5.0 (1.0, 8.0), [-2.0, 12.0]	3.8 (3.7), 3.5 (0.2, 7.0), [-2.0, 11.0]	5.6 (3.6), 7.0 (2.0, 8.0), [0.0, 12.0]	1.73 (0.29, 3.17)***	0.022
Change at 14 weeks	5.3 (4.0), 5.0 (1.8, 9.0), [-2.0, 12.0]	4.8 (3.4), 4.0 (2.5, 7.0), [0.0, 12.0]	5.8 (4.4), 6.0 (1.0, 10.0), [-2.0, 12.0]	1.05 (-0.81, 2.91)***	0.275

Continuous variables are mean (SD), median (IQR), [range]
FMUE: Fugl Meyer Upper Extremity score, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/7, 14 weeks = 78/14)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/5, 14 weeks = 39/8)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/6)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
FMUE Sensory total (0-12)*					
Baseline	7.1 (2.1), 8.0 (8.0, 8.0), [0.0, 8.0]	7.2 (2.0), 8.0 (8.0, 8.0), [0.0, 8.0]	7.0 (2.3), 8.0 (8.0, 8.0), [0.0, 8.0]		
6 weeks	7.5 (1.5), 8.0 (8.0, 8.0), [0.0, 8.0]	7.4 (1.9), 8.0 (8.0, 8.0), [0.0, 8.0]	7.6 (1.0), 8.0 (8.0, 8.0), [4.0, 8.0]		
14 weeks	7.7 (1.0), 8.0 (8.0, 8.0), [2.0, 8.0]	7.6 (1.3), 8.0 (8.0, 8.0), [2.0, 8.0]	7.8 (0.6), 8.0 (8.0, 8.0), [5.0, 8.0]		
Change at 6 weeks	0.4 (1.7), 0.0 (0.0, 0.0), [-8.0, 7.0]	0.1 (1.7), 0.0 (0.0, 0.0), [-8.0, 5.0]	0.6 (1.7), 0.0 (0.0, 0.0), [-1.0, 7.0]	0.42 (-0.16, 1.00)***	0.162
Change at 14 weeks	0.5 (1.3), 0.0 (0.0, 0.0), [0.0, 7.0]	0.4 (1.0), 0.0 (0.0, 0.0), [0.0, 5.0]	0.5 (1.5), 0.0 (0.0, 0.0), [0.0, 7.0]	0.19 (-0.11, 0.49)***	0.228

Continuous variables are mean (SD), median (IQR), [range]
FMUE: Fugl Meyer Upper Extremity score, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
MAL Quantity (0-5)*					
Baseline	0.3 (0.3), 0.1 (0.0, 0.4), [0.0, 1.4]	0.2 (0.3), 0.1 (0.0, 0.3), [0.0, 1.4]	0.3 (0.3), 0.2 (0.1, 0.4), [0.0, 1.3]		
6 weeks	1.3 (1.2), 0.9 (0.4, 2.3), [0.0, 4.6]	1.2 (1.1), 0.9 (0.1, 2.0), [0.0, 3.5]	1.5 (1.3), 0.9 (0.7, 2.5), [0.0, 4.6]		
14 weeks	1.7 (1.4), 1.6 (0.4, 2.5), [0.0, 4.9]	1.4 (1.3), 1.3 (0.3, 2.0), [0.0, 4.6]	2.0 (1.6), 1.7 (0.6, 3.1), [0.0, 4.9]		
Change at 6 weeks	1.1 (1.1), 0.8 (0.3, 1.9), [-0.4, 3.9]	0.9 (0.9), 0.7 (0.1, 1.5), [-0.1, 3.2]	1.2 (1.1), 0.8 (0.4, 2.1), [-0.4, 3.9]	0.19 (-0.20, 0.57)***	0.350
Change at 14 weeks	1.5 (1.3), 1.4 (0.3, 2.4), [-0.6, 4.4]	1.2 (1.2), 1.1 (0.1, 1.7), [-0.1, 4.3]	1.7 (1.4), 1.5 (0.5, 2.6), [-0.6, 4.4]	0.40 (-0.12, 0.92)***	0.133

Continuous variables are mean (SD), median (IQR), [range]
MAL: Motor Activity Log, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
MAL Quality (0-5)*					
Baseline	0.2 (0.2), 0.1 (0.0, 0.4), [0.0, 1.0]	0.2 (0.2), 0.1 (0.0, 0.4), [0.0, 0.8]	0.2 (0.2), 0.1 (0.1, 0.3), [0.0, 1.0]		
6 weeks	1.2 (1.1), 0.8 (0.4, 1.8), [0.0, 4.2]	1.0 (0.9), 0.7 (0.1, 1.7), [0.0, 3.1]	1.4 (1.2), 0.9 (0.6, 2.1), [0.0, 4.2]		
14 weeks	1.5 (1.3), 1.2 (0.4, 2.4), [0.0, 4.6]	1.2 (1.1), 1.1 (0.2, 1.9), [0.0, 3.8]	1.8 (1.4), 1.4 (0.5, 3.0), [0.0, 4.6]		
Change at 6 weeks	1.0 (0.9), 0.7 (0.3, 1.6), [-0.1, 3.8]	0.8 (0.8), 0.6 (0.1, 1.3), [-0.1, 2.7]	1.1 (1.0), 0.8 (0.4, 1.9), [-0.1, 3.8]	0.26 (-0.08, 0.61)***	0.143
Change at 14 weeks	1.3 (1.2), 1.1 (0.3, 2.0), [-0.3, 4.3]	1.0 (1.0), 0.9 (0.1, 1.8), [-0.2, 3.5]	1.5 (1.3), 1.2 (0.4, 2.7), [-0.3, 4.3]	0.45 (-0.04, 0.93)***	0.075

Continuous variables are mean (SD), median (IQR), [range]
MAL: Motor Activity Log, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): 1-1.1 (Simpson and Eng 2012)

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
MAL % of tasks (0-100%, 1 task = 5.9%)*					
Baseline	12.3 (12.8), 5.9 (0.0, 17.6), [0.0, 47.1]	11.6 (13.3), 5.9 (0.0, 17.6), [0.0, 47.1]	13.0 (12.5), 11.8 (5.9, 17.6), [0.0, 47.1]		
6 weeks	40.4 (28.3), 35.3 (17.6, 64.7), [0.0, 94.1]	36.1 (28.7), 35.3 (11.8, 55.9), [0.0, 88.2]	44.5 (27.7), 35.3 (23.5, 64.7), [0.0, 94.1]		
14 weeks	46.5 (31.8), 47.1 (23.5, 70.6), [0.0, 100.0]	39.9 (31.0), 41.2 (11.8, 64.7), [0.0, 94.1]	52.6 (31.7), 55.9 (27.9, 76.5), [0.0, 100.0]		
Change at 6 weeks	28.0 (22.4), 23.5 (11.8, 41.2), [-11.8, 76.5]	24.2 (21.5), 23.5 (0.0, 41.2), [-5.9, 76.5]	31.6 (22.9), 29.4 (11.8, 47.1), [-11.8, 76.5]	6.71 (-2.29, 15.70)***	0.149
Change at 14 weeks	34.0 (26.7), 35.3 (11.8, 52.9), [-11.8, 94.1]	28.2 (25.2), 23.5 (5.9, 47.1), [-5.9, 76.5]	39.4 (27.2), 41.2 (17.6, 54.4), [-11.8, 94.1]	9.90 (-1.67, 21.48)***	0.099

Continuous variables are mean (SD), median (IQR), [range]
MAL: Motor Activity Log, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
VAS upper arm pain (0-10)**					
Baseline	0.9 (1.4), 0.0 (0.0, 1.0), [0.0, 7.0]	0.8 (1.3), 0.0 (0.0, 1.0), [0.0, 5.0]	0.9 (1.4), 0.0 (0.0, 1.8), [0.0, 7.0]		
6 weeks	1.6 (1.8), 1.0 (0.0, 3.0), [0.0, 6.0]	1.7 (1.8), 1.0 (0.0, 3.0), [0.0, 6.0]	1.5 (1.8), 1.0 (0.0, 2.0), [0.0, 6.0]		
14 weeks	1.8 (1.8), 1.5 (0.0, 3.0), [0.0, 7.0]	1.9 (1.9), 1.5 (0.0, 3.0), [0.0, 7.0]	1.8 (1.7), 1.5 (0.0, 3.0), [0.0, 6.0]		
Change at 6 weeks	0.7 (1.6), 0.0 (0.0, 2.0), [-4.0, 5.0]	0.9 (1.6), 0.0 (0.0, 2.0), [-2.0, 5.0]	0.5 (1.5), 0.0 (0.0, 1.0), [-4.0, 4.0]	-0.39 (-1.09, 0.32)***	0.287
Change at 14 weeks	0.9 (2.2), 0.5 (0.0, 2.0), [-4.0, 7.0]	1.0 (2.4), 1.0 (0.0, 2.0), [-4.0, 7.0]	0.8 (2.1), 0.2 (0.0, 2.0), [-4.0, 5.0]	0.03 (-0.84, 0.91)***	0.942

Continuous variables are mean (SD), median (IQR), [range]
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, VAS: Visual Analogue Scale, **lower represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MIS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MIS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MIS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
Secondary outcomes					
VAS lower arm pain (0-10)**					
Baseline	0.6 (1.3), 0.0 (0.0, 1.0), [0.0, 8.0]	0.8 (1.6), 0.0 (0.0, 1.0), [0.0, 8.0]	0.5 (0.8), 0.0 (0.0, 1.0), [0.0, 3.0]		
6 weeks	1.1 (1.7), 0.2 (0.0, 1.5), [0.0, 8.0]	1.4 (1.9), 1.0 (0.0, 3.0), [0.0, 7.0]	0.9 (1.6), 0.0 (0.0, 1.0), [0.0, 8.0]		
14 weeks	1.2 (1.8), 0.0 (0.0, 1.5), [0.0, 7.0]	1.1 (1.7), 0.0 (0.0, 2.0), [0.0, 6.0]	1.2 (1.9), 0.5 (0.0, 1.1), [0.0, 7.0]		
Change at 6 weeks	0.5 (1.9), 0.0 (0.0, 1.0), [-5.0, 7.0]	0.6 (2.1), 0.0 (0.0, 1.0), [-5.0, 6.8]	0.4 (1.6), 0.0 (0.0, 1.0), [-2.0, 7.0]	-0.43 (-1.23, 0.37)***	0.299
Change at 14 weeks	0.5 (2.2), 0.0 (-0.2, 1.0), [-8.0, 7.0]	0.2 (2.5), 0.0 (-0.5, 1.0), [-8.0, 5.0]	0.7 (1.9), 0.0 (0.0, 1.1), [-2.0, 7.0]	0.02 (-0.89, 0.92)***	0.969

Continuous variables are mean (SD), median (IQR), [range]
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, VAS: Visual Analogue Scale, **lower represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Table 35: Outcome analysis in the intention-to-treat population – Change in other (non-upper limb) secondary clinical measures at the 6 and 14 week assessments

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
mRS (0-5)**					
Baseline	3.6 (0.7), 4.0 (3.0, 4.0), [2.0, 5.0]	3.7 (0.7), 4.0 (3.5, 4.0), [2.0, 5.0]	3.5 (0.7), 4.0 (3.0, 4.0), [2.0, 5.0]		
6 weeks	3.1 (1.0), 3.0 (2.0, 4.0), [1.0, 5.0]	3.2 (1.0), 3.0 (2.5, 4.0), [1.0, 5.0]	3.0 (0.9), 3.0 (2.0, 4.0), [1.0, 4.0]		
14 weeks	2.8 (0.9), 3.0 (2.0, 3.0), [0.0, 5.0]	2.9 (0.7), 3.0 (3.0, 3.0), [1.0, 4.0]	2.8 (1.0), 3.0 (2.0, 3.0), [0.0, 5.0]		
Change at 6 weeks	-0.5 (0.8), 0.0 (-1.0, 0.0), [-2.0, 1.0]	-0.5 (0.9), 0.0 (-1.0, 0.0), [-2.0, 1.0]	-0.5 (0.7), -1.0 (-1.0, 0.0), [-2.0, 1.0]	-0.07 (-0.39, 0.24)***	0.647
Change at 14 weeks	-0.7 (0.8), -1.0 (-1.0, 0.0), [-3.0, 1.0]	-0.7 (0.9), -1.0 (-1.0, 0.0), [-2.0, 1.0]	-0.8 (0.8), -1.0 (-1.0, 0.0), [-3.0, 1.0]	-0.09 (-0.44, 0.26)***	0.611

Continuous variables are mean (SD), median (IQR), [range]
mRS: modified Rankin Scale, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, **lower represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
BI (0-20)*					
Baseline	10.9 (4.8), 10.0 (7.0, 16.0), [3.0, 19.0]	10.6 (4.4), 10.0 (7.0, 14.5), [4.0, 18.0]	11.1 (5.1), 10.0 (7.0, 17.0), [3.0, 19.0]		
6 weeks	14.6 (4.8), 16.0 (13.0, 18.0), [0.0, 20.0]	14.4 (4.9), 15.0 (13.0, 18.0), [0.0, 20.0]	14.7 (4.9), 16.0 (13.0, 19.0), [4.0, 20.0]		
14 weeks	15.8 (4.8), 17.0 (15.0, 19.0), [0.0, 20.0]	15.8 (4.6), 17.0 (15.0, 19.0), [2.0, 20.0]	15.7 (5.1), 17.0 (14.8, 19.2), [0.0, 20.0]		
Change at 6 weeks	3.6 (3.6), 3.0 (1.0, 6.2), [-7.0, 15.0]	3.6 (3.6), 4.0 (1.0, 7.0), [-7.0, 8.0]	3.5 (3.7), 2.0 (1.0, 5.0), [-3.0, 15.0]	0.05 (-1.54, 1.64)***	0.950
Change at 14 weeks	4.6 (4.4), 4.0 (1.0, 8.0), [-4.0, 15.0]	4.9 (4.1), 5.0 (2.0, 8.0), [-3.0, 15.0]	4.4 (4.6), 4.0 (1.0, 6.0), [-4.0, 15.0]	-0.52 (-2.48, 1.44)***	0.604

Continuous variables are mean (SD), median (IQR), [range]

BI: Barthel Index, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): 1·85 points in the early subacute recovery phase (Hsieh *et al.* 2007)

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
SIS Total (0-100)*					
Baseline	51.7 (10.3), 50.3 (43.6, 58.7), [27.4, 76.9]	51.9 (9.8), 50.3 (43.2, 58.8), [27.4, 68.2]	51.5 (11.0), 49.7 (44.4, 58.4), [32.7, 76.9]		
6 weeks	62.2 (16.8), 61.3 (52.4, 74.7), [17.2, 93.9]	60.2 (17.7), 58.5 (52.7, 72.0), [17.2, 93.9]	64.0 (15.8), 63.2 (52.2, 74.7), [38.6, 90.9]		
14 weeks	65.8 (17.6), 65.6 (53.7, 78.3), [22.5, 94.8]	63.8 (18.3), 61.4 (53.7, 76.9), [22.5, 94.8]	67.6 (17.0), 66.8 (54.9, 80.0), [30.3, 93.6]		
Change at 6 weeks	10.1 (12.5), 9.5 (3.4, 15.7), [-33.1, 43.1]	8.0 (13.1), 9.7 (3.1, 13.5), [-33.1, 38.5]	12.1 (11.8), 9.4 (5.1, 19.7), [-9.6, 43.1]	2.95 (-2.41, 8.31)***	0.284
Change at 14 weeks	13.6 (13.8), 12.9 (3.2, 25.9), [-17.7, 46.6]	11.4 (13.2), 11.1 (1.3, 21.7), [-17.7, 32.5]	15.5 (14.2), 13.7 (5.2, 26.3), [-9.1, 46.6]	2.43 (-3.94, 8.81)***	0.457

Continuous variables are mean (SD), median (IQR), [range]
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference,
SIS: Stroke Impact Scale, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
SIS Hand (0-100)*					
Baseline	2.4 (7.8), 0.0 (0.0, 0.0), [0.0, 45.0]	1.8 (6.7), 0.0 (0.0, 0.0), [0.0, 40.0]	2.9 (8.9), 0.0 (0.0, 0.0), [0.0, 45.0]		
6 weeks	28.2 (29.6), 17.5 (0.0, 46.2), [0.0, 95.0]	23.6 (27.1), 15.0 (0.0, 37.5), [0.0, 85.0]	32.6 (31.5), 25.0 (5.0, 55.0), [0.0, 95.0]		
14 weeks	37.8 (34.4), 30.0 (5.0, 70.0), [0.0, 95.0]	31.4 (32.3), 20.0 (0.0, 60.0), [0.0, 95.0]	43.8 (35.7), 32.5 (10.0, 77.5), [0.0, 95.0]		
Change at 6 weeks	25.7 (28.9), 12.5 (0.0, 45.0), [-10.0, 90.0]	21.7 (26.7), 10.0 (0.0, 35.0), [0.0, 85.0]	29.5 (30.8), 20.0 (0.0, 55.0), [-10.0, 90.0]	6.41 (-3.22, 16.03)***	0.197
Change at 14 weeks	35.4 (33.8), 25.0 (5.0, 65.0), [-15.0, 95.0]	29.7 (32.0), 15.0 (0.0, 60.0), [0.0, 95.0]	40.6 (35.1), 30.0 (10.0, 75.0), [-15.0, 95.0]	8.92 (-3.83, 21.68)***	0.176

Continuous variables are mean (SD), median (IQR), [range]
N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, SIS: Stroke Impact Scale, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): ≥8.44 points from acute to subacute (Kao and Pai 2023)

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/6, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
EQ-5D-5L Total (0-25)**					
Baseline	15.2 (3.7), 15.0 (13.0, 18.0), [5.0, 22.0]	15.4 (3.6), 15.0 (13.5, 18.0), [7.0, 22.0]	15.1 (3.9), 15.0 (13.0, 18.0), [5.0, 22.0]		
6 weeks	12.8 (3.5), 13.0 (10.0, 15.2), [6.0, 20.0]	13.0 (3.4), 13.0 (10.5, 15.5), [6.0, 20.0]	12.7 (3.7), 12.0 (10.0, 15.0), [6.0, 20.0]		
14 weeks	12.9 (4.4), 13.0 (9.0, 16.0), [6.0, 23.0]	13.4 (4.5), 14.0 (9.0, 16.0), [6.0, 23.0]	12.4 (4.4), 12.0 (9.0, 15.2), [6.0, 21.0]		
Change at 6 weeks	-2.3 (2.8), -2.0 (-5.0, 0.0), [-8.0, 4.0]	-2.3 (2.5), -2.0 (-4.0, -0.5), [-7.0, 2.0]	-2.3 (3.1), -2.0 (-5.0, 0.0), [-8.0, 4.0]	0.14 (-0.97, 1.26)***	0.802
Change at 14 weeks	-2.0 (3.6), -2.0 (-4.0, 0.0), [-9.0, 9.0]	-1.6 (3.6), -2.0 (-4.0, 0.0), [-9.0, 9.0]	-2.4 (3.5), -2.0 (-5.2, -1.0), [-9.0, 4.0]	-0.52 (-2.15, 1.10)***	0.531

Continuous variables are mean (SD), median (IQR), [range]
EQ-5D-5L: EquroQuol Five Dimensions and Five Levels, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, **lower represents better outcome, ***Minimal Clinically Important Difference (MCID): 0.18 (range 0.03-0.54) (Coretti *et al.* 2014)

Outcomes (min-max)	**All** (N_{OBS}/N_{MISS}: 6 weeks = 78/7, 14 weeks = 78/9)	**Usual Care group** (N_{OBS}/N_{MISS}: 6 weeks = 39/4, 14 weeks = 39/6)	**SaeboGlove group** (N_{OBS}/N_{MISS}: 6 weeks = 39/2, 14 weeks = 39/3)	**Adjusted mean difference (95% CI)**	**p-value**
EQ-5D-5L VAS (0-100)*					
Baseline	58.4 (19.3), 60.0 (45.0, 73.8), [10.0, 100.0]	59.2 (18.5), 60.0 (47.5, 77.5), [20.0, 90.0]	57.5 (20.3), 60.0 (45.0, 70.0), [10.0, 100.0]		
6 weeks	63.2 (18.5), 65.0 (50.0, 77.5), [5.0, 100.0]	63.5 (19.7), 65.0 (50.0, 80.0), [30.0, 100.0]	62.8 (17.5), 65.0 (50.0, 75.0), [5.0, 90.0]		
14 weeks	65.4 (19.2), 70.0 (50.0, 80.0), [7.0, 90.0]	65.0 (19.8), 70.0 (50.0, 80.0), [10.0, 90.0]	65.8 (18.9), 70.0 (57.5, 80.0), [7.0, 90.0]		
Change at 6 weeks[1]	4.1 (22.3), 5.0 (-10.0, 20.0), [-80.0, 80.0]	4.6 (25.1), 0.0 (-10.0, 20.0), [-50.0, 80.0]	3.6 (19.8), 5.0 (-7.0, 20.0), [-80.0, 35.0]	-1.73 (-9.71, 6.24)***	0.671
Change at 14 weeks	5.4 (23.0), 5.0 (-10.0, 20.0), [-70.0, 50.0]	5.3 (26.5), 10.0 (-10.0, 25.0), [-70.0, 50.0]	5.6 (19.8), 5.0 (0.0, 20.0), [-50.0, 40.0]	-0.63 (-9.44, 8.19)***	0.890

Continuous variables are mean (SD), median (IQR), [range]
EQ-5D-5L VAS: EquroQuol Five Dimensions and Five Levels Visual Analogue Scale, N_{OBS}/N_{MISS}: Number of observations in data set/ Number of missing observations in data set, p-value ≤0.05 represents significant between group difference, *higher represents better outcome, ***Minimal Clinically Important Difference (MCID): Not found, [1]: N_{OBS}/N_{MISS} is 39/5 as VAS in Usual Care group as it was missed in one stroke survivor who was too unwell to score it

4.4.6 Safety

4.4.6.1 Premature withdrawals

Details of all withdrawals with reasons are summarised by group in the Flow Chart above (Figure 23 above). No stroke survivors withdrew for safety reasons.

4.4.6.2 Adverse events

A total of 19 adverse events ((12 Control, 7 SaeboGlove) were reported in 18 stroke survivors (18/78; 23.1%) (Table 36 and 37 respectively overleaf).

Of the 19 adverse events, nine were SAEs considered to be unrelated/ theoretically unrelated to the SaeboGlove therapy, two in each group due to upper limb injuries/accidents and one and four in the intervention and control group respectively due to hospital admissions (*3 SaeboGlove* - 2 falls with hemiparetic upper limb injury, 1 admission (chest infection), *6 Control* – 4 admissions/extended admissions (2 chest infection, 1 Transient Ischaemic Attack, 1 Headaches and 2 hemiparetic upper limb injuries (fall, inattention accident)) (Tables 36 and 37 overleaf).

The remaining 10 adverse events were considered possibly related/theoretically related to SaeboGlove therapy (Tables 36 and 37 overleaf). There were no USADEs in either group. One was a SADE (*1 Control* – shoulder pain that jeopardised patient and required intervention to prevent persistent disability/incapacity) judged to be mild and anticipated. Nine were ADEs and considered to be mild and anticipated (*4 SaeboGlove* - 3 hand pain, 1 small skin marks and hand pain and *5 Control* - 4 hand pain, 1 shoulder pain).

Thus, SADEs were similar in both groups. However, there was a trend for more SAEs in the control group due to an increase in the number of hospital admissions/extended hospital admissions that were felt to be unrelated/theoretically unrelated to the SaeboGlove therapy.

Table 36: Adverse events: Usual Care group

Adverse event no.	Type	Detail	Related/hypothetically related to EMPOWER Intervention?	Resolved within 14 weeks?
1	SAE	Prolonged admission, - developed pneumonia, UTI, renal failure with new dialysis all in quick succession	No	Yes - with sequelae
2	SAE	Admission with exacerbation of COPD	No	No
3	SAE	Admission with transient paretic upper limb weakness due to TIA	No	Yes
4	SAE	Admitted with headaches	No	No
5	SAE - Other medical event	Hemiparetic shoulder injury due to inattention walking through door (hand left on door handle)	No	No
6	SAE - Other medical event	Fall at home resulting in paretic upper limb shoulder injury/pain	No	No
7	***SADE - Other medical event***	***Shoulder pain requiring input from GP, Orthopaedic specialists and musculoskeletal physiotherapy – mild, anticipated***	***Possibly related***	***No***
8	***ADE***	***Shoulder pain – mild, anticipated***	***Possibly related***	No
9	***ADE***	***Hand pain – mild, anticipated***	***Possibly related***	No
10	***ADE***	***Hand pain – mild, anticipated***	***Possibly related***	No
11	***ADE***	***Hand pain – mild, anticipated***	***Possibly related***	Yes
12	***ADE***	***Hand pain – mild, anticipated***	***Possibly related***	Yes

ADE: Adverse Device Event, COPD: Chronic Obstructive Pulmonary Disease, GP: General Practitioner, SADE: Serious Adverse Device Event, SAE: Serious Adverse Event, TIA: Transient Ischaemic Attach, UTI: Urinary Tract Infection

Table 37: Adverse events: SaeboGlove group

Adverse event no.	Type	Detail	Related/hypothetically related to EMPOWER Intervention?	Resolved within 14 weeks?
1	SAE	Admitted with exacerbation of COPD	No	Yes
2	SAE - Other medical event	Inadequate equipment on discharge home resulting in fall and paretic upper limb shoulder injury/pain	No	No
3	SAE - Other medical event	Fall outdoors resulting in fracture of paretic upper limb (humeral)	No	No
4	***ADE***	***Hand pain – mild, anticipated***	***Possibly related***	No
5	***ADE***	***Hand pain – mild, anticipated***	***Possibly related***	No
6	***ADE***	***Hand pain – mild, anticipated***	***Possibly related***	Missing (withdrew - medical/social issues)
7	***ADE***	***Small faint red skin mark over 3rd & 5th knuckle (MCP joint) with occasional discomfort over knuckles and distal ulnar prominence after period wearing glove – mild, anticipated***	***Possibly related***	Yes

ADE: Adverse Device Event, COPD: Chronic Obstructive Pulmonary Disease, MCP: Metacarpal Phalangeal, SAE: Serious Adverse Event

4.4.7 Deviations

Protocol deviations are shown in Table 38 below. No deviations affected the safety or willingness of participating stroke survivors. Eighteen deviations occurred, all unavoidable, relating to late data collection. Fourteen involved delayed measurement of face-to-face outcomes only as patient facing contact was ceased during the initial Covid-19 lockdown. Seventeen may in theory have impacted data integrity.

Table 38: Protocol deviations

No. of deviations	Related to Covid-19		Unrelated to Covid-19		Total	
	Usual Care Group	SaeboGlove Group	Usual Care Group	SaeboGlove group	Usual Care group	SaeboGlove group
Enrolment						
1	0	1* - Within post stroke time but randomised 6 days late	0	0	0	1
6 week assessment						
5	1 - F2F measures 268 days late 1 - F2F measures not done as participant withdrew before that was permitted	3 - F2F measures mean (range, SD) days late - 160.7 (96.0 - 217.0, 60.9)	0	0	2	3
14 week assessment						
12	2 - F2F measures mean (range, SD) days late 156.5 (100.0 – 213.0, 79.9) 1 - F2F measures not completed as restrictions did not permit this before the participant passed away	6 - F2F measures mean (range, SD) days late 99.8 (40.0 – 161.0, 50.3)	1 - Due to illness assessment staggered 7-65 days beyond intended timeline (ARAT 63 days beyond)	2 - F2F measures mean (range, SD) days late 24 (22-26, 2.83)	4	8
Total						
18	5	10	1	2	6	12

ARAT: Action Research arm Test, F2F: Face-to-Face, SD: Standard Deviation, *No impact to data integrity

Deviations were balanced between groups at enrolment and the 6 week primary outcome. More deviations occurred in relation to the 14 week outcome visit due to there being a greater number of stroke survivors randomised to the SaeboGlove group at the onset of Covid-19 (Table 38).

Related to Covid-19: Fifteen deviations occurred as Covid-19 safety restrictions relating to face-to-face contact were followed which altered the timing of research visits. Of these, one involved a stroke survivor who was discharged suddenly just after being approached about the study. This stroke survivor was recruited within the 60 day post stroke cut off. However, an inpatient Covid-19 outbreak occurred at the time of his discharge which meant he had to isolate for 14 days. This combined with weekends and limited immediate access to clinic space/outcome staffing meant that he was screened/randomised 6 days beyond the intended two week recruitment period post discharge.

Five deviations involved the 6 week primary outcome visit. Subjective outcomes were scored within protocol time frames for all five visits. However, face-to-face measures which included the primary outcome (ARAT, FMUE) were late for four of these visits (*3 SaeboGlove* – Mean (range, SD, median, IQR) 160.7 days (96.0 - 217.0, 60.9, median (IQR) 169 days (121), *1 Control* - 268 days) and not done for one visit (*1 Control* – subjective data 15 days late) as he withdrew prior to it being collected.

Nine involved the 14 week outcome visit. Subjective outcomes were scored within protocol time frames for all nine visits. However eight face-to-face measures (ARAT, FMUE) were complete late (*2 Control* – Mean (range, SD) 156.5 (100.0 – 213.0, 79.9), median (IQR) 156.5 days (*), 6 *SaeboGlove* – Mean (range, SD) 99.8 (40.0 – 161.0, 50.3, median (IQR) 95 days (102.3), and one was not completed as restrictions did not permit this before the participant passed away (*1 Control*).

Unrelated to Covid-19: The remaining three non-Covid-19 deviations all occurred as the 14 week visit was late due to significant illness (hospitalisation/prolonged hospitalisation) (*1 Control* - assessment staggered 7-65 days beyond intended timeline (ARAT 63 days beyond), *2 SaeboGlove* – Mean (range, SD) 24 (22-26, 2.83), median (IQR) 24 days (*).

4.5 Discussion

4.5.1 Summary of findings

This chapter has reported the outcome evaluation of a six week supported self-management upper limb intervention commenced in stroke survivors in the acute to early subacute phase of recovery. The trial aimed to establish if usual care plus the EMPOWER Help for Hands Programme (self-directed, repetitive functional-based upper limb practice supported using a DHO and four upper limb therapy progress reviews) improved upper limb recovery compared to usual care plus additional upper limb usual care (therapy input based on National Clinical Guidelines i.e. self-directed and repetitive functional-based practice (as able) that was supported through the provision of four upper limb therapy progress reviews). Stroke survivors had upper limb disability and severe hand impairment, including reduced or absent active digital extension, wrist, elbow, or shoulder movement. The study achieved the revised recruitment target of ≥80% statistical power and any differences in baseline characteristics were not thought sufficient to bias results.

The key findings from the outcome evaluation in the RCT in the SUSHI trial are summarised below.

4.5.1.1 Key findings

Interventions

During the intervention period (weeks 1-6) the mean number of usual care upper limb therapy weekdays therapists reported delivering were balanced between groups. Similarly, the time stroke survivors reported spending on upper limb therapy with a therapist over the entire intervention and follow up period (weeks 1-14) were also balanced.

Although, stroke survivors in the Usual Care group received less upper limb reviews by therapists (primarily due to withdrawal because of allocation group disappointment and gaps in usual NHS care after discharge) they reported spending more upper limb therapy time with a therapist over the intervention period (weeks 1-6).

Despite this additional therapist contact in stroke survivors in the Usual Care group, during weeks 1-6, the time Usual Care group stroke survivors reported spending on upper limb therapy without a therapist was much less during weeks 1-6 and 1-14. Overall the total time Usual Care group stroke survivors reported spending on upper limb therapy (with and without a therapist) was a *mean* and *median* of 8.7 hours and 12.0 hours less respectively over weeks 1-6 and a *mean* and *median* total of 6.8 hours and 18.9 hours less respectively over weeks 1-14 respectively.

Primary outcome

The change in the ARAT Total score and ARAT Grasp, Grip and Pinch subscores were all statistically significantly improved in the SaeboGlove group compared to the Usual Care group at the 6 week outcome visit. However, the change in the ARAT Gross subscores between groups was not.

Secondary outcomes

The change in the FMUE Motor Hand and Total scores were both statistically significantly improved in the SaeboGlove compared to the Usual Care group at the 6 week visit. However, no other secondary outcome measures were statistically significant at any point in time. This includes no between group difference in proximal or distal upper extremity pain despite the SaeboGlove group spending more time engaged in repetitive, functional-based upper limb rehabilitation.

Although the changes in MAL score between group were not statistically significant, the recovery rate in the SaeboGlove group in terms of the number of MAL ADL tasks that stroke survivors reported using their affected upper limb in was more than twice that reported in the Usual Care group between the 6 and 14 week visits when the six week intervention had stopped (1.4 tasks versus 0.6 tasks (Section 4.4.5.3, Table 34, increase in Usual Care group: 0.6 (39.9-36.1/5.9%; 0.6 tasks, SaeboGlove group: 1.4 (52.6-44.5/5.9%; 1.4 tasks).

Minimal Clinically Important Difference

Minimal Clinically Important Difference (MCID) values i.e. the smallest change in an outcome that a patient would identify as important (Jaeschke *et al*. 1989) were identified for six measures (ARAT Total, FMUE Motor Total, MAL Quality, BI,

SIS Hand, EQ-5D-5L Total). Four of these were within the 95% confidence interval for the corresponding outcomes (ARAT Total, FMUE Motor Total, SIS Hand, EQ-5D-5L Total) (Tables 32 and 33). This was the case for these measures at both the 6 and 14 week visits (Tables 32 and 33) and may be an indicator that stroke survivors assigned to the SaeboGlove group experienced improvements in these four measures at the 6 and 14 week visits that were clinically meaningful compared to those experienced in the Usual Care group. This is particularly likely for the measures where the between group difference exceeded the corresponding MCID (6 weeks: ARAT Total, FMUR Motor Total, 14 weeks: FMUE Motor Total, SIS Hand) (Tables 32 and 33) (Page 2014). Additionally, as the MCID is within the 95% confidence interval for four of the measures this may suggest that the difference/improvements in these four measures may be found to be statistically significant in a trial with more statistical power (Page 2014).

Safety

No safety concerns were identified for either intervention.

4.5.1.2 Relationship to published literature

Certainty of positive effect in systematic review is strengthened

The systematic review of RCTs in Chapter 2 compared interventions utilising a non-robotic DHO intervention to usual care or usual care plus a placebo intervention in stroke survivors with moderate to severe upper limb functional capacity, primarily in the chronic phase of recovery (Alexander *et al*. 2021a). It found a positive effect in favour of the use of non-robotic DHOs in terms of upper limb function and dexterity. However, this positive effect was considered to lack certainty as it was confounded by the small number of studies and included participants, and a high risk of bias largely due to poor methodological reporting (e.g. of the sample, intervention delivery) and a lack of good quality, multi-site, adequately powered RCT(s) with long term follow up.

The RCTs in the SUSHI trial was a good quality, multi-site, adequately powered RCT with long term follow up. It also included stroke survivors with moderate to severe upper limb functional capacity, primarily no capacity, who were recruited in the acute to early subacute phase of recovery. Thus, the findings in this RCT in the SUSHI trial, likely in a more severe group, are consistent with the

systematic review findings. This increases certainty on the positive effects observed in the systematic review in favour of the use of non-robotic DHOs to improve upper limb recovery after stroke. It also provides much needed information on longer term outcomes and intervention effects in the acute to subacute phase of stroke recovery.

The EMPOWER Programme - First accessible intervention to improve upper limb function, regardless of digital extensor weakness severity, and efficient in terms of outcome

The findings in this systematic review and RCT in this thesis contrast previous research. Unlike stroke survivors with mild or moderate upper limb motor impairment research suggests those with severe motor impairment receive less upper limb rehabilitation and do not receive active, functional-based or meaningful upper limb rehabilitation due to the increased difficulties stroke survivors and their therapists experience when active movement is limited (Barker and Brauer 2005; Stockley *et al*. 2019; Meads *et al*. 2020). Instead, upper limb compensatory strategies that lack salience (i.e. importance) (Barker and Brauer 2005; Meads *et al*. 2020), a key principle required to optimise neuroplasticity and recovery (Table 1, (Nudo and Milliken 1996; Kleim *et al*. 1998)), are often favoured by therapists (Meads *et al*. 2020).

The EMPOWER Programme – First intervention to improve upper limb function in stroke survivors with severe hand impairment who lack active digital extension

Additionally, no evidence-based interventions have previously been identified to improve upper limb function in stroke survivors who lack the minimum active digital extension movement required to access functional-based interventions (e.g. in CIMT) (Kwakkel *et al*. 2003; Veerbeek *et al*. 2014b; Kwakkel *et al*. 2015b; Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). Consequently, when insufficient movement is present to access functional-based rehabilitation clinical guidelines recommend that the target of upper limb rehabilitation becomes maintaining the upper limb (e.g. passive movements and positioning to prevent secondary complications or impairments) not recovering lost function (Intercollegiate Stroke Working Party 2023). Thus, the identification of an intervention that significantly improves upper limb function in stroke survivors with severe hand impairment including reduced or absent active digital extension, wrist, elbow, or shoulder movement is a novel finding.

The EMPOWER Programme – Potential to improve quality of life and reduce inpatient stay through faster (i.e. more efficient) recovery of upper limb function

Reduced upper limb function is known to negatively impact quality of life (Lai *et al*. 2002; Morris *et al*. 2013) and ADL independence (Sveen *et al*. 1999; Bleyenheuft and Gordon 2014). Additionally, an increased severity of upper limb motor paresis increases upper limb functional recovery time (Wade *et al*. 1983; Nakayama *et al*. 1994) and the duration of inpatient hospital stay (Persson *et al*. 2012; Langhorne and Baylan 2017; García-Rudolph *et al*. 2020). For example, the difference in the duration of inpatient hospital stay for stroke survivors with and without initial impaired arm and hand function has been found to be a mean of 13.5 days and 7.8 days respectively (Persson *et al*. 2012). Thus, the slower recovery of upper limb function typical in this subgroup is likely to negatively impact quality of life and independence, and will inevitably increase inpatient costs for healthcare organisations (Unit cost per day of standard NHS hospital bed: £586.59, (Guest *et al*. 2020)).

The between group differences observed in two quality of life measures (SIS Hand and EQ-5D-5L Total) in SUSHI were within the 95% confidence interval at the 6 and 14 week assessments (Table 33). Thus, it is possible that the improvement observed in quality of life measures in the SaeboGlove group may reflect a clinically meaningful improvement in upper limb function (and/or impairment) (Page 2014) and the accelerated recovery observed.

The EMPOWER Help for Hands programme utilised a patient centred approach which is associated with satisfying health service needs (H.K. Kristensen *et al*. 2016). Consistent with this approach, it responds to several unmet needs of stroke survivors identified in Chapter 1, their wish to be supported and enabled to engage in more self-practice activities out with formal therapy sessions, receive more therapy provision in general and more access to manageable and meaningful i.e. salient upper limb rehabilitation content (Barker and Brauer 2005; Luker *et al*. 2015; Meads *et al*. 2020). Thus, improvements in quality of life may instead reflect other non-physical benefits, not identified in the RCT, such as accommodating the perceived unmet support needs of stroke survivors (e.g. inadequate information, support, therapy provision, self-directed and

meaningful therapy opportunities, good communication and autonomy (Barker and Brauer 2005; McKevitt *et al*. 2011; Luker *et al*. 2015; Stroke Association 2016; Abrahamson and Wilson 2019; Meads *et al*. 2020)).

The EMPOWER Programme – More efficient in terms of therapist time (input) and therapy engagement (output)

In the SUSHI trial stroke survivors in the SaeboGlove group received less therapist contact time yet carried out a mean and median of 8.7 and 12.0 hours of extra repetitive, functional-based, self-directed upper limb rehabilitation involving a SaeboGlove over the six week intervention period (Table 29). Slower recovery of upper limb function, typical in this severe subgroup (Wade *et al*. 1983; Nakayama *et al*. 1994; Persson *et al*. 2012), is known to negatively impact stroke survivors' motivation to engage in rehabilitation and therapy time predicts motor recovery (Luker *et al*. 2015; Meadmore *et al*. 2019; Meads *et al*. 2020). Thus, as the SaeboGlove group appeared to be more motivated to carry out a greater duration of upper limb rehabilitation and the recovery of upper limb function was faster in this group this is an important finding. It highlights that the EMPOWER Help for Hands intervention is beneficial at the behavioural level. This beneficial therapy behaviour is likely to reflect the ability of therapists to provide more meaningful i.e. motivating, functional-based tasks with the aid of a DHO in this group (Meadmore *et al*. 2019; Meads *et al*. 2020). It also suggests that the EMPOWER Help for Hands intervention is a more efficient intervention than the usual care based intervention delivered in the Control group in terms of therapist input (therapist time), therapy output (stroke survivor engagement) as well as outcome.

Relative to similar trials the additional therapy input in SUSHI was small, only involving a maximum of four additional upper limb reviews with a therapist in both groups. Yet, the positive findings contrasts other RCTs involving stroke survivors with moderate to severe motor impairment in the acute to subacute phase of recovery where repetitive functional based therapy of the same dose (20 hours of therapist time over two weeks, (Dromerick *et al*. 2009)) or of a dose involving 30 additional hours (Winstein *et al*. 2016b) were found to be neutral in effect compared to usual care. Similarly, neutral effects have also been found in RCTs involving a similar group but predominantly in the chronic phase where

repetitive functional based therapy with a dose of 36 additional hours of therapist/therapy assistant was compared to usual care (Rodgers *et al*. 2019).

However, the findings in SUSHI are consistent with an RCT by Kwakkel et al. (2016) (Kwakkel *et al*. 2016) involving a group in the acute to early subacute phase (≤14 days post stroke) with slightly higher upper limb function than in SUSHI (ARAT: 23.9 (13.9) versus 13.3 (11.8)). Stroke survivors received three weeks of either modified CIMT or usual care (guideline based) upper limb therapy. A statistically significant difference in favour of modified CIMT was found immediately, three and seven weeks post intervention for upper limb function (Kwakkel *et al*. 2016). However, the modified CIMT group received 7.5 more hours of therapy with a therapist plus additional constraint therapy conducted out with formal 1:1 therapy. Thus, the increased therapy time in this group may be a confounding factor. Like SUSHI, delayed functional improvement in the Usual Care group meant that there was no statistically significant difference at a follow up visit (21 weeks post intervention). The reason for such delayed functional improvements is unclear. However, as they were observed in the subacute phase of recovery they may reflect increased use and coinciding recovery of the stroke affected upper limb in response to their discharge home during this period to an environment that is functionally likely to be more complex (e.g. provides less help or requires engagement in meal preparation, laundry, dressing in clothes that are more challenging to don/doff) (McLaren *et al*. 2020).

4.5.2 Limitations

Three primary recruitment challenges were clearly evident which resulted in a revised recruitment target of ≥80% statistical power:

(1) Direct or indirect implications from the Covid-19 pandemic
e.g. all trial activity was stopped during the initial 4 month lock down in both Health Boards, isolation issues throughout the Covid-19 pandemic prevented/ceased research activity/trial staff movement, the dedicated research therapy area servicing all discharged trial participants in the largest health board was converted into a discharge lounge to manage pressures meaning that clinic space availability was much less reliable for

discharged participant visits. Furthermore, the target population appeared to change reducing eligibility as stroke survivors were admitted with more significant morbidity due to prolonged NHS/social care disruption. Although support from the clinical team was sought to provide reliable carer support when this was essential to provide the SaeboGlove intervention in times where visiting of informal carers was stopped/interrupted this was not always feasible and therefore prevented recruitment in some cases.

(2) In one health board there were some challenges obtaining clinic space for therapy research as clinic spaces were regularly reserved for medical clinics in case they were needed but were frequently not. This prevented recruitment of some recently discharged stroke survivors within protocol timelines. This challenge was sometimes greater in part due to simultaneous challenges accommodating trial staff activities (e.g. annual leave), stroke survivor/carer needs and protocol recruitment timelines.

(3) The absence of a dedicated/established rehabilitation specific research system in Health Boards in Scotland (Forth Valley, Lothian, Fife, and Tayside), some accounted for in prestart recruitment plans who were interested in becoming recruitment sites prevented their involvement. This was also the case for three Trusts in England (Newcastle, North East and North Cumbria, and Leicestershire, only one with some limited therapy research resources).

While the study achieved the revised recruitment target of ≥80% power for the primary outcome, 14 of the 78 participating stroke survivors did not attend the 14 week visit. Thus, this introduces the possibility that the sample utilised was not sufficiently large to detect a real between group difference in upper limb function at the 14 week time point.

The majority of baseline measures were balanced but there were very slight differences in gender and hand dominance between group which theoretically may introduce confounding factors. However, randomisation occurred using a minimisation algorithm designed to adjust for apparent baseline indifferences and the differences observed were not felt to be sufficient to cause bias.

It was not possible to conceal group allocation from stroke survivors/carers, their therapist, or their clinical team as one treatment involved wearing a glove during trial rehabilitation and the other did not, and this introduced two potential sources of bias (Performance and attrition bias).

Firstly, an objective (not subjective) primary outcome was selected for blinded assessments and the research physiotherapist was asked to avoid imparting any group superiority bias to all individuals involved. Despite these measures, unblinding may have positively or negatively influenced rehabilitation behaviours (e.g. therapy participation or support provided), introducing potential bias to the study outcomes (Performance Bias).

Secondly, stroke survivors were only recruited when trial staff were satisfied that stroke survivors/carers had realistic expectations of their study involvement. However, unblinding of stroke survivors at allocation meant that there was still a slightly higher dropout rate in the control group due to treatment allocation disappointment. Unfortunately, this meant that there were slightly fewer primary outcome visits attended by control group participants and this may impart some bias (Attrition Bias).

The mean number of usual care upper limb therapy weekdays therapists-reported delivering during weeks 1-6 (Table 28) and the time stroke survivor-reported spending on upper limb therapy with a therapist over the entire intervention and follow up period (weeks 1-14) (Table 29) were balanced. However, the frequency of upper limb therapy reviews over weeks 1-6 was lower in Usual Care group participants (18 fewer reviews) (Table 30). Theoretically, if it is assumed that upper limb therapy reviews in Usual Care group participants were approximately 1 hour, as in the SaeboGlove group, this would equate to 27.7 (18 hours x 60 minutes; 1080 minutes, 1080 minutes/39 stroke survivors; 27.7) minutes less of therapist contact time per Usual Care group participant. Consequently, bias may have been introduced in favour of the SaeboGlove group due to limitations associated with trying to deliver research protocols within a clinical therapy service which could not be avoided given the rehabilitation research resources available in Scotland to run the study.

However, the upper limb therapy time Usual Care group stroke survivors reported spending with a therapist over weeks 1-6 was a mean of 45 (309-264) and median of 36 (236-200) minutes more than in the SaeboGlove group (Table 29) which is likely to reflect performance bias e.g. the perceived need for upper limb usual care therapy with a therapist being less in the SaeboGlove group as they are receiving a novel intervention. Thus, although Usual Care group participants received less upper limb therapy reviews the overall therapist contact time at the 6 week primary outcome visit is likely to have been greater in the Usual Care group.

Despite this additional therapist contact/input over the intervention period in stroke survivors in the Usual Care group during weeks 1-6 (Table 29), during weeks 1-6 and 1-14 the time Usual Care group stroke survivors reported spending on upper limb therapy without a therapist was much less (Table 29). Consequently, the total therapy time (with and without a therapist) that this group reported spending on their upper limb was much lower than in the SaeboGlove group during weeks 1-6 (mean 8.7 and median 12.0 hours less) and weeks 1-14 (mean 6.8 and median 18.9 hours less).

Thus, the poorer outcomes in the Usual Care group immediately post intervention cannot be explained by a difference in (i.e. lower) upper limb therapist-reported contact frequency or stroke survivor-reported therapist contact time. Instead the poorer outcomes in the Usual Care group are likely to reflect a difference in therapy content or factors at a behavioural level that drive engagement in it e.g. the intervention being too easy/challenging or less relevant, motivating, or interesting. This suggests that the SaeboGlove may have aided self-directed, functional-based practice which may explain the better outcomes in the SaeboGlove group.

Although protocol deviations were balanced at enrolment and the 6 week primary outcome visit there were more in the intervention group at the 14 week visit (8 versus 4). Consequently, some bias may have been introduced to the 14 week outcome data. Similarly, although SADEs were balanced, SAEs were higher in the control group and may infer bias, possibly due to a difference in attention for self-directed therapy between groups.

A limitation of this study is that generalization of the findings to the target population, as a whole, is limited as all SUSHI participants resided in Scotland. Additionally, while stroke survivors in the RCT were permitted to have cognitive and language deficits and these demographics were retrospectively considered by researchers to be primarily mild with a small proportion being moderate, they were not measured to be able to guide transferability judgements to other settings. However, this decision was made as such measurements were not felt to be practical for use in busy clinical settings and would increase participation burden in this severely affected group.

4.5.3 Strengths

Overall, the risk of bias was likely to be low (Table 20). While the sample was small, the study achieved adequate statistical power. Randomisation using a minimisation algorithm designed to adjust for apparent baseline indifferences and concealment of group allocation at randomisation was achieved using a central online randomisation service (Selection Bias). Thus, the study sample can be assumed to be truly randomised, and as it included a control arm confounding factors should be balanced between groups (e.g. spontaneous recovery, baseline characteristics etc). Consequently, this increases confidence that differences in outcomes observed are likely to reflect differences in the interventions studied.

Despite the added disruptions due to the Covid-19 pandemic data completeness for outcomes and participant retention throughout the study was high. Similarly, outcome assessor consistency also was high at repeat assessment visits thereby minimising inter rater reliability issues.

Great efforts were made to maintain allocation concealment in outcome assessors. Consequently, the success of outcome assessor blinding was 97.2% and 92.6% at the primary and secondary outcome visits respectively. Thus, despite the visible nature of the interventions studied bias from the unblinding of assessors was small, particularly at primary outcome visits (Detection Bias).

All planned outcomes (Alexander *et al*. 2021b), whether positive, neutral or negative, were reported (Reporting Bias). Additionally, great efforts were made to minimise other sources of bias. Performance bias was minimised by using an

objective primary outcome and minimising treatment superiority bias. Attrition bias was minimised as realistic participation expectations from stroke survivors/carers were demonstrated prior to enrolment, weekly contact was maintained with control and intervention groups over weeks 1-14, the experimental intervention was also offered to the control group after the 14 week visit and data completeness was reviewed regularly/addressed where possible.

The primary outcome selection was guided by PPI work involving stroke survivors from the target population which recommended an outcome that would reflect meaningful change in independence in life tasks (Appendix F). The collection of outcomes were selected to represent all ICF categories (World Health Organisation 2001; Kwakkel *et al*. 2017) and are supported for use in upper limb stroke rehabilitation RCTs by key stakeholders (stroke survivors, carers, and clinicians with upper limb rehabilitation expertise (Duncan Millar *et al*. 2021)). The outcomes used are also widely used in stroke rehabilitation research (Santisteban *et al*. 2016; Rodgers *et al*. 2019; Dawson *et al*. 2021), included measurement of ADL, extended ADL and AEs (as recommended in Chapter 2) and have been shown to have robust psychometric properties (Section 4.3.2.4).

Long term follow up was included to permit an assessment of sustainability or change in early outcomes (recommended in Chapter 2 and Appendix F). Additionally, outcome assessors received face to face training on the assessments before recruitment commenced, independently co-scored each outcome measure a minimum of 3 times with the research physiotherapist who had over five years' scoring experience and were provided with a training manual with standardised assessment procedures for them to refer to (Appendix H).

The study design responded to gaps in the current research by including stroke survivors with severe hand impairment who often have the poorest upper limb outcomes and lack sufficient active movement to be able to successfully access meaningful, guideline-based therapy in clinical or research settings (Chapter 1). Similarly, it responds to research gaps previously identified (Chapter 2, Appendix F) by including stroke survivors in the acute to subacute phases of recovery and reporting their ethnicity.

Establishing initial permissions for clinic space use for discharged stroke survivors in one Health Board (Lanarkshire) was very complex and time consuming as it covered a large geographical area and therefore involved many community sites and therapy teams. Additionally, the reporting of therapy delivery/engagement in stroke rehabilitation trials is typically poor (Bernhardt *et al*. 2019; Alexander *et al*. 2021a). However, these activities were prioritised to optimise recruitment, upper limb therapy review balance and the collection of accurate information on the usual upper limb care received by both groups at all locations.

The EMPOWER Help for Hands intervention design was led by a physiotherapist who was a clinical expert in stroke rehabilitation, supported by four senior stroke rehabilitation academics and refined through piloting and PPI work (Appendix F, Table 18 above). Although a lack of research resource prevented clinical therapists delivering the intervention there was great interest in doing so. The intervention content and dose was reported using equator guidelines (TIDieR) (Hoffmann *et al*. 2014), efforts were made to optimise fidelity (weekly phone reminders to all stroke survivors/carers to complete booklets and attend upcoming trial visits, review reminders for therapists (clinical and research), review of booklets by therapists at reviews). The RCT is also accompanied by a process evaluation (Chapter 5) which will report on factors relating to support that affect implementation.

4.5.4 Implications for practice

Without a cost effectiveness evaluation there is currently insufficient evidence to be able to recommend routine use of the EMPOWER Help for Hands programme.

However, the intervention was found to be safe. Additionally, upper limb recovery was enhanced in the SaeboGlove group. The SaeboGlove group received less upper limb therapist contact time yet carried out more self-directed upper limb therapy over the intervention period and had a significantly and non-significantly higher level of upper limb function immediately post intervention and at the 14 week timepoint respectively. Thus, the EMPOWER Help for Hands programme appears to be a more efficient intervention in terms

therapist time (therapy input), recovery time and post intervention outcome. Consequently, there is currently sufficient evidence to recommend the implementation of the programme into clinical practice if SaeboGloves are already available to stroke survivors e.g. within the clinical service or via purchase by stroke survivors. If stroke survivors fulfil eligibility criteria for SaeboGlove use and a glove is available therapists should support them to use it to follow the EMPOWER Help for Hands programme.

Additionally, as all components of the EMPOWER programme, apart from using a DHO, were already evidence and guideline-based therapists could consider utilising the programme in their practice in stroke survivors without a DHO when one is not available if active movement permits this.

4.5.5 Implications for research

To determine if the EMPOWER Help for Hands programme should be implemented routinely in the group studied a cost effectiveness analysis and process evaluation are indicated to inform successful implementation. A process evaluation involving a descriptive qualitative analysis of patient, carer and therapist perceived self-management support needs, barriers, and facilitators for clinical implementation will be reported in Chapter 5. Additionally, a process evaluation involving a descriptive quantitative analysis of implementation data collected during the conduct of the RCT in Chapter 4 and a cost effectiveness analysis will be conducted out with this thesis.

Additional RCTs are required to determine if upper limb function remains significantly improved in the SaeboGlove group immediately post intervention in other settings/countries or if it remains insignificantly different to the Usual Care group after follow up. Ideally such trials should be delivered within research funded clinical therapy services to ensure adequate resources for research activities (staff and clinic space) and evaluation of the intervention in the clinical setting it is intended for use in. Securing recruiting sites and an exploration of the complexity of discharge pathways/community clinic arrangements at different Health Boards should ideally be arranged prior to the commencement of a future trial. Extending the intervention period (e.g. by 2-3 weeks or while functional upper limb rehabilitation goals remain should also be

considered with a view to optimising treatment effect (e.g. in ARAT Gross and Grasp subscores) and sustainability. Similarly, further between group differences may be detected if statistical power is increased to 90%. Upper limb recovery was accelerated in the SaeboGlove group evidenced by a statistically significant improvement in the upper limb outcome measures at 6 weeks (ARAT Total, Grasp, Grip, Pinch and FMUE Total and Hand scores), and an increased rate of use of the affected upper limb reported in the MAL ADL tasks. Thus, it is possible that the length of hospital stay may have differed between groups. Consequently, it is recommended that the length of hospital stay should be added to future study outcomes. Additionally, as the recovery rate in terms of the % MAL ADL tasks the affected upper limb was habitually used in was higher between the 6 and 14 week visits in the SaeboGlove group it is also recommended that future studies add an additional follow up visit beyond the 14 week visit to determine if outcomes insignificant at the 14 week visit subsequently become significant. Recording the proportion of stroke survivors with an ARAT Total score in each upper limb functional capacity (no, poor, limited, notable and full capacity (Hoonhorst *et al*. 2015)) is also recommended at outcome as well as the baseline visits to highlight change.

The intervention could also be evaluated in conjunction with other evidence-based interventions (e.g. non-invasive vagal nerve stimulation (Intercollegiate Stroke Working Party 2023)) or in other groups who have reduced upper limb function due to neurological conditions (e.g. stroke survivors in the chronic phase of recovery or people with Multiple Sclerosis, brain, and spinal cord injuries). If evaluated in groups with moderate to high wrist/digital spasticity a DHO with more extensor assist strength (e.g. the SaeboFlex) may be required. The intervention could also be provided in a 1:1 therapist:stroke survivor format in stroke survivors who display willingness but lack capacity or the ability to engage in upper limb rehabilitation in a self-directed format.

The accessible nature of the intervention creates a novel research opportunity as for the first time it offers a unified upper limb therapy approach and context that could be studied in different groups of stroke survivors side by side to understand their differing treatment responses. For example the intervention could be used in the following groups along with a respective control group –

stroke survivors with (1) no active digital extension, (2) active but reduced digital extension and (3) full digital extension (but without using a DHO/SaeboGlove). Such work could be paired with baseline imagining (e.g. brain MRI, corticospinal tract motor evoked potentials elicited by transmagnetic stimulation) to better understand the recovery potential of these groups.

4.6 Conclusions

Conducting this RCT was challenging. The Covid-19 pandemic increased trial complexity and disrupted trial activities. Only one of the two participating Health Boards (one of six participating hospitals) had a dedicated therapy research resource. Additionally, seven interested NHS Health Boards/Trusts in Scottish and English were unable to participate due to them having nil/negligible therapy research resources. These factors negatively impacted recruitment and highlight a lack of stroke therapy research resources in Scotland and England.

Despite these challenges, the EMPOWER Help for Hands intervention was found to be a safe intervention that significantly improved upper limb function (ARAT Grasp, Grip, Pinch and Total) immediately post intervention in stroke survivors with reduced upper limb function and severe hand impairment including reduced or absent active digital extension, wrist, elbow, or shoulder movement. A significant improvement in upper limb impairment (FMUE Hand and total) in favour of the EMPOWER intervention was also observed at this timepoint. An improvement in these outcomes was sustained at the 14 week visit but without significant. Thus, the sustainability of the between group differences observed at the 6 week time point remains uncertain.

To the author's knowledge this is the first upper limb intervention that has been found to improve upper limb function in stroke survivors with severe hand impairment including absent active digital extension. Further adequately powered RCTs, possibly with an increased intervention duration (e.g. for the time while there are active rehabilitation goals to work on) or increased statistical power, are required to ensure that treatment effects are optimal, sustained, and identifiable.

Chapter 5

Process evaluation in the SUSHI Trial: A descriptive qualitative analysis of factors relating to self-management support that moderate, or influence, intervention fidelity from a stroke survivor, carer, and therapist perspective

5 Chapter 5: Process evaluation in the SUSHI trial: A descriptive qualitative analysis of factors relating to self-management support that moderate, or influence, intervention fidelity from a stroke survivor, carer, and therapist perspective

5.1 Introduction

Chapter 1 highlighted key challenges facing upper limb rehabilitation and recovery after stroke and proposed non-robotic dynamic hand orthoses (DHOs) as aids to rehabilitation with the potential to overcome many of these challenges regardless of active digital extensor weakness severity. Unmet physical rehabilitation needs and preferences of stroke survivors were described (insufficient therapy provision, information and support, use of meaningful and progressive rehabilitation tasks, and empowerment) (McKevitt *et al*. 2011; Luker *et al*. 2015; Stroke Association 2016; Abrahamson and Wilson 2019). Furthermore, the need to structure existing rehabilitation services and interventions in ways that help to fulfil these perceived unmet physical rehabilitation needs and preferences was emphasized to optimise positivity and coping (Luker *et al*. 2015), and therapy motivation and engagement essential in rehabilitation (Langhorne *et al*. 2011; Meadmore *et al*. 2019; Meads *et al*. 2020).

Chapter 1 also highlighted that stroke rehabilitation interventions are typically complex interventions i.e. they have several components that often interact and/or rely on human behaviour to successfully deliver them as they are intended (Skivington *et al*. 2021). It emphasized that this complexity makes measuring the relative effectiveness of components of such interventions difficult, standardising, recording, and describing such interventions complex, and interpretating and replicating findings in intervention trials that evaluate complex interventions a particular research challenge (DeJong *et al*. 2004; N. Kristensen *et al*. 2016; Pfadenhauer *et al*. 2017).

The EMPOWER Help for Hands Programme is a complex intervention involving a dynamic hand orthosis (DHO) that attempts to respond to the perceived unmet rehabilitation needs set out in Chapter 1. Chapter 3 summarised the initial

development of this programme (Pilot version) by the author of this thesis prior to this doctorate commencing and highlighted learning gained from the results of a related feasibility pilot trial (The SaeboGlove Evaluation Trial (T-SET)) and a subsequent Patient and Public Involvement (PPI) activity.

Chapter 3 also highlighted that, to overcome the challenges inherent in complex intervention evaluation and to successfully develop sufficient evidence-base to be able to influence policy and practice surrounding complex interventions, an outcome evaluation should be accompanied by a process evaluation (Luker *et al*. 2016; Public Health England 2018b; Rodgers *et al*. 2020). Consequently, a mixed methods approach involving a process evaluation was justified in the methodology selected to evaluate the EMPOWER Help for Hands programme in the SUSHI trial (Chapter 3).

Chapter 4 summarised further refinement of the EMPOWER Help for Hands intervention (Version 1.0) in response to the development activities described in Chapter 3. It also reported the outcome evaluation (RCT) in the SUSHI trial which randomised participating stroke survivors to receive (1) usual care plus the EMPOWER Help for Hands Programme (self-directed, repetitive functional-based upper limb practice supported using a dynamic hand orthosis and four upper limb therapy progress reviews), or (2) usual care plus additional upper limb usual care (therapy input based on National Clinical Guidelines i.e. self-directed and repetitive functional-based practice that was supported through the provision of four upper limb therapy progress reviews). It found that although the SaeboGlove group received less upper limb therapy time with a therapist during the intervention period (weeks 1-6) they carried out more upper limb therapy without a therapist and overall (with and without a therapist) during weeks 1-6 and 1-14 (Table 29) and had a significant improvement in upper limb function (Action Research Arm Test (ARAT) score) immediately post intervention.

This chapter reports the process evaluation designed and conducted to understand adherence to/engagement with the EMPOWER Help for Hands programme (Chapters 3, Figure 15, and Chapter 4, Table 18 (Alexander *et al*. 2021b), above) in the outcome evaluation (RCT) reported in Chapter 4. The findings from the process evaluation are intended to complement the findings in

the outcome evaluation by aiding their interpretation and translation into other settings.

The process evaluation includes a descriptive qualitative analysis of factors relating to support that moderate, or influence, adherence to/engagement with the intended implementation of this self-management intervention (fidelity) from a stroke survivor, carer, and therapist perspective (Figure 24).

Figure 24: Assessment of factors that moderate (or influence) adherence to/engagement with the intended intervention implementation (fidelity)

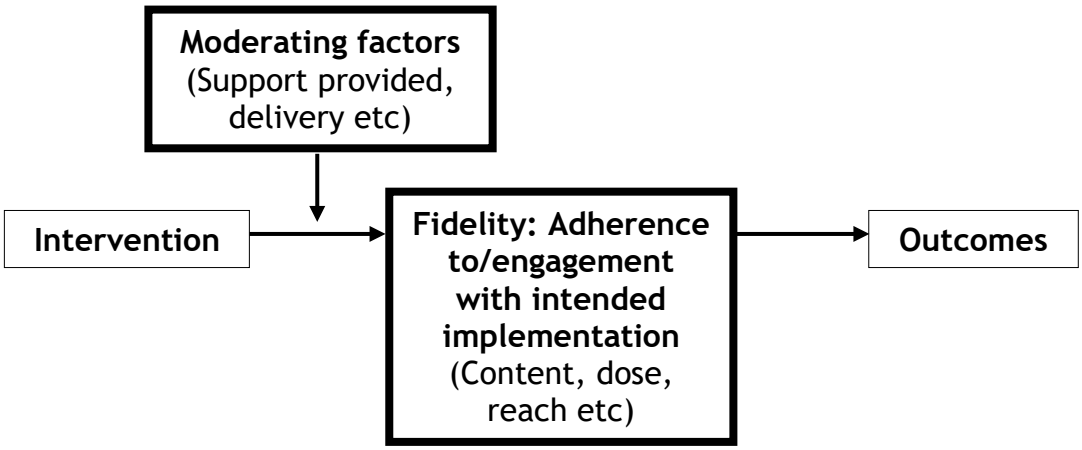


Figure 24 is used and adapted from Carroll *et al.* 2007, available at: A conceptual framework for implementation fidelity | Implementation Science | Full Text (biomedcentral.com) under a Creative Commons CC BY 2.0. Full Terms at Creative Commons — Attribution-NonCommercial 2.0 Generic — CC BY-NC 2.0

The process evaluation will address Objective 2b from Chapter 1.

5.2 Objectives

The objective in this process evaluation was:

- To explore, understand and describe factors relating to support that moderate, or influence, intervention fidelity of the EMPOWER Help for Hands self-management programme in the SUSHI trial from a stroke survivor, carer, and therapist perspective

5.3 Methods

5.3.1.1 Summary of design & regulatory approval

The process evaluation was concurrent and embedded within the RCT reported in Chapter 4 (Alexander *et al*. 2021b) with data analysis taking place independently for the purpose of complementarity (Chapter 3). It therefore involved the same setting and same pool of stroke survivors allocated to the SaeboGlove group. It used a generic inductive descriptive qualitative analysis of semi-structured interviews with stroke survivors randomised to receive the EMPOWER intervention in the RCT, informal supporting carers and clinical occupational and physiotherapists to explore and describe factors relating to self-management support that appeared to moderate, or influence, the fidelity of intervention implementation.

Regulatory approvals were gained as part of the RCT as reported in Chapter 4.

The Consolidated criteria for reporting qualitative research interviews and focus groups (COREQ) was used to ensure quality reporting and methodological rigor (Tong *et al*. 2007).

5.3.1.2 Sampling

Stroke survivors randomised to the SaeboGlove group in both participating Health Boards in the RCT in Chapter 4, their informal supporting carers and clinical occupational and physiotherapists were sampled. These groups were included to capture differing perspective on the self-management support needs of stroke survivors based on their experiences either supporting (carers and therapists) or being supported with (stroke survivors) the therapy early after stroke.

As the goal of qualitative research is to obtain a rich understanding of different experiences due to contextual influences purposive sampling (where individuals are selected based on desired characteristics) was used to enhance contextual variation (Palinkas *et al*. 2015). Consistent with this approach, to optimise variation sampling was iterative i.e. those who were initially recruited influenced the characteristics of subsequent recruits (Palinkas *et al*. 2015).

Interviews were mainly carried out over the first 12-18 months of the study to stagger the study workload and were carried out within eight weeks of stroke survivors completing the EMPOWER programme to offer flexibility and convenience for interviewees while aiding accurate recall.

Stroke survivors provided their written consent to be invited to take part in the qualitative interviews when enrolling for the RCT. They were then selected from an anonymised study database to ensure representation of stroke survivors from both participating health boards and those differing in gender (male, female), age (≤65 years, >65 years), time since stroke (≤1 month, >1 month), severity of upper limb disability (ARAT 0-10, 11-28) and informal carer support (informal carer/no informal carer). No stroke survivors with an ARAT of 29-46 were included as this group was introduced late as part of the first substantial amendment (Chapter 4, Table 14), represented a small (7/39=18%) and more capable group and only one stroke survivor in this group was recruited in the time between the amendment being approved and the available interview timeline. However, this stroke survivor was not invited for interview as it was not felt to be appropriate as she fell and broke her affected upper limb soon after the intervention had finished and was therefore dealing with other care priorities. Stroke survivors were not excluded due to cognitive or language impairments, but these characteristics were not specifically measured in the RCT to reduce participation burden and therefore could not inform the sample frame.

Informal carers of interviewed stroke survivors were selected to capture their perspective on the self-management support needs surrounding the intervention. Selection was made to capture their experience supporting stroke survivors with different characteristics (gender (male, female), age (≤65 years, >65 years), time since stroke (≤1 month, >1 month), severity of upper limb disability (ARAT 0-10, 11-28) and their experience providing informal carer support (acting as sole carer, sharing care with formal carer(s)).

All therapists were working in a stroke rehabilitation unit in one of the two participating health boards. Therapists were selected to ensure representation according to their discipline (occupational/physiotherapist), experience (post seniority: band 5 rotational, band 6 rotational, band 6 stroke specialist with time

(years) working in stroke rehabilitation being recorded) and exposure to stroke survivors differing in carer support (informal carer/no informal carer). Therapists observed the intervention intermittently and often supported stroke survivors with aspects of their daily practice (e.g. donning the SaeboGlove) when informal carer support was limited/unavailable (formal carer). Efforts were made to involve therapists (clinical or research) in the delivery of reviews to increase transferability of findings to other therapy settings as the delivery of complex interventions often varies (Pfadenhauer *et al*. 2017). Although clinical teams were very enthusiastic about doing this limited clinical therapy resources and the absence of stroke research therapy staff and infrastructure meant that resources did not permit this.

5.3.1.3 Recruitment

Stroke survivors and therapists were sent a letter of invitation to take part in up to two interviews (Appendix M) and an information sheet (Appendix M). Carers who were selected were invited in the same letter sent to stroke survivors. Stroke survivors and therapists were asked to respond by contacting the SUSHI research team by telephone or email. Stroke survivors expressed their personal interest and nominated any invited interested carers if the stroke survivor him/herself was agreeable to this.

After one week non responders were contacted by a member of the SUSHI research team by telephone to ask if they were interested. If a message was left on their answering machine with a family/staff member asking them to call the study team and they did not return the call within a two week period, it was presumed that they did not wish to take part.

Respondents who expressed interest were telephoned by a researcher conducting interviews. The researcher explained the purpose of the interview(s) and agreed a meeting time and place with a private room (at the stroke survivors' local hospital and during their inpatient stay where possible/at therapist's place of work) that was convenient to the stroke survivor (with/without carer)/therapist for a first interview to take place. Stroke survivors and supporting carers were interviewed together (interview lasting no

more than 1.5 hours) or separately (each interview lasting no more than one hour) depending on their preference/convenience.

At the end of the initial interview, interviewees were asked for their permission to be contacted for a potential second interview if the interviewer had any questions that needed clarified during his/her analysis of the initial interview. If they declined, they were not contacted. However, if they agreed and clarification was needed, they were contacted by telephone for a second interview lasting no more than 30 minutes (i.e. increased/prolonged engagement with interviewees) to ensure sufficient understanding (Corbin and Morse 2003; DeJonckheere and Vaughn 2019). Prior to any potential second interview, stroke survivors/therapists were re-contacted by a researcher to check that they were still willing to take part in the second interview.

Written consent to be interviewed was sought prior to each interview (Appendix M).

5.3.1.4 Data collection

The purpose of this qualitative study was to gain sufficient understanding of the self-management support needs influencing the implementation of the intervention to be able to implement it successfully in a clinical context. To do this an in-depth understanding of the context surrounding the users experience was felt to be essential. For this reason, individual interviews were chosen over focus groups to allow more time to discuss topics/deviant cases in detail (prolonged engagement (Corbin and Morse 2003; DeJonckheere and Vaughn 2019)). Similarly, semi-structured interviews were chosen over structured interviews to allow flexibility for additional questioning to gain a thick description of experiences encountered e.g. on the beliefs and motives that influenced experiences/therapy engagement or factors that emerged as being important to interviewees that had not been previously anticipated (prolonged engagement (Corbin and Morse 2003; DeJonckheere and Vaughn 2019)).

Additionally, individual semi-structured interviews are often the preferred method for researchers to explore and capture representative views of individuals who are vulnerable or who may feel inhibited sharing sensitive

information (Box and Shawe 2014; Dean *et al*. 2014; Crowe *et al*. 2015; Dempsey *et al*. 2016) while simultaneously ensuring that they feel safe and at ease (Dempsey *et al*. 2016). Cognitive, language and mood deficits are common after stroke (Stroke Association 2018). Although all stroke survivors sampled had capacity, no specific limits for such deficits were set in the eligibility criteria (Chapter 5). Furthermore, the opinions of therapists with differing experience levels and seniority, and therefore possibly differing views were sought. Thus, an individual semi-structured interview format was also felt to be the best method to obtain an honest and rich account of the experiences encountered by more vulnerable individuals or therapists with mixed levels of experience.

Interviews were conducted face-to-face and covered key areas influencing implementation such as the impact of stroke, their therapy experience, barriers/facilitators to successful implementation/engagement, expectations, and impact of usual NHS stroke rehabilitation and the EMPOWER programme. Acceptability of the EMPOWER programme and motives to get involved in the trial were also covered (Table 39). Additionally, for carers and therapists, their relationship to stroke survivors and role supporting rehabilitation was clarified and explored for context (Table 39).

Table 39: Topic guide for stroke survivors, informal carer & therapist interviews

	Stroke survivors	Carers	Therapists
Relationship to stroke survivor & role in supporting stroke recovery			
Relationship to stroke survivor & role in supporting their recovery		✓	✓
Stroke impact			
Stroke impact	✓	✓	✓
Stroke rehabilitation - NHS service provision			
Experience/perceptions of support received/delivered Barriers/facilitators encountered or anticipated Expectation/benefit & impact	✓	✓	✓
EMPOWER programme			
Acceptability of intervention & motive to get involved in trial Experience/perceptions of support received/delivered Barriers/facilitators encountered or anticipated Expectation/benefit & impact	✓	✓	✓

Questions were similar for all groups but not identical and followed an interview guide (Appendix N) that was piloted on a stroke survivor and therapist from another upper limb rehabilitation study. Questions were based on those utilised in another mixed methods upper limb intervention trial with a similar design (Rodgers *et al*. 2020), with minor project specific modifications made and agreed in conjunction with a qualitative expert in the researcher's supervisory team (LK).

For stroke survivors and carers questions focused on their own experience of stroke and therapy. For therapists questions focused more on their professional views on the EMPOWER programme and routine therapy provision within NHS

stroke services including what worked well and didn't, and how the EMPOWER programme may impact routine NHS services and best be supported in such an environment.

Questions were open ended to avoid leading language and probing techniques were used with sufficient time to encourage people to offer more detail where further understanding or clarification seemed important (prolonged engagement) (Corbin and Morse 2003; DeJonckheere and Vaughn 2019).

Interviews were audio-taped with the interviewees written consent. Additionally, the researcher(s) conducting the interviews wrote field notes to aid interpretation of interview data later.

5.3.1.5 Data Management and Qualitative Analysis

Transcription

Interviews were transcribed using transcription software (Trint 2021), then anonymised and checked for accuracy with corrections made to create a verbatim transcript to minimise bias.

Thematic Analysis

Interview data were then analysed using Thematic Analysis, an approach that aims to identify, understand and construct themes within a dataset (Braun and Clarke 2006). Thematic Analysis consists of six stages that were followed; familiarisation with the data, generating preliminary codes, searching for themes among the codes, reviewing the themes, defining and naming the chosen themes and producing the final report (Braun and Clarke 2006).

Familiarisation with the data: Audio recordings were listened to during the transcription process. Transcripts and field notes were re-read several times and factors relating to self-management support that appeared to moderate implementation were highlighted and given a keyword in the margin.

Generating preliminary codes: Transcripts were read again to identify potential moderators of implementation/engagement from the dataset with particular attention given to highlighted text. Preliminary codes for moderators of

intervention fidelity from a supported self-management perspective were systematically and manually identified and labelled in Microsoft word. Previous transcripts and preliminary codes were repeatedly reviewed leading to the removal, division or joining of some preliminary codes and the eventual formation of final codes.

Searching for themes among the codes: Codes were then reviewed to identify patterns which were developed into themes. The apparent importance of codes in relation to the study objective were considered. Additionally, to aid the identification of patterns, the audit trail of data convergence from transcripts and to help all involved researchers independently assess and confirm/refute the findings i.e. to establish that data and interpretations of the findings were clearly derived from the data (Johnson *et al*. 2020) the frequency of the appearance of codes were also considered (Tables 45-47 below).

Reviewing the themes: Following these patterns in the data codes were organised into broader themes and sub-themes. A coding tree of themes/subthemes was constructed (Section 5.2.4.3). The data associated with each theme/subtheme and then the data set as a whole were reviewed (constantly compared) to ensure that each theme/subtheme was true to the data. To aid quality and rigor, the structure and interpretation of the tree and data supporting it was then peer reviewed leading to subsequent refinement (peer debriefing) (Johnson *et al*. 2020).

Defining and naming themes: The developed themes were then named, and each sub-theme was given a brief description to summarise its coverage. To prevent bias qualitative analyses were completed prior to the commencing of analyses in the RCT.

Producing the final report: Illustrative quotes were selected to evidence named themes/subthemes with reflections made to ensure they related to the objective of this qualitative study.

Sample size

Data saturation, the stage in qualitative research when sufficient data have been gathered to allow for appropriate conclusions to be made, is often considered to

be the gold standard for determining the end point of qualitative analyse (Guest *et al*. 2006; Roy *et al*. 2015). Despite this, definitions and descriptions of this standard vary (Low 2019; Braun and Clarke 2021). Some researchers have attempted to 'operationalise' data saturation and offer specific recommendations on the number of interviews required to reach it prior to data collection and analysis (Guest *et al*. 2006; Constantinou *et al*. 2017). However, others view this as 'oversimplistic', believing that ongoing insights are inevitable with ongoing data collection (Low 2019; Braun and Clarke 2021). Instead, they favour a more pragmatic approach that recognises that data saturation judgements are generated through data interpretation in relation to the research question and are therefore subjective and cannot wholly be determined in advance (Low 2019; Braun and Clarke 2021). Consistent with the pragmatic approach to this work justified in Chapter 3, a pragmatic approach to data saturation was adopted, as explained further below.

The sample size was determined using an iterative approach to data collection and analysis. Initially, a purposive sample representing more than 20% of the SaeboGlove group and with at least six participating stroke survivors in the SaeboGlove group (12/55 (22%)), four carers and four therapists (two physiotherapists and two occupational therapists) from each Board were planned with final numbers for each of the three groups being determined by saturation of themes (where no new themes in the data arose) (Francis *et al*. 2010) and resources permitting. However, Covid-19 disruptions and challenges opening other recruiting sites due to limited clinical therapy resources/therapy research staffing and infrastructure meant that fewer stroke survivors were recruited to the RCT than planned (39 instead of 55). Additionally, much more stroke survivors were recruited in one of the Health Boards (NHS GGC) due to greater Covid-19 restrictions in research activity in the other Board (NHS Lanarkshire) (87% (34/39) versus 13% (5/39) respectively). Additionally, a large amount of rich data representing all key characteristics set out in the sampling plan had been collected and themes from data collected were consistent between different health boards, groups and individuals, and no new themes were identified from the last interview from each group suggesting that data saturation had been reached (Francis *et al*. 2010).

This meant that interviews were stopped after interviewing 18% (6/34) and 20% (1/5) of the SaeboGlove group at NHS GGC and NHS Lanarkshire respectively. It also meant that while four carers, two occupational and two physiotherapists were interviewed in NHS GGC as planned, only one carer, one occupational and one physiotherapist from NHS Lanarkshire were interviewed.

5.3.1.6 Research team & reflexivity

Unlike quantitative research, the researcher is integral to the qualitative research process, including the data collection and analysis, and any conclusions drawn and the influence of bias, therefore, is more difficult to control (Al-Busaidi 2008; Bryman 2008). Consequently, researcher reflexivity is the gold standard for determining trustworthiness in qualitative research and involves giving systematic consideration to the context in which knowledge is constructed, particularly the researchers background and role as it has the potential to influence/bias the findings (Teh and Lek 2018).

Six researchers were involved in this qualitative process evaluation and contributed to the write up (LK, JD, PL, FVW, JA, CS). The role of these researchers in the trial and their background will now be reported for transparency to aid reflection on their potential influence on the research process and outcomes.

Trial design & oversight: To ensure the design was constructed based on the experiences and influences of multiple researchers with differing backgrounds and expertise five of the researchers were involved in the planning of this qualitative study (LK, JD, PL, FVW, JA). They also contributed to the design of the outcome evaluation in this thesis.

LK, JD, PL and FVW are Professors in nursing, stroke medicine, stroke medicine and neurological rehabilitation respectively. All provided academic oversight to the SUSHI trial. LK is a specialist in qualitative and implementation science research and provided expertise, oversight, and guidance at all stages to ensure methodological quality. JD was the Chief investigator in the SUSHI trial and JD, PL and FVW supervised the work in this thesis. JA is a physiotherapist, specialist in stroke rehabilitation and the author of this thesis.

Conduct of study: Three of the researchers involved in the trial design (LK, JD, JA) and a further sixth researcher who was not (CS) conducted study activities: sampling (JD), recruitment, interviews and transcription (CS and JA for the first 10 and last eight respectively) and analysis (Initial coding: JA and CS independently for the first 10 and JA only for the last eight due to resource limitations). Peer review took place (JA and CS for each other and in conjunction with JD and LK) to check for researcher bias and to review data and the final themes/subthemes and findings (peer debriefing) (Johnson *et al*. 2020), with disagreements between individual judgements being resolved through discussion. None of the researchers, except JA, were known to interviewees prior to the interviews taking place.

CS is a male and was a fourth-year medical student in his early 20s carrying out an intercalated research course to gain qualitative research knowledge/experience when the interviews took place. CS had no prior experience of stroke care or rehabilitation prior to his involvement in this process evaluation and consequently was likely to have little preconceptions to influence the research process.

Motivation and role of primary researcher (JA): JA is a female and was in her early 40s with 16 years of experience in stroke rehabilitation when this research was conducted. She had held a full-time stroke research position in NHS Greater Glasgow and Clyde for seven years. She has written this thesis and led the programme of research in it, developed the EMPOWER Help for Hands programme and delivered therapy reviews to all the stroke survivors interviewed in this process evaluation. Her motivation for doing this came from awareness that poor upper limb outcomes after stroke, and the treatment options available in her field to help people recover and alleviate associated distress, had remained unchanged throughout her career. A desire to empower and enable people after stroke to positively influence their own recovery, to respond to their understandable wish for the stroke care community to prioritise identifying new effective upper limb treatments (Pollock *et al*. 2014c) and to better understand stroke survivor and carer perspectives on the self-management support needs for such treatments were additional drivers. It is recognised that preconceived ideas she may have had from her previous stroke rehabilitation

experience may impart bias on the study findings (Teh and Lek 2018). Consequently, such potential influences were sense checked throughout the data collection and analysis processes by keeping a field note diary of her reflections and peer debriefing discussions to ensure all interpretations were considered.

Interviewee/interviewer relationship: Negative effects have been proposed when a clinical relationship exists between an interviewee and interviewer. A possibility being that, because of such a relationship, interviewees may feel an obligation to participate, or feel unable to speak honestly about their experience, particularly negative experiences (Kvale 1996; Hoddinott and Pill 1997; Richards and Emslie 2000). To negate this potential effect the second interviewer (JA) only interviewed interviewees after the intervention period had ended. Additionally, at the start of each interview she always emphasized that she was very keen to hear about the negative, as well as positive, experiences interviewees had to allow the therapy to be improved further so that more people could ultimately be supported to use the therapy more successfully in the future.

Positive effects of an established relationship in qualitative research include interviewees feeling more comfortable, and being in an environment that is better equipped to deal with any upset that may arise (Hoddinott and Pill 1997). Trust and a rapport in qualitative interviews are considered paramount to ensure that interviewees are at ease and feel able to talk freely (Kvale 1996; Hoddinott and Pill 1997). These characteristics are essential in therapeutic clinical relationships (Chipidza *et al.* 2015; Jackson 2017) and may well have already been well established between JA and the people she interviewed. Thus, these characteristics combined with her declaration of her wish to identify and ameliorate factors that could hinder successful therapy participation may have enabled stroke survivors to feel safe enough to speak honestly.

5.3.1.7 Rigor & reporting

Chapter 3 highlighted that transparent reporting and demonstrating methodological rigor, known as trustworthiness, in qualitative research is essential to reduce the subjectivity and potential bias associated with such methods and to assure "trustworthiness" of findings (Lincoln and Guba 1985; Sandelowski 1993; Rolfe 2006).

To ensure transparent reporting and demonstrate methodological rigor/trustworthiness in this qualitative study the Consolidated criteria for reporting qualitative research interviews and focus groups (COREQ) was used (Appendix O) (Tong *et al*. 2007). Additionally, a summary of methods adopted to improve rigor/trustworthiness are summarised in Table 40 overleaf (Korstjens and Moser 2018; Johnson *et al*. 2020; Ramanadhan *et al*. 2021) based on the qualitative rigor criteria set out in Chapter 3 (Table 11, above) (Lincoln and Guba 1985; Korstjens and Moser 2018).

Table 40: Summary of methods used to enhance rigor in qualitative study

Criteria for rigor*	Summary of methods used to enhance rigor
Credibility The confidence that the research findings are 'truthful' i.e. represent the participants' original data/views and the context.	Purposive sampling Prolonged engagement Deviant cases explored Constant comparisons between data and interpretation with peer debriefing between four researchers Thick description of interviewee views to gain in-depth understanding of intervention/intervention context with illustrative quotes to evidence themes Triangulation of methods (field notes, audio recording & transcription), sources (stroke survivors, informal carers & therapists, two health boards) & researchers (JA, CS, LK, JD) Validation of findings (lay summary in Appendix P) by interviewees to check accuracy
Transferability The degree to which the research findings can be transferred to other contexts/settings or with other groups of participants.	Purposive sampling Recruitment until no new themes were identified (saturation) Thick description of interviewees, setting and findings
Dependability The stability of findings over time if the inquiry were replicated with the same participants in the same context.	Audit trail of methods Researcher reflexivity on motivations/possible bias Deviant cases explored Peer debriefing between four researchers Themes derived from verbatim transcripts Triangulation of methods (field notes, audio recording & transcription), sources (stroke survivors, informal carers & therapists, two health boards) & researchers (JA, CS, LK, JD)
Confirmability The degree to which the findings of an inquiry are determined by the participants and conditions of the inquiry and not by the biases, motivations, interests, or perspectives of the inquirer i.e. they are clearly derived/confirmed by the data.	Audit trail of methods Researcher reflexivity on motivations/possible bias Triangulation of methods (field notes, audio recording & transcription), sources (stroke survivors, informal carers & therapists, two health boards) & researchers (JA, CS, LK, JD) Validation of findings (lay summary in Appendix P) by interviewees to check accuracy Findings concluded prior to knowing RCT findings

***Summarised from Lincoln and Guba 1985**

5.4 Results

5.4.1 Sample

The sample included 18 interviewees: seven stroke survivors, five carers and six therapists (Tables 41 and 42 respectively).

No stroke survivors, carers or therapists declined to be interviewed, be contacted for a possible follow-up interview, or dropped out during the study. Two stroke survivors (P3, P6) were invited for a brief follow-up interview to seek clarity on interpretation during the analysis of the initial interview and both accepted.

5.4.2 Stroke survivors, carers, and therapists

Stroke survivors and carers

The characteristics of stroke survivors for both health boards including any carer support they received and which stroke survivors had an informal carer interviewed are presented in Table 41.

Table 41: Stroke survivor characteristics and carers interviewed

Stroke survivor	Gender	Age	Time since stroke (days)	UL severity		Disability (mRS)	Informal carer	
				Function (ARAT)	Hand impairment (FM Hand)		Supporting trial therapy?	Interviewed?
P1	Male	79	39	15	3	4	Y	Y
P2	Male	74	24	9	2	4	Y*/**	Y
P3	Male	73	46	4	2	4	N**	-
P4	Female	82	21	11	2	4	Y	Y
P5	Female	61	24	13	2	3	Y	Y
P6	Female	64	59	0	3	4	N**	-
P7	Male	52	7	18	2	4	Y	Y

ARAT: Action Research Arm Test, FM: Fugl Meyer, mRS: Modified Rankin Score, N: No, P: Participating stroke survivor, Y: Yes, *Informal carer help three days/week, **Some help from healthcare professionals provided

All stroke survivors were white and Scottish as all stroke survivors recruited during the timeline available for the qualitative study were white and Scottish. Additionally, they were all still receiving usual NHS care therapy at the time of their interview. Although the cognitive and language deficits of interviewed

stroke survivors were not specifically recorded, they were considered retrospectively by interviewers to be mild.

Four stroke survivors were male and three were female. Their mean (SD) age was 69.3 years (10.7), median (IQR, range) 73.0 years (18.0, 52-82), time since stroke 31.4 days (17.5) median 24.0 days (25.0, 7-59), upper limb function (ARAT) was 10.0 points (6.3) median 11.0 (11.0, 0-18). Their median (IQR) hand impairment (FM hand) was 2.0 (1.0, 2-3) mean 2.3 points (0.5) and disability (modified Rankin Score) was 4.0 (0.0, 3-4) mean 3.9 (0.4). All participating stroke survivors received at least some carer help, four (57%) from an informal carer, two (29%) from formal carers (healthcare professionals) and one (14%) from a combination of informal and formal carers.

Six of the stroke survivors were from Health Board 1 and one was from Health Board 2.

Demographics were not collected for carers.

Therapists

Three physiotherapists and three occupational therapists were interviewed, with each discipline having a range of experience in terms of their post seniority and time working in stroke rehabilitation (0.3-26.4 and 0.5-11.1 years respectively) (Table 42). Two physiotherapists and two occupational therapists were from Health Board 1 and one physiotherapist, and one occupational therapist was from Health Board 2.

Table 42: Therapist characteristics

Therapist	Experience		Experience supporting stroke survivor…	
	Post seniority	Time working in stroke rehabilitation (years)	…with informal carer	…without informal carer
PT1	Band 5, rotational	0.3	Y	N
PT2	Band 6, rotational	1.6	Y	N
PT3	Band 6, stroke specialist	26.4	Y	Y
OT1	Band 5, rotational	0.5	N	Y
OT2	Band 6, rotational	1.5	Y	N
OT3	Band 6, stroke specialist	11.1	Y	N

OT: Occupational therapist, PT: Physiotherapist

As planned, all interviews took place within eight weeks of the intervention finishing, on a median (IQR, range) of 9.5 (24.5, 21-51) days after the intervention finished (Table 43).

Table 43: Interview day relative to last intervention day (Day 0)

Interviewees	Interview day relative to last intervention day
P1	13
P2	-1*
P3	8
P3+	9
P4	51
P5	21
P6	9
P6+	10
P7	-6**
P1's carer	13
P2's carer	16
P4's carer	51
P5's carer	21
P7's carer	-6**
PT1	-21***
PT2	13
PT3	-7****
OT1	8
OT2	-9****
OT3	29

Reasons for early interviews: *Scheduling, **Covid outbreak started, and disruption anticipated, ***Imminent discharge date for stroke survivor being supported and therapist was rotating to a different hospital, ****Stroke survivor being supported had already left the inpatient service, +Follow-up interview

5.4.3 Overview of coding tree of constructed themes and subthemes and transcripts containing data supporting them

Four main themes were prevalent across the entire data set (Themes 1-4) (Table 44) and contributed to the fulfilment of the research objective (Section 5.2.2). All themes were formed from a number of subthemes, each representing a distinct facet within the broader theme (Table 44 overleaf).

Themes 1-3 are factors relating to self-management support that moderate, or influence, implementation of/engagement with stroke rehabilitation in general i.e. they are not specific to the EMPOWER intervention but provide important contextual information to inform its further development and implementation. However, all four themes include factors relating to self-management support that moderate, or influence, the EMPOWER intervention.

Table 44: Coding tree of constructed themes and subthemes: Factors relating to support that moderate, or influence, fidelity of the EMPOWER Help for Hands Programme

Theme		Sub-theme
1	Rehabilitation is hard work	Physical demand
		Emotional demand
2	Stroke severity heightens the rehabilitation challenge and support required	Range and magnitude of symptoms
		Post-stroke fatigue
3	More meaningful upper limb therapy is needed/wanted	Restoring normality* lost due to upper limb problems is needed/wanted
		Therapy is valued to restore normality* and fuels perseverance despite the rehabilitation challenge
		Limited engagement in upper limb therapy limits normality* recovery
		Limited engagement in meaningful** therapy tasks limits motivation and normality* recovery
4	The EMPOWER*** intervention is acceptable and HELPs**** support engagement	**H**ope to recover normality* is instilled and expectations are fulfilled
		Efforts are rewarded through meaningful** progress and structure
		Lends sufficient physical and emotional support in daily self-practice
		Physiotherapist experience, expertise, and alliance provides much needed physical and emotional support

***Normality = carrying out desired pre-stroke everyday activities/roles, having usual pre-stroke self-image and usual pre-stroke emotional wellbeing**

****Meaningful therapy/recovery = therapy/recovery clearly relates to movement in the stroke affected upper limb that stroke survivors need to be able to use that upper limb to restore normality**

*****EMPOWER principles (Intervention components) = Equips patients with the tools needed (e.g. SaeboGlove, written/video instructions) to carry out meaningful exercise involving everyday tasks (e.g. eating, drinking, self-care), Motivates patients by setting shared intensity goals, logging/monitoring daily self-practice activity and identifying and overcoming barriers to daily self-practice exercises, Provides a progress review every 1-2 weeks so that exercises remain challenging and progressive, Optimises self-management support at therapy reviews by coaching independence in exercises, progression, and tailoring, Weans from help provided for some/all exercises as able (e.g. reduce help provided by SaeboGlove bands and glove), Engages carer support whenever possible, and Reminds participants of the ultimate goal and need to transfer knowledge and skills gained into everyday life (e.g. increase use of the stroke affected hand in everyday tasks).**

******HELPs = Hope to recover normality is instilled and expectations are fulfilled, Efforts are rewarded through meaningful progress and structure, it Lends sufficient physical and emotional support during daily self-practice, and Physiotherapist experience, expertise, and alliance provides much needed physical and emotional support**

The number of transcripts containing data supporting Themes 1-2, 3 and 4 along with their included sub-themes are presented in Tables 45, 46 and 47 respectively.

Table 45: Transcripts containing data supporting Themes 1-2 and included subthemes

Transcripts	Themes 1-2 with subthemes			
	1 Rehabilitation is hard work		2 Stroke severity heightens the rehabilitation challenge and support required	
	Physical demand	Emotional demand	Range and magnitude of symptoms	Post-stroke fatigue
Participating stroke survivor (n=7)				
P1	✓	✓	✓	-
P2[NDH]	✓	✓	-	✓
P3[NDH]	✓	✓	-	✓
P4	✓	✓	✓	-
P5	✓	✓	✓	✓
P6[NDH]	✓	✓	-	-
P7[NDH]	✓	✓	✓*	✓
Carer (n=5)				
P1	✓	✓	✓	✓
P2[NDH]	-	✓	✓	-
P4	✓	✓	-	-
P5	✓	✓	✓*	✓
P7[NDH]	✓	✓	✓*	✓
Physiotherapist (n=3)				
PT1	✓	✓	✓	✓
PT2	✓	✓	✓	✓
PT3	-	-	✓	-
Occupational Therapist (n=3)				
OT1	✓	✓	✓	-
OT2	✓	✓	✓	✓
OT3	✓	✓	✓	✓
Total interviewees / groups (n = 18 / 4)	16 / 4	17 / 4	14 / 4	11 / 4
	17 / 4		16 / 4	

[NDH] = Non dominant hemiparesis, * = Fatigue only

Table 46: Transcripts containing data supporting Themes 3 and included subthemes

Transcripts	Themes 3 with subthemes			
	3 More meaningful** upper limb therapy is needed/wanted			
	Restoring normality* lost due to upper limb problems is needed/wanted	Therapy is valued to restore normality* and fuels perseverance despite the rehabilitation challenge	Limited engagement in upper limb therapy limits normality* recovery	Limited engagement in meaningful** therapy tasks limits motivation and normality* recovery
Stroke survivor (n=7)				
P1	✓	✓	✓	✓
P2[NDH]	✓	✓	✓ (A-C+)	-
P3[NDH]	✓	✓	✓ (M)	-
P4	✓	✓	✓ (M)	✓
P5	✓	✓	✓	✓
P6[NDH]	✓	✓	✓ (M)	-
P7[NDH]	✓	✓	✓ (M, A-C+)	✓
Carer (n=5)				
P1	-	✓	✓	✓
P2[NDH]	-	✓	-	-
P4	-	✓	-	-
P5	-	✓	-	-
P7[NDH]	✓	✓	✓ (M, A-C+)	-

M/A-C: Upper limb deprioritised in and out of therapy in favour of Mobility (M) or activities of daily living using Compensatory (i.e. unilateral upper limb) strategies (A-C)
NDH: Non dominant hemiparesis
+: perceived lack of need by stroke survivors to engage the affected upper limb in activities of daily living due to the limited function required within a hospital environment until discharge planning/discharge home
***Normality = carrying out desired pre-stroke everyday activities/roles, having usual pre-stroke self-image and usual pre-stroke emotional wellbeing**
****Meaningful therapy/recovery = therapy/recovery clearly relates to movement in the stroke affected upper limb that stroke survivors need to be able to use that upper limb to restore normality**

Transcripts	Themes 3 with subthemes			
	3 More meaningful** upper limb therapy is needed/wanted			
	Restoring normality* lost due to upper limb problems is needed/wanted	Therapy is valued to restore normality* and fuels perseverance despite the rehabilitation challenge	Limited engagement in upper limb therapy limits normality* recovery	Limited engagement in meaningful** therapy tasks limits motivation and normality* recovery
Physiotherapist (n=3)				
PT1	✓*** (ULR<LLR)	✓	✓ (M)	✓
PT2	✓*** (ULR<LLR)	✓	✓ (M)	✓
PT3	✓	✓	✓ (M)	✓
Occupational Therapist (n=3)				
OT1	✓***	✓	✓ (A-C+)	✓
OT2	✓***	✓	✓ (A-C)	✓
OT3	✓*** (ULR<LLR)	✓	✓ (M, A-C)	-
Total interviewees / groups (n = 18 / 4)	14 / 4	18 / 4	15 / 4	10/4
	18 / 4			

M/A-C: Upper limb deprioritised in and out of therapy in favour of Mobility (M) or activities of daily living using Compensatory (i.e. unilateral upper limb) strategies (A-C)
+: perceived lack of need by stroke survivors to engage the affected upper limb in activities of daily living due to the limited function required within a hospital environment until discharge planning/discharge home
***Normality = carrying out desired pre-stroke everyday activities/roles, having usual pre-stroke self-image and usual pre-stroke emotional wellbeing**
****Meaningful therapy/recovery = therapy/recovery clearly relates to movement in the stroke affected upper limb that stroke survivors need to be able to use that upper limb to restore normality**
*****upper limb recovery is often poor, especially when weakness is severe, ULR<LLR: upper limb recovery poorer than the lower limb recovery**

Table 47: Transcripts containing data supporting Theme 4 and included subthemes

Transcripts	Theme 4 with subthemes							
	4 The EMPOWER*** intervention is acceptable and HELPs**** support engagement							
	Hope to recover normality* is instilled and expectations are fulfilled	**Efforts are rewarded through meaningful** progress and structure**	**Lends sufficient physical and emotional support during daily self-practice**				**Physiotherapist experience, expertise, and alliance provides much needed physical and emotional support**	
			SaeboGlove		Carer		Information/ Guidance	Tailoring
			Ph	E	Ph	E		
Participating stroke survivor (n=7)								
P1	✓	✓	✓	✓	-	✓	✓	✓(1P)
P2[NDH]	✓	✓	✓	✓	✓	-	✓	✓(1P, 2)
P3[NDH]	✓	✓	✓	✓	✓	✓	✓	✓(1P, 2)
P4	✓	✓	✓	✓	✓	✓	✓	✓(1, 2)
P5	✓	✓	✓	✓	✓	✓	✓	✓(1V, 2S)
P6[NDH]	✓	✓	✓	✓	✓	✓	-	✓(1)
P7[NDH]	✓	✓	✓	✓	-	✓	✓	✓(1, 2S)
Carer (n=5)								
P1	✓	✓	✓	✓	✓	✓	✓	✓(1PV, 2S)
P2[NDH]	✓	✓	✓	✓	✓	✓	✓	✓(1PV)
P4	✓	✓	✓	✓	-	✓	✓	✓(1)
P5	✓	✓	✓	✓	✓	✓	✓	✓(1PV, 2S)
P7[NDH]	✓	✓	✓	✓	✓	✓	✓	✓(1, 2S)

NDH: Non dominant hemiparesis, Rehabilitation demand – Ph: Physical, E: Emotional. Tailoring – 1: Tailoring of therapy (e.g. tasks, intensity goals) and support provided at review visits, tailored support may include a preference for paper instructions (P), video instructions (V) or both paper and video instructions (PV), 2: Tailoring by stroke survivors/carers in daily practice, tailoring may include scheduling of daily commitments (e.g. usual care therapy, visiting) (S) to manage fatigue/rest and self-practice. *Normality = carrying out desired pre-stroke everyday activities/roles, having usual pre-stroke self-

image and usual pre-stroke emotional wellbeing, **Meaningful therapy/recovery = therapy/recovery clearly relates to movement in the stroke affected upper limb that stroke survivors need to be able to use that upper limb to restore normality, ***EMPOWER principles (Intervention components and ****HELPs principles: Please see Table 44 above.

Transcripts	Theme 4 with subthemes							
	4 The EMPOWER*** intervention is acceptable and HELPs**** support engagement							
	Hope to recover normality* is instilled and expectations are fulfilled	Efforts are rewarded through meaningful** progress and structure	Lends sufficient physical and emotional support during daily self-practice				Physiotherapist experience, expertise, and alliance provides much needed physical and emotional support	
			SaeboGlove		Carer		Information/ Guidance	Tailoring
			Ph	E	Ph	E		
Physiotherapist (n=3)								
PT1	✓	✓	-	✓	✓	✓	✓	✓(1P, 2S)
PT2	✓	✓	✓	✓	✓	✓	-	✓(1, 2S)
PT3	✓	✓	✓	✓	✓	✓	✓	✓(1V)
Occupational Therapist (n=3)								
OT1	✓	✓	✓	-	✓	✓	✓	✓(1, 2S)
OT2	✓	✓	✓	✓	✓	✓	✓	✓(1P, 2S)
OT3	✓	✓	-	-	✓	✓	-	✓(1, 2S)
Total interviewees / groups (n = 18 / 4)	18/4	18/4	18/4				18/4	
	18/4							

Rehabilitation demand – Ph: Physical, E: Emotional.
Tailoring – 1: Tailoring of therapy (e.g. tasks, intensity goals) and support provided at review visits, tailored support may include a preference for paper instructions (P), video instructions (V) or both paper and video instructions (PV), 2: Tailoring by stroke survivors/carers in daily practice, tailoring may include scheduling of daily commitments (e.g. usual care therapy, visiting) (S) to manage fatigue/rest and self-practice
***Normality = carrying out desired pre-stroke everyday activities/roles, having usual pre-stroke self-image and usual pre-stroke emotional wellbeing**
****Meaningful therapy/recovery = therapy/recovery clearly relates to movement in the stroke affected upper limb that stroke survivors need to be able to use**

that upper limb to restore normality
*****EMPOWER principles (Intervention components and ****HELPs principles: Please see Table 44 above.**

5.4.4 Description of factors relating to self-management support that moderate, or influence, intervention fidelity of the EMPOWER Help for Hands programme in the SUSHI trial from a stroke survivor, carer, and therapist perspective

Theme 1 - Rehabilitation is hard work (Interviewees / groups 17/4)

The first major theme "Rehabilitation is hard work" highlighted that rehabilitation participation after stroke was felt to be a challenging process. Two sub-themes contributed to this theme, with each highlighting different aspect of the challenge encountered (i) Rehabilitation is physically demanding and (ii) Rehabilitation is emotionally demanding.

Physical demand (Interviewees / groups 16/4):

There was a shared sense across the transcripts that engaging in rehabilitation was physically hard and typically involved sustained physical effort to make meaningful (desired/useful) progress.

> '…every time [we went to a SaeboGlove review] we knew that within the two week period [between reviews] that that was where we we're going to go [progress] to…we kind of knew that the next stage would be difficult…Knowing that, oh there's more hard work.' (P5's carer)

> '…they [stroke survivors] need to…put in hard work…if somebody is willing to put the work in, I have found [in usual NHS care] that they do get more back whereas if somebody is just like not willing to do exercise out with [1:1] therapy then they will be slower to recover or maybe not recover.' (OT3)

Emotional demand (Interviewees / groups 17/4):

Notably, the emotional demands involved in engaging in rehabilitation after stroke were even more prevalent across the transcripts than the physical demands (17/18 versus 16/18 transcripts) (Table 45).

Emotional demands widely centred around the emotional upset of having had a stroke and/or the need to expend effort to engage in a process where progress, or success was seen as uncertain or falling short of their hopes or expectations. A fear of trying and failing, engaging but experiencing disappointment /frustration or feeling overwhelmed by the process and feeling like 'giving up'

were all raised and highlighted as common challenges to rehabilitation motivation and perseverance.

> '…if you give in and say you can't do this, you're not going to progress…Whether you actually achieve that [progress] or not is in the lap of the gods…You've just got to be able to hope that you know, if you keep at it hard enough, you'll be able to do it, if not tomorrow, the next day…you can feel quite drained' (P4)

> 'Obviously with such a significant change [in normal life post-stroke], their mood can be affected quite easily and everyone can understand that so…it can be very hard to get them to engage in the whole [usual NHS rehabilitation] process [in general] and then that can obviously limit the input they are receiving…and [if] they aren't making the functional gains that they would like…that can feed into that like whole "well if it's not really working for me then what is the point in trying. So that can be really difficult…' (PT2)

Theme 2: Stroke severity heightens the rehabilitation challenge and support required (Interviewees / groups 16/4)

The second major theme "Stroke severity heightens the rehabilitation challenge" highlighted how the severity of the symptoms encountered after a stroke can increase the challenge to successfully engaging in rehabilitation by increasing the physical and emotional demands to do so. Two prominent sub-themes contributed (i) The range and magnitude of symptoms and (ii) Post-stroke fatigue.

The range and/or magnitude of symptoms (Interviewees / groups 14/4):

The range and/or magnitude of the symptoms encountered after a stroke (e.g. weakness, inattention, sensory disturbance, spasticity, cognitive or perceptual deficit, mood disturbance, fatigue, swelling) were noted across all four groups to contribute to the challenges an individual encounters participating in rehabilitation. This was often accompanied by recognition that this increased challenge would necessitate increased external support to be able to successfully engage in rehabilitation.

> '..before the glove…the hand would just lie there…whatever the stroke's done to his brain [resulted in him having an inattention], he forgets he's got that hand there. So, sometimes he forgets he can use that for things [activities] and I kind of have to remind him that hand's there.' (P1's carer)

> ‘Well, I think that [challenges we encounter encouraging rehabilitation through self-management in usual care therapy includes]…people who probably are cognitively affected…so they will…need the verbal prompts, guidance…that one to one…input to try and work on [the] upper limb…There's obviously the people who have got...sensory impairment who have poor awareness of their affected side [inattention] and don't even realise they’ve got a side that is not working properly. So, you've got these challenges to try and overcome, eh, yeah. I think there are some people, that…want everything done for them or to them…They just are not motivated...to help themselves...I guess pain is another thing, if they're sore, they might not want to do it… then again you know if they've got family that you know are good at motivating them, or therapists…then possibly that would help…’ (PT3)

Post-stroke fatigue (Interviewees / groups 11/4):

Post-stroke fatigue was more prevalent than any other (non-motor) post-stroke symptom across the transcripts. It appeared to increase both the physical and emotional challenges associated with rehabilitation and highlighted the difficulties encountered by all groups when trying to balance managing fatigue and rehabilitation participation to aid overall recovery.

> ‘...you're tired. I mean, you're physically tired, so you're doing something [rehabilitation] that's making [you] even tireder...I think the challenges come from the fatigue…I didn't go "yippee, let’s do that [therapy] today…’ (P5)

> ‘…we [each therapy discipline] aim for them [stroke survivors] to be seen for 45 minutes but [for] quite a lot of the patients, quite a big symptom from stroke is fatigue so they just can't be in a gym setting with you chucking loads of stuff at them for 45 minutes…’ (PT2)

Theme 3 – More meaningful upper limb therapy is needed/wanted (Interviewees / groups 18/4)

This theme highlighted that all interviewees unanimously felt that stroke survivors wanted/needed more upper limb therapy to try to optimise upper limb recovery, and this appeared to be the central driving force for them to access and participate in additional rehabilitation opportunities. More meaningful, intensive, or self-management orientated upper limb therapy options were particularly favoured and appeared to contribute to this drive.

Four sub-themes contributed to this theme (i) Restoring normality lost due to upper limb problems is needed/wanted, (ii) Therapy is valued to restore

normality and fuels perseverance despite the rehabilitation challenge, (iii) Limited engagement in upper limb therapy limits motivation and normality recovery, (iv) Limited engagement in meaningful therapy tasks limits motivation and normality recovery.

Restoring normality lost due to upper limb problems is needed/wanted (Interviewees/groups: 14/4):

Upper limb problems were reported to have a big impact after stroke, contributing significantly to the loss of independence and normality experienced. Such problems were frequently linked to a reduced ability/independence in carrying out everyday tasks previously taken for granted (e.g. getting out of bed, washing & dressing, making meals, using cutlery, opening containers/packets, eating usual foods, wearing usual clothes, standing up from a chair, using a walking aid or mobile phone) and extended ADL, hobbies and interests (e.g. DIY repairs, driving, playing guitar, piano, knitting, crochet, poker, working out, controlling/holding dog, gardening). They also contributed to a loss of different life roles both at home (e.g. due to the need to rely on family for care, difficulty sharing burden of everyday household/family tasks such as making meals, playing with or caring for children, mowing grass) and out with the home (e.g. unable to write a birthday card to a grandchild or type/write at work) and appeared to negatively impact stroke survivors self-image (e.g. due to the loss of their good posture and/or the physical person they once were). This loss of abilities, independence, roles and self-image in normal (i.e. desired pre-stroke) life associated with upper limb problems was often linked to negative emotions (e.g. feeling frustrated, burdensome, or dissatisfied in life). Consequently, trying to recover some normality (abilities, independence, roles, self-image and emotional wellbeing) after stroke was a priority for all groups interviewed.

> ‘No, no, I couldn't do any of that [wash my hair]. I couldn't, I couldn't feed myself, there was no, I mean zero movement in my right hand…And it felt terrible having to rely on people [dissatisfied]…[I’m] Not back driving or working, starting to write…I mean, I want to go back to work part time…I am…a trained yoga instructor…[so] not having that posture…I looked at myself…in the mirror…and I thought ‘it’s just a poor soul’, I didn't like what I saw…my arm was completely dead…like a ton weight on my body…I want to get better…I want to

> achieve the best I can be. I want to achieve 98 percent if I can't get 100 percent…' (P5)

> 'Hugely. I feel it's [the impact of upper limb problems on the lives of the stroke survivors has] got a vast impact on people's lives…It can be quite a loss of different roles…and independence with both kind of personal care…but also then the kind of wider scope of extended tasks, work, and the different activities that people would like to do…if you think maybe a typical day…of being able to do your own sort of grooming, so your hair, brush your teeth, shaving, dressing, ability to dress and do fastenings and buttons, any kind of bilateral tasks, if anyone has an upper limb weakness they've got a marked impairment or difficulty in doing any of those kind of tasks. Eating, feeding…it takes quite a lot of adaption…writing and feeding, kitchen work as well, from just anything…work related…if anyone used their upper limbs predominantly in a kind of work setting, typing, engineering, all those kind of things, driving, there is quite a large impact…I am one of the occupational therapists so I am involved in the upper limb…More focusing on…trying to improve the functional use [of it so I am keen on]…anything that is going to ultimately change patient care and patient outcome [for the upper limb]…'(OT2)

Likely reflecting their unique experience being able to draw recovery comparisons across different therapies and stroke survivors, Therapists (5/6) highlighted that although the recovery of upper limb problems required to restore normality was perceived to vary, it was typically felt to be poor, with 3/6 therapists perceiving it to be poorer than the lower limb (Table 46). Poor upper limb recovery was particularly felt to be poor for stroke survivors with more severe upper limb weakness who were perceived to recover less pre-stroke normality i.e. have more persistent problems.

> 'I feel that predominantly…you see the recovery more in the bigger joints, so possibly from an upper limb point of view you might see more recovery around the shoulder and the elbow…[but] you need kind of recovery throughout all your joints to lead on to more kind of functional use…My experience is that it [upper limb recovery] probably is less so than the lower limb [and] I am finding that the more dense [upper] limb weakness [is] in the initial stages, we are not seeing the same recovery…'. [OT3]

Therapy is valued to restore normality and fuels perseverance despite the rehabilitation challenge (Interviewees / groups 18/4):

Unanimously across all transcripts was the belief that rehabilitation, upper limb or otherwise, was valuable as it offered the means to help restore normality that had been lost due to stroke. This was often accompanied by the belief that

more rehabilitation participation would lead to more recovery and was therefore needed/wanted. Thus, such beliefs around the value of rehabilitation were felt to fuel motivation, perseverance and personal effort and support ongoing therapy engagement despite challenges encountered.

> '[I believe] More physiotherapy [is valuable for my recovery], I benefit from physiotherapy…I don't just mean psychologically, I mean physically better…[I got involved in the trial as normally] I'm quite a physical person. I run, I jog, I play sports, I'm active, I walk my dog …I drive, I want to get back to work, I want to ride my bike…And the bike is a big part of my life. I cycle, I cycled almost everywhere, to work, to the shops sometimes, em, to the school…for parents' night I would cycle…it's what I do. I always have done. I cycled the length of the country once, I enjoy it. It keeps me fit…I play with my children. Em, I cut the grass, I use a lawnmower. I do the gardening…These are all drivers for me [to engage in rehabilitation], big [drivers]…Sometimes it's [trial therapy] a real effort, but I don't hide from that. It has been challenging in some cases, some of the movement has been difficult. But I feel positive about the challenge. And in the main, I've overcome them. And what I take that to mean is that [the trial therapy] gives me a better functionality than I would have had without it. Unquestionably, in my view.' (P7)

> '…he was so motivated [to engage in therapy as he believed it could recover some independence]…always willing to do more…and that really showed…[at]…first…he had no movement at all and then…he was managing to shave, get himself washed, open…things…there is only so much that we [therapists] can do but they need to take ownership…and be willing to put in hard work and try and progress, I think their participation and motivation is probably one of the biggest [most important] parts of their own rehab [for progress to occur]...' (OT2)

Limited engagement in upper limb therapy limits motivation and normality recovery (Interviewees / groups 15/4):

Although more therapy was felt to lead to greater restoration of pre-stroke normality, therapy time was felt by all groups to be limited by limitations in NHS resources in both health boards. Consequently, such views appeared to drive interviewees motivation to engage in/support additional therapy participation to supplement the usual NHS therapy provided in hospital, with self-management opportunities such as the EMPOWER programme being favoured.

> '…they've [inpatient NHS therapists] only got so much time like, ya know. Then they move on [to the next person]…You could maybe say today I could maybe do a wee bit more like…I don't think I would

> be…as advanced [in progress] as this like, you know, getting 15/20 minutes [only] every day for five days…There is only so much [recovery] you can do in a gym [in usual NHS therapy] like in 15 to 20 minutes and…compared to four hours with this glove [trial therapy]…' (P2)

> 'it can always be quite a slow process to try and increase the strength [so] it just seems that it would be quite a positive thing [trial involvement]…if they [stroke survivors] are like the motivated patient who self manages as much as possible then that is like a window [potential recovery opportunity] right there where you could get them to do so much more that we [therapists] don't necessarily have the time…to spend with them to do all that extra stuff…Because like [the] 45 minutes [of 1:1 inpatient NHS therapy time we aim for] out of their day is not really that long when you think about it and they all say that they're bored and they want more to do' (PT2)

Resource constraints were not felt to be restricted to the hospital environment but were also reported to limit upper limb rehabilitation after discharge when awaiting or involved in community rehabilitation. Thus, more upper limb rehabilitation was also felt to be wanted/needed to try to optimise recovery after discharge home.

> 'Take all the help [therapy] we can get…that glove [trial therapy] has…given the both of us [me and my husband] so much…because there was three and a half weeks that I was out of hospital before I saw an NHS physiotherapist. So that would of been a lost three and a half weeks [of recovery progress]…If I hadn't taken the opportunity of this SUSHI [Saebo]Glove I wouldn't have seen anyone for three and a half weeks.' (P5)

> '…we [physiotherapist] were chatting…about upper limb rehab and how it sort of seems to…not be the main focus of things [in inpatient rehabilitation]. And when people go into community…things [upper limb rehabilitation] sort of seem to stop. So it [trial therapy] seemed really interesting…something that the patients could concentrate on and something that the family members can get involved with… obviously they [SaeboGlove group participants] get a better chance…[to improve their upper limb recovery]' (PT1)

Although interviewees expressed that they wanted more upper limb therapy and recovery, limited NHS resources were often perceived to result in the need to divert resources to other competing rehabilitation priorities, often to facilitate discharge home. Five examples of this resource diversion were evident across the transcripts:

- More therapy time dedicated to recovery of the lower limb/mobility
- More therapy time dedicated to recovery of independence in activities of living without use of the affected upper limb
- Less upper limb therapy time when impairment is more severe
- Less 1:1 therapist time dedicated to the upper limb as upper limb rehabilitation was often transferred to stroke survivors, support workers or family
- Rehabilitation for the upper limb was often a small and/or passive part of another intervention

These examples will now be presented for context to highlight the competing priorities that appeared to be driving interviewees wish for increased upper limb therapy opportunities in the face of perceived resource limitations:

More therapy time dedicated to recovery of the lower limb/mobility: There was widespread agreement across all groups that there was a greater emphasis on and more opportunity available for lower limb/mobility versus upper limb therapy. This pattern was observed in and out of formal 1:1 NHS therapy.

> '[if it wasn't for the study] the hand versus the lower limb therapy is quite a contrast in time that's devoted to it…when you've only got a [1:1 usual NHS therapy] visit once a week [at home] then you've got a few days where you don't have anything [1:1 NHS therapy] on. So, I think it's been good that he [participating stroke survivor] can do it [trial therapy] himself…[out with formal 1:1 therapy on] the down days…he's so determined to…progress between sessions…he does work hard in between...' (P7's carer)

> '…there is not so much kind of [upper limb] self-management [therapy]…out with formal [1:1] therapy sessions [in usual NHS care]…[but] on the ward [out with 1:1 therapy] if somebody gets a bit of recovery in their lower limb they are more likely to be up and standing more…mobilising more [with the nurses on the ward]…getting

> used more than potentially the upper limb…so…I was happy that we were having something [trial therapy] that was going to supplement the normal…therapy' (OT3)

More therapy time dedicated to recovery of independence in activities of living without use of the affected upper limb: A similar pattern was observed across three groups for therapy involving the practice of activities of daily living using compensatory strategies within formal therapy. Tasks that would normally be executed using two upper limbs were often adapted and practiced without the affected upper limb to prioritise functional independence in the task over upper limb rehabilitation and restoration.

> 'I can do [dress] all the top bit [of my body] myself…and [my Occupational Therapist] was showing me how to put my bra on…I've to fasten it first and put it on [one handed] like a jumper…over your head…I just shuffle it about until you get it on.' (P6)

> '…one of my ladies was wanting to write a birthday card for her Grandson and she realised she couldn't do it [with her right dominant affected hand] so we had to work with her other upper limb. Teaching her how to be left-handed…we had one lady who was only about 46 and…we were having to teach her how to wash her hair with only the left [unaffected] hand…putting the bottle of shampoo, like, directly onto her head…using the left hand to massage it in…' (OT1)

Less upper limb therapy time when impairment is more severe: Limited upper limb therapy time due to competing priorities was often felt to be more pronounced in people with more severe upper limb impairment. Reasons for this appeared to centre around a perception that other rehabilitation efforts were likely to be more worthwhile given resources available i.e. that it was better to divert limited resources to types of therapy considered to be more fruitful in this group or across therapy caseloads, more able stroke survivors who were perceived to be faster progressing and therefore more motivated to engage, more capable of engaging physically and/or mentally in the rehabilitation process or to less dependent stroke survivors to facilitate a swifter discharge home.

> 'there wasn't a lot of room for that kind of therapy [upper limb therapy] while I was in the hospital because…of the physical limitations of my hand and arm…so the therapy, it was extremely useful and they did work very hard, but it tended to concentrate on other aspects of…you know, getting you ready to go home, you know…

> that was one thing that obviously was very much in their minds. You know, they wanted it to be able to transition [transfer]…and make sure that you could safely move to a chair, you know, that kind of thing, that was all covered very adequately…I don't think…[there] was very much what they could have done, frankly, given obviously that they were very stretched.' (P4)

> 'I suppose it [the rehabilitation process in people with different severities of disability] comes down to priority…in the kind of time constraints of the ward…it might be that somebody is needing discharged and there is a lot more [1:1] input needed so maybe somebody who is more on the dependent level of the scale, their [1:1 therapy] intensity [i.e. time] maybe drops for a short time…so that there might be times when there is more intensity for those who are functionally more able and likely to be progressing…' (OT3)

Less 1:1 therapist time dedicated to the upper limb as upper limb rehabilitation was often transferred to stroke survivors, support workers or family : As well as receiving less upper limb therapy time in general, time constraints often meant that dedicated 1:1 time with a qualified therapist was also more limited for the upper limb compared to other forms of therapy (e.g. rehabilitation involving the lower limb/mobility, ADL). This often meant that there was a feeling that upper limb therapy needed to be transferred/relegated in some way to stroke survivors, support workers or family.

> 'I think it's…more [usual NHS therapy] with my leg [than my arm that I get] because I can sit and do certain things with my hand [myself] that I can't do [myself] when I'm walking.' (P3)

> '…I can't spend as long on the upper limb as I would maybe on the lower limb and standing [due to competing priorities],…I always try and do a bit of upper limb, but I would try to say to the patient, 'These are things you can do yourself'…I would show relatives…things' (PT3)

Rehabilitation for the upper limb was often a small and/or passive part of another intervention: Additionally, competing priorities meant that time allocated to the upper limb was often not dedicated solely to it, instead it was often a small and/or passive component of another intervention e.g. the upper limb was placed on a surface passively or with weight bearing encouraged through it during the practice of another more predominant standing or ADL task.

> ‘If I'm walking too much [in therapy] and need a rest and they'll [therapists] say we'll do your arm noo while you’re sitting [resting], it’s in-between [walking].’ (P3)

> ‘…[therapy may involve] a functional task, like self-care or kitchen or quite structured kind of cognitive tasks, but you would always…try and incorporate the upper limb…even if it was a case of just having it placed so they are getting a wee bit more of a bilateral feedback into the brain…more kind of passive than a more active capacity (OT3)

Limited engagement in meaningful therapy tasks limits motivation and normality recovery (Interviewees / groups 10/4):

There was a consensus that upper limb therapy tasks that were meaningful (i.e. clearly related to pre-stroke normality) were particularly useful to recover normality and this increased motivation to engage. Typically, this was accompanied by a declaration that the link between upper limb therapy tasks and the restoration of normality was limited in NHS therapy and that more meaningful NHS therapy was therefore needed/wanted to drive therapy engagement to aid recovery i.e. to help them fulfil therapy goals they valued thereby making effort expended seem more likely to be worthwhile.

> ‘[It is important in rehabilitation to know] where that [exercise you are given] leads to [in your life], ‘you've got to be able to do that [exercise] because that leads to be able to write, et cetera, et cetera’. And then I think, well, I want to be able to do that…[but] The NHS therapy…I just don't feel it’s as goaled, as specialised…towards helping me move this hand, and it working [as the trial therapy], disjointed, a little bit disjointed. I'm not…being negative, but still good, still good advice…’ (P5)

For therapists, their wish for more meaningful therapy was often linked to challenges they encountered trying to engage stroke survivors in such activities. In stroke survivors with more severe upper limb weakness this difficulty was mainly due to the limited treatment options they had available to them to aid recovery given the lack of active movement present in the upper limb.

> ‘…we were just discussing this the other day…me and some of the other physios. We haven’t had much recovery in upper limbs recently…it [the upper limb] can just be quite difficult to work on [therapy] if somebody's got a really dense weakness you are quite limited in what you can do with them obviously just trying to maintain their range of movement in all their joints…I think probably just having a bit more specific equipment [like the SaeboGlove] to do with

> [the] upper limb would be quite helpful [for us as therapists to aid recovery]…[to]…lead your therapy…different tasks you could do with them…[to help] grade it up as the movement gets better' (PT2)

However, sometimes therapists wish for more meaningful upper limb therapy options centred more around a challenge to offer sufficient variety to maintain interest and engagement, regardless of severity i.e. limited availability of meaningful tasks in general.

> 'I think honestly, like the glove that has been used in the trial…is quite good for rehab as well because…[in] our usual [NHS] therapy there is only so much you can do before it can become quite repetitive…you do get a bit stuck and you're like I don't know what else to do…there is only so many times you can [remain motivated to] stack cones or pick up marbles. We do try and adapt things…use more cones or smaller cones or smaller items…it [trial therapy] is just different ideas and something new…anything that could help somebodies' recovery…it is worth trying.' (OT2)

Despite this perceived need/want for more meaningful therapy to help restore normality three groups (not physiotherapists) expressed that the true magnitude of this need was not evident prior to the introduction of more complex functional tasks around discharge home. This was because there was felt to be limited essential need for bilateral upper limb use in hospital prior to this time, particularly for stroke survivors who's dominant upper limb was unaffected as unilateral strategies were felt to be less challenging to them (e.g. in hospital stroke survivors are often confined to their bedside with no need for independence in meal preparations and can easily/naturally simplify pre-stroke clothes choices or food preferences from a menu to avoid the need to use two hands in this setting). Consequently, this limited function required in hospital was felt to reduce stroke survivors perceived need for therapy engagement until this point when the value of participating in meaningful therapy tasks earlier became more evident.

> '…within the hospital there was less emphasis on my arms [to understand its need at home]…Once I got home…It became clear to me that…for the functionality I required [at home]…the physical therapy hitherto was not quite adequate…In hospital I typically had soup to eat [selected meals to avoid need for a knife and fork], so it didn't strike me that…how to use a fork was an immediate concern [need]…My right [dominant] hand is unaffected…[At] home and when I've begun to eat different foods [along with my family] and try and

> use a fork [and]…getting dressed I've always worn loose jogging pants and t-shirts [in hospital]…and [at home] I have my full wardrobe, clearly, putting on trousers, putting on a belt, em, fastening a shirt were things I never tried in a hospital…' (P7)

> 'He's still in this kind of hospital bubble and [I] don't think he's realising what's going to happen at home yet…we took him to the kitchen [in preparation for discharge]…he didn't realise how much he was [over] using that right [dominant unaffected] hand [in hospital due to his left upper limb being affected],…[in the kitchen he was] having to hold jars…open tins…and spread butter, all with his left [affected] hand, I don't think he quite realised [how much he needed the affected hand] until we did the practical stuff [kitchen practice prior to discharge], coz he's sitting there every day and the nurses are giving him the tea and coffee every day and the toast…when he realised this is how it's going to be when you go home, I think [it]…gave him a bit more motivation [to do more therapy involving the affected hand].' (OT1)

Theme 4 – The EMPOWER intervention is acceptable and HELPs support engagement (Interviewees / groups 18/4)

This theme highlighted that all interviewees unanimously felt that the intervention represented a welcome opportunity for stroke survivors with severe hand impairment to improve their normality. This was because it enabled them to acquire additional therapy support, including knowledge, that they needed/ wanted to self-manage the rehabilitation challenges they encountered and/or support the therapy engagement needed to try to aid meaningful progress.

Four sub-themes contributed to this theme (i) **H**ope to recover normality* is instilled and expectations are fulfilled, (ii) **E**fforts are rewarded through meaningful** progress and structure, it (iii) **L**ends sufficient physical and emotional support during daily self-practice, and (iv) **P**hysiotherapist experience, expertise, and alliance provides much needed physical and emotional support.

Hope to recover normality* is instilled and expectations are fulfilled** ***(Interviewees / groups 18/4):

This sub-theme highlighted, unanimously across all transcripts, that the intervention was perceived to be acceptable. Prior to commencing the EMPOWER Programme the intervention made sense to all groups that the glove and/or help provided could assist people with hand opening difficulties to access and engage better in more hand (and arm) therapy. Consequently, it

represented a chance to try something different that offered additional hope and a sense of renewed control over their ability to aid meaningful recovery.

> ‘Just normal [everyday] movements all involve use of your right hand…the object of the study obviously was explained that it was particularly good to involve movements of the hand…that is what made me very keen to join…it certainly makes perfect sense…the action of the, the glove…the movements that they were trying to sort of maximise, shall we say. It certainly sounded perfectly sensible that something of that kind would be, would be useful…’ (P4)

> ‘…it seemed like a good idea if this glove can help…getting people to engage and…be able to…do…kind of functional activity because…it is allowing for them to be able to do that [functional-based] movement that they would otherwise not be able to do themselves [through usual care therapy alone] and it's obviously the repetitions [the glove allows] that feed into neuroplasticity that are, em, hopefully going to help their recovery of…upper limb hand function…you know [and] if they've got family [to support it] that…would help…’ (PT3)

All stroke survivors interviewed required assistance to get the glove on due to limited finger movement, cognitive issues and/or other perceived challenges at the time of their recruitment. Some interviewees felt that the SaeboGlove looked complicated when they first saw it. However, some stroke survivors gained independence putting it on due to improved movement or familiarity as therapy progressed. Importantly, despite any challenges encountered/anticipated using it, it was perceived to be easy to use after demonstration and use first hand and the intervention seemed to fulfil or even exceed expectations.

> ‘Well, everything [in the trial therapy] was useful, everything was useful, but the glove helped with my hand which to me was good. And everything was what it said it would do, it says on the tin ‘It will help you with do this’ and the next thing [it is] [fulfilling hopes/expectations]…but, pretty much happy with it…Well, it [therapy without the glove] wouldn't of got me to open my hand up as I have got now…[Instead of waiting for staff to help me put it on] I just started putting it on [taking control]…The first time it was very, well, no very difficult, it was difficult as you hadn't done it before…After that it was alright, it was alright after that…You found ways to put it on [independently]…’ (P3)

> ‘…[the research physio] was…showing us the glove and showing us the exercises that patients would do as well which was really interesting…it's [trial therapy] good because his family can, can see

> what he's doing and they've been taught how to put it on and take it off…It's just really good to see him doing all these exercises and how much better that he is getting at them as well and…I thought it [putting the glove on] would be a little bit more complicated than it actually is [when I initially saw it] but once it is…explained and shown how to take it on and off [it's not complicated]…Yeah, so I think expectation wise it has been really good.' (PT1)

<u>E</u>fforts are rewarded through meaningful** progress and structure (Interviewees / groups 18/4):

Meaningful progress in the trial was observed in many forms across all transcripts (e.g. going from no hand movement to hand movement, curled fingers and a droopy wrist to straight fingers and the ability to control/move the wrist, needing the glove to perform functional-based movement to not needing it, stroke survivors not using the hand out with therapy in normal everyday functional tasks to using it in such tasks, doing little movement before becoming fatigued to doing more, having slow or no progress with the recovery of desired movements to having clearer/faster progress and having reduced proximal compensation from the start to finish).

Such progress created positivity which in turn supported ongoing therapy participation as the effort to engage seemed worthwhile. For example, interviewees appeared to make a direct link between stroke survivors' self-practice of exercises provided and progress made in these exercises which increased drive to participate in daily self-practice therapy.

> 'I looked forward to it [trial therapy]…to see what else [other movement progress would] kick in [start]…before [I started trial therapy] I could not open my hand…and then…After about two or three times [i.e. days] with the glove [my hand opening and closing got better]. Quick, quickly…it helped get my hand going…definitely…I [can now] hold, a pot of [face] cream [without the glove in my trial therapy]…' (P6)

> '…we had been doing a little bit of work during most [usual NHS physiotherapy] sessions with his upper limb and we had started to plateau a little…but everything was improving when he was part of the trial…Obviously if something is starting to get better they just generally feel a bit better and they'll be a wee bit more motivated… just before the trial started the patient was unable to complete the 9-hole peg test [in his NHS physiotherapy]…and certainly [now without the glove] when he is sitting [at his bedside] he would try and use cutlery [provided for his trial therapy] with…two hands together [the

> knife and fork simultaneously], he was trying…drinking [in his trial therapy too]…it [his hand/arm function] has certainly come on quite a bit.' (PT2)

Similarly, increasing habitual use of the affected hand in day-to-day life was another component of the programme (Figure 15 in Chapter 3, Table 18 in Chapter 4) and progress made engaging in it created positivity that meaningful recovery was taking place. Consequently, a direct link between stroke survivors' participation with this component and progress made in everyday life increased drive to engage in this component.

> '…whether I'm picking up a fork or moving a bottle or, or picking a bottle to drink from the project has given me a knowledge [confidence] of arm movement and stability and finger positioning and strength that together gives me a much better ability to function [in life] than I would have had but for the project. I have had some arm [usual NHS] physiotherapy,…and…It was and without a word of criticism, it was vague and inspecific…It enabled me to lift a large cone from the right side and move it to the left side…to lift a bouncy ball and put it…in a cone for example. But the SUSHI project has enabled me to be much more specific than I think that more vague and inspecific physio would have.' (P7)

> '…certainly [before the trial] when he was using the stedy [an aid to stand up and transfer] he was just using his dominant [unaffected] side [only], so just pulling himself up through that side [hand] and [during the trial therapy period]…[unprompted] he was starting to use the two hands together and then…he liked to try to [laughs] just pull himself up with the affected side [only] [and] when he is sitting [in his room] he would try…to do a bit more like drinking and using that [affected] hand to help [in daily life]…I think emotionally it [his trial progress] was probably really positive…he was really invested in the upper limb getting better' (PT2)

There were **two** key components of the intervention that offered structure which appeared to be very useful to help stroke survivors/carers notice progress made thereby driving participation. These components were *'Use of graded exercises including weaning from the SaeboGlove'* and *'Movement repetition and skill targets provided enabled self-monitoring of meaningful progress':*

Use of graded exercises including weaning from the SaeboGlove: The use of graded (i.e. increasingly more challenging) exercises in the programme supported participation by contributing to a sense that progress was expected and being made.

> '…the challenges are a set of exercises that you are given at a session…and, you…try and do these things…because most of these movements are aimed at…hand movements that you want to be able to do…They [exercises provided] become more and more difficult…the earlier exercises not very long ago…seem now to be quite simple…They are now quite normal…And the challenges are being able to do those and move on to the next one…Yes, yes, it's all about the progression…Ooh, yes. No point in stopping still. You've got go for progress all the time because otherwise you stay the way you are, which is not really what you're looking for.' (P4)

> 'I know that [the research physiotherapist] will obviously be coming and adjusting things and maybe making exercises a wee bit harder [as they progress]…it's interesting to see the progressions [in trial therapy] and the different things you can do with it [trial therapy]… But…I've just found that my patient is really motivated to use it…again it's all about the motivation aspects and it's [increasing exercise difficulty] showing that 'I can do this'…setting those challenges and showing progress' (PT1)

For stroke survivors and carers reducing or stopping using the SaeboGlove in daily therapy provided an additional indicator that meaningful progress in self-practice therapy sessions and life was being made. This along with knowledge that the SaeboGlove was only available to them for a limited six week period also appeared to fuel motivation and perseverance to engage.

> '…having the glove…made us try so much harder because…if he couldn't be bothered exercising…we were just like no we will just do it because it saves us from missing a day if the glove is there. If we didn't have the glove it would be like "eugh, let's do it tomorrow…so I think for other patients if it [the SaeboGlove] kind of gets them motivated, once they take it away...in my opinion, I think it's a good thing because…you no longer need it [to continue to progress and it indicates that] so your hand is working fine without it' (P1's carer)

Additionally, all carers and all but one stroke survivor (P7) expressed that six weeks was sufficient time to use the glove with many reporting that they reduced/stopped using the glove during this time as it was no longer needed.

> 'I think the timescale [we had the glove for (approximately four of the possible six weeks)] was, was correct for [my wife]…You need to, to, to remove…the assistance the glove gives you… Because she was, she was more than competent doing…a variety of exercises with the glove so…you think well it's now time to move into the next year of school…' (P5's carer)

Several interviewees offered additional insights to support successful ongoing engagement in therapy participation/progress after SaeboGlove use is stopped if individuals, on occasion, wished to use it for longer. For example, one stroke survivor seemed uncertain if he had had the glove for long enough or not. He had just had his last therapy review around five weeks into the intervention at the time of the interview and had full active digital extension without the glove on so was considered to no longer need the extensor assistance the extensor assist band on the glove provided to make extension easier. Instead, he was given exercises without the glove involving a standard elastic band to resistance [not assist] digital extension movements to progress their strength further. He appeared to associate the glove with rapid progress made and was apprehensive that that would stop when he stopped using it. However, he expressed that he thought that on balance he remained satisfied he could continue with his therapy/progress as he was provided with exercises that built on progress made with the glove and suggested that this approach may help others who wished to use one for longer.

> 'I don't want to give the glove back [laugh]. I still enjoy it…So my understanding from a session I did with [the research physiotherapist] today is that some of the exercises, some of the resistance [assistance from the gloves extensor assist bands] could be …simulated simply by using an [regular] elastic band to resist [increase extensor difficulty], not assist [decrease extensor difficulty]…I think you will with committed participants…find a belligerence to give up the glove…So I think that that level of creativity [with a regular elastic band] might supplant me, provide the patient with that ongoing satisfaction, that ongoing activity. I don't want to, I don't want to lose the benefit of the glove…I want to continue the rapid progress I have made…' (P7)

Additionally, one carer who felt six weeks of glove use had been long enough for the stroke survivor she had supported suggested that it might be reasonable to extend use slightly by a couple of weeks to maintain ongoing therapy satisfaction for stroke survivors who wished to use one for longer.

> 'Yes, as I say, now without the glove he's able to open and close his hand…But I imagine if there is going to be a few percent who are going to be extremely upset about it [the glove being taken back], then maybe they could have it for an extended period of two weeks.' (P2's carer)

No similar comments were made by therapists about weaning of the glove use, possibly reflecting their limited direct input in trial therapy progression and weaning of the glove at therapy reviews.

Movement repetition and skill targets provided enabled self-monitoring of meaningful progress: Stroke survivors and carers widely reported that recording of movement repetitions against an intensity goal (quantity) and movement skill in meaningful tasks against a quality goal highlighted in take-home instructions offered the means for them to self-monitor progress made and to overcome challenges encountered (e.g. insecurities on how/when to self-progress or to problem solve movement difficulties when they arose by referring to instructions provided). This ability to self-monitor and problem solve in turn seemed to create positivity and hope that participation and progress observed was leading to meaningful recovery, or develop insight into the effort (e.g. the number of repetitions) required by stroke survivors daily for desired progress to be made. Consequently, stroke survivors were felt to be more willing to maintain and/or exert greater participation effort and perseverance (e.g. to 'push' further). The following two quotes provide evidence that represent stroke survivors/carers with a preference for video and paper instructions:

> '…self-assessment [was useful]…you improve by consistency, and…by pushing yourself at times. Sometimes it was progress in numbers without the quality…Sometimes with less numbers with better quality. And that [improved quality] was the time to…push a wee bit further [in quantity]… And you know…we'd use the videos that were done [at reviews, on our phone]…I would say, 'well let's watch a wee video here'...[it was] definitely a good tool to, to benchmark [technique and progress]…and say right who's correct…it [the intervention] gave us a structure, it gave us a daily routine…you know…logging what you're doing on a daily basis [repetitions against a goal and exercise duration in their self-management booklet], seeing improvement and then being positive about where that would lead us…it's important to self-monitor on a daily basis…you know, short term i.e. daily. And then with the monitoring [therapy reviews] whether its fortnightly, or three weekly or whatever it is to bring it [progress] home to you' (P5's carer)

> '…the book [provided] is useful, very simple, you just write in how many exercises you done that day…We also had like a page printed off explaining exactly word for word how to do each exercise and how many points to count so…if I wasn't here or somebody else [another carer] was doing it with him it made it easier for him to know what to count and how many he's done and how to mark the book and all that

> sort of stuff. Pretty simple… Aye, [recording repetitions against a target was] definitely [helpful for recovery],…it made us keep going and say [participant] done 50, he would like well if I just done 50 I can do another 50 [100] and then think no I push myself to do 150…because he was trying to serve his goals he was trying a lot harder…even when I was nae here…he was just using his hand all the time [in and out of therapy].' (P1's carer)

Although recording repetitions against a target was felt by stroke survivors/carers to be useful for noticing progress several stroke survivors highlighted that it did increase treatment burden (e.g. was felt to be 'annoying', 'wearisome' or 'a chore'). Nevertheless, the value of recording repetitions was felt to outweigh its burden as all references to it in transcripts suggested it was a key component of the intervention for progress to be made. For example, one stroke survivor expressed that the burden associated with recording repetitions may depend on individual factors (e.g. personality, existing stressors) and require increased support in some instances. She highlighted that in such cases recording repetitions shouldn't be removed from their therapy programme as despite the increased burden they perceived, progress highlighted by it was likely to be useful to motivate them to continue to engage/recover.

> '…it's quite a chore, obviously, to…record…in the beginning. I think [someone]…not used to do anything like that [would] find that difficult. But there's no way around [it] they have to do it…No, no [it's not best to take it out of the programme for such individuals]…there will be certain personalities that have never been used to any kind of rigour…in their day. So…it will be just, just, a harder place to achieve [from]…Yeah, I think once they see that progress [it will help them engage], because that's what's been encouraging for us…it did encourage me to do more and to try harder.' (P5)

Therapists did not make comments specifically on how the recording of repetitions or instructions provided in trial therapy highlighted upper limb progress, possibly reflecting their limited direct input in trial therapy reviews and exercise progression.

Lends sufficient physical and emotional support during daily self-practice (Interviewees / groups 18/4):

There were two main components of the intervention that were considered to provide much needed physical and emotional support to reduce treatment burden i.e. to offset the effort/work required from stroke survivors during their

daily self-practice (Themes 1-2), the SaeboGlove and carer help. This support appeared to be key to enable stroke survivors to more easily access and/or successfully/positively engage with meaningful upper limb therapy:

SaeboGlove: All groups appeared to feel that the SaeboGlove offered much needed physical and emotional support (16/18 interviewees for each type of support, Table 47). The structure and mechanism provided physical assistance which seemed to allow stroke survivors to move in a way that was reassuringly familiar to them, helped them generate more movement more easily and to engage in more meaningful tasks. In turn, the physical assistance experienced appeared to create increased confidence and belief that recovery they hoped for at the trial outset was possible, gave stroke survivors/carers a greater sense of them being able to control/influence recovery and consequently empowered them to engage positively with therapy as their efforts seemed more likely to be worthwhile.

> '…being new to it [stroke rehabilitation] it was difficult, that [the SaeboGlove] made it easier, but once I get the hang of it, I can do it without the glove. The glove is a great starter…you think "oh, I'll not be able to do that" and then you slowly watch it opening up and you know you can do it…Then if you have the glove you can just keep practicing with it, just trying to do it....The bands that go on the back, that try and straighten as you move about…because when you let go you could feel it [the hand] moving [open] and you could see it…you can see it, then you can do it, [then] without the glove you could actually see the movement better [too], and then you were doing it yourself [without the SaeboGlove]…' (P3)

Such observations were also evident amongst therapists who appeared to appreciate the possible value of this physical support, normally not available in usual NHS therapy, to offer stroke survivors with severe hand impairment new, more engaging and empowering therapy opportunities.

> '…I think sometimes when…they aren't seeing the change that they want [in usual NHS therapy] they can get quite frustrated so it is quite nice to see their [his] engagement increase again and their [his] motivation increase [as he started progressing again]…Like there was quite a lot of it [therapy] that the patient could do [in the trial] [laughs]. It didn't [lack variety and] just have one or two things to work on…I think without the glove, the exercises that I could give him to do, probably wasn't as many [varied] exercises and it wasn't as

> functional. Whereas with the glove he was able to spend more time working on his grasp [himself] and his, em, functional tasks like using cutlery and the cups…everything was improving…so it was quite nice [positive/satisfying] to see that…' (PT2)

Carer input: All groups appeared to feel that the physical and emotional support from carers was very important to the successful engagement of stroke survivors in trial therapy, with the need for emotional support being acknowledged more frequently (17/18 versus 15/18 interviewees). Support from carers appeared to be important to help reduce overall post-stroke treatment burden and maintain motivation and engagement, with more personal effort and greater perseverance being required by stroke survivors in its absence.

Physical assistance was often required to help don/doff the glove, assist with exercises or to locate their self-management booklet to record repetitions against daily goals. By making participation easier, physical assistance often indirectly contributed to emotional support. Emotional support was also often felt to be required to share responsibility for therapy delivery/performance (i.e. to feel togetherness/in it together), particularly early on when it was less familiar (e.g. to keep track of repetitions during therapy or detail taught) and to support and encourage positive participation and perseverance (e.g. to remind stroke survivors why their participation may help them, encourage them to 'put the required work in' and highlight daily progress made as it occurred to make efforts invested feel worth their while).

> 'I was helping [my uncle] when I could put the glove on…talking about you know how many reps. In the beginning there is a lot to, you know, learn…we were doing that together…I think…there would have been times [without my part-time support] where my Uncle would have been overwhelmed with everything that was going on around about when he had nurses, OTs, physios, speech therapists, then [the research physiotherapist], another therapist coming in…so I could help him perhaps where he's not picked up on earlier conversations with [the research physiotherapist] about the glove…filling in the blanks and reminding him of you know why it was a good idea for the glove…[without my support] there would be some days where he might not have wanted to put on the glove because you can get fed up when you're in a hospital for any length of time and you're…coming to terms with before the stroke being completely independent…to then struggling, so there is a lot going on emotionally.' (P2's carer)

> ‘I think it's helpful to have somebody there to do it with them because his wife was so supportive and she was like "right, we're doing your exercises, and this is what we're going to do". Whereas I think if you were by yourself, if you were able to get it on and off, which is fine but, you might just think oh well, I'll just not do that or I'll just do it for not as long but if you've got somebody there you have somebody to motivate you to try and do it.’ (OT2)

To support successful engagement, several interviewees offered additional insights into individual factors that should be considered to ensure adequate carer support and minimise perceived treatment burden (e.g. being able to accommodate stroke survivors perceived carer support needs, sufficient carer support when patience is limited i.e. when treatment burden is less well tolerated and reducing the carer support required, in general, by staggering the intervention start with other competing challenges such as imminent discharge preparations/discharge home or the commencement of other therapies). For example, one stroke survivor pointed out that perceived treatment burden trying to get the glove on (e.g. by themselves or by seeking help from ward staff) without an informal carer may depend in part on an individual’s patience/temperament and their willingness to seek alternative help and available support.

> ‘The bands are pretty footery…They can come flying off [when trying to attach them]…but I am quite chuffed now, I have been putting it on myself at the weekend twice now. And my niece when she comes up [three days/week] as well…she helps me put it on and is a dab hand at putting it on…I always managed to get someone to come and give us a hand like [when she wasn’t there]…[without help] you've got to have a lot of patience with this glove. Somebody that is not a very good temperament…I don’t think they will be able to do it themselves like you know. They will need help or at least with the bands, especially at the beginning…’ (P2)

Consistent with this view another stroke survivor highlighted that while she was willing to work hard to aid her recovery, enjoyed the trial therapy and could follow paper/video instructions, carer support remained essential to her participation. This perceived need for external support appeared to centre around the feeling that a sense of ‘togetherness’ and direction (i.e. emotional support) was needed to ‘enjoy’ it and remain actively engaged in it.

> ‘…the idea of being together [helps my participation]…a crowd round you….it [trial therapy] was…enjoyable [positive/satisfying]…you’ve got

> to work at it. You can't just sit back and no do anything [nothing]…You definitely need [carer] support. Yeah, [If you had pictures or videos to guide your therapy without a carer] I don't think you would do them…I don't think I would be motivated to do [it]…you [would] just sit watch it and think, 'Oh aye, OK', but if somebody was there, you'd say, 'no, you need to do that, you need to do that, that's fine'. Somebody is there with me. A booklet…I would look at it and think, 'Right, well, I did that, so I don't need to do that'. And toss it aside. I'm lazy that way though…I need somebody there [laughs], ordering me about, probably is the right word…' (P6)

One stroke survivor was admitted just before Christmas. Consequently, there were delays in his usual NHS care starting and this meant that both his NHS and trial therapy were commenced in the same week in the New Year. Although grateful for the additional therapy support offered through the trial, this stroke survivors carer pointed out that staggering the start-up of each of these interventions (NHS and trial therapy) should be prioritised, if possible, to reduce treatment burden and the support needed from carers to ensure ongoing participation.

> '…the stroke that he had was just before Christmas so for the first couple of weeks there didn't seem to be much [therapy] happening. Now I don't know if that was because it was a holiday period…but when the [usual care] physiotherapy…and…occupational health [therapy] started and also getting the offer to take part in a research trial as well [simultaneously], you know that was for me, encouraging [positive] that he could get that offer of additional help…[but]…at the beginning [of a stroke and therapy starting] there is a lot to take in so [me] just being there and to kind of help [support] him [and]…[as] it was one more thing to do and sometimes he just couldn't be bothered with [motivated] having another thing to do [overwhelmed]…[so] it might be worth considering you know if it [the trial starting] were maybe a week later…maybe just kind of staggering that [the start time for usual care and trial therapy]. It would help for the patient to retain that [cope with therapy input/information given] so that is the only thing…maybe just a week after he has been introduced into his [NHS] physio and OT…But obviously you don't want to leave it too long' (P2's carer)…

Physiotherapist experience, expertise, and alliance provides much needed physical and emotional support (Interviewees / groups 18/4):

There was widespread acknowledgement across the transcripts that the therapist's input was felt to reduced therapy burden for stroke survivors and this

often appeared to instil trust in the therapist, self-management, and ongoing engagement.

There were three main factors relating to the therapists' input that helped to do this, therapist experience, therapist expertise, and therapists shared effort to try to aid recovery.

Therapist experience: A disparity in previous rehabilitation/recovery experience (in general, using a SaeboGlove) between the research physiotherapist and interviewees often meant that interviewees instilled therapist trust that she understood how rehabilitation typically worked.

A disparity in previous rehabilitation/recovery experience (in general, using a SaeboGlove) between the research physiotherapist and interviewees often instilled trust that the therapist had the knowledge required/sought to normalise rehabilitation/recovery experiences and/or to aid recovery. Consequently, interviewees were keen to be led by or learn from the therapist and this supported engagement.

> 'I would try and do certain things [self-chosen exercises] on my own…but whether I'm doing it the right way rather than the wrong way, I'll need to get the therapists to give me instruction on that…Very, very [important to take guidance from a therapist], they know what they are doing, they've been there before, I haven't so I've got to take their lead. What they say, I'll take [do i.e. trust]…Yeah, and I just hope that it [my hand and arm] does get better…the guidance was essential…it showed me…'that way it's easier [to generate movement]', it helps you to move your arm, your hand…' (P3)

> '…we're [NHS therapists] talking about the exercises [provided by the research physiotherapist who has experience using a SaeboGlove] …stuff like if you [other NHS therapists have] tried doing [these types of exercise before with stroke survivors] cos I've…seen [the research physiotherapist] in the Saebo trial doing that [particular exercises]…[In NHS therapy] I kept forgetting about [rehabbing] the supination pronation [palm up and down movement] and this trials made me more aware of doing all those exercises and how much of a functional impact they can have [to orientate the hand in a task]. Em, for example, my lady that can now, you know, turn her wrist over [palm up], hold something in her hand…the supination pronation [palm up and down] stuff, there was none of that at all before the trial…It [practicing and progressing these movements] really boosted

> her mood…She wants therapy [to engage in] all the time…she really, really benefited from it so the patients are really, really enjoying it' (OT1)

Therapist expertise: Two main sources of therapist expertise appeared important to maintain/develop this trust and instil self-management and ongoing engagement; expert information/guidance, and expert tailoring.

Expert information/guidance

Despite the challenges associated with rehabilitation and recovery after stroke, even in the presence of more severe symptoms (i.e. hand impairment) interviewees often expressed that therapy review visits in the trial were positive encounters that supported motivation to maintain engagement. For example, trusted expert information/guidance often appeared to reduce personal challenges encountered (e.g. a lack of belief that recovery was possible/participation was worthwhile) and bring focus by linking therapy tasks to a meaningful endpoint. Additionally, information/guidance provided was often felt to offer reassurance around the validation of efforts made being 'right' i.e. 'worthwhile' as they were generating progress and therefore merited further therapy advice that could help them move closer again to achieving their ultimate goals.

> 'I didn't feel it [trial participation] burdensome at all. No, I thought that the, the amount of attention [effort], shall we say, that was being given [to try to address my problems] was sort of really, very welcome and very beneficial…And somebody has to assess the progress, I think…the therapist is showing you the progress…if they're putting you onto things that are more and more difficult…[without the therapists input at reviews]…it could make it [my participation in self-practice] quite complacent, you know, sort of 'Yes, I could do that. Yes, I can do that.' But perhaps you can't really, you know, perhaps you're not actually achieving the whole [detail i.e. doubting if efforts made are truly 'right' or 'worthwhile']…the therapist can point out…whether you're actually getting the movement right [you need]…doing it in a way that will actually lead you on to doing the finished movement [achieving their ultimate goal]…I don't think the person involved is actually capable of doing that. I think it needs somebody outside…just to say, 'It's that finger that needs to move [to achieve your goal]…' (P4)

> 'I think…[at trial therapy review sessions] they are getting everything explained to them, they are getting followed up, they've got set exercises to do during the day which is great, gives them something

> [positive] to focus on, em, and I think patients as well can see the difference that it is making…I think you need somebody like a physio, or an OT or a doctor telling [reassuring] you, you know 'there is potential here, that's [the efforts you are making are] great [to try to aid recovery]'…because people seem, do not realise how well they're doing [doubt progress is worthwhile] until you point it out to them.' (PT1)

Expert tailoring

Tailoring of therapy by therapists at review visits was a key part of the EMPOWER intervention (Figure 15 in Chapter 3, Table 18 in Chapter 4) and expertise in it was widely felt by all groups to be essential to meet stroke survivor's individual supported self-management needs/preferences to engage successfully with the intervention.

The provision of graded therapy tasks to stroke survivors set at the right difficulty level, intensity (daily movement repetition target) and with the inclusion of meaningful tasks, where available, to balance positivity and progress based on individual needs and preferences was felt to be key to manage treatment burden and maintain participation motivation.

> 'Like [research physiotherapist] had a…small coin of soap, like a hotel soap that he was struggling with to pick up and be able to put between the pads of his fingers, whereas now he can do like a ten pence piece. So I think I guess in terms of money and things like that…I have faith that that's gonna come…I think the [research physiotherapist] is very good at like…pitching [the intervention] at the right level…So, like she'll pick tasks that…that aren't too frustrating and aren't too easy…Maybe people…might give up on it if they're finding it too hard [to]…progress…but she [the research physiotherapist] tailers…like how many reps [movement repetitions] to do things like that and what tasks to do to [meet the] individual needs and abilities and things. So, I don't think there's a whole lot that would put people [off trial therapy, I] wouldn't think.' (P7's carer)

> '…I think sometimes [in NHS therapy]…it [therapy] is more [i.e. too] difficult for them [stroke survivors with more severe upper limb problems] to [be able to] carry out any sort of exercises as well. And [then] we talk [to them] about things like your imagination exercises…[but] I think you [therapists] really need to be a good motivator…to let them understand that [by taking the time to imagine movement] you are trying to make connections [within the brain to aid recovery] and for them to [want to] keep going [with that in therapy] but I think sometimes the motivation levels can be a little bit flatter which in turn makes it [therapy engagement] harder…Yeah [taking part in the trial has impacted the stroke survivors therapy

> participation]…in a good way [laughs]. Because I really think it is good for [individual] patients to have set challenges and set tasks…so I think it definitely makes them want to participate a wee bit more…He'll usually do it when his wife is there so that she can help him with it…it is definitely something that people can do themselves [i.e. it feels achievable]…with the kind of oversight by the therapist [at reviews]…' (PT1)

Similarly, the tailoring of therapy support at reviews to accommodate stroke survivors/carers preferred format for take away instructions to reference (e.g. paper, video) was also felt to be important to maintain motivation and support engagement.

> 'See everyone's different so they [stroke survivors] need to be handled in a different way…[To help stroke survivors progress therapists need to] Just look at them and decide how they are getting on…and judge the person's personality type…Some people are different, different attitudes to life…Aye [different things motivate different people]…Other people might take longer [than six weeks using the glove], other people might take less time, it depends how bad their stroke is…me alone, I'm straightforward talking, rather than [mimics a therapist with a gentle, soft voice] 'Oh this, that, that, nice', just telling the truth and get on with it. But again it depends if the person can take the truth or not…[The therapist needs to] Go back to the individual, size them up [assess their individual needs] and say 'well I know you can do it…so let's do it this way'…like the instructions I was, the paper instructions I was given with the pictures showing what to do [was helpful to give the information I needed]…Ouch, no [I would not want a video information resource]. But that's only me, you [the therapist] can do whatever suits the patient.' (P3)

> 'Yes, I think so [you need to individualise instructions]…look at the patient and see what…kind of level they are at as far as modern technology is concerned and see whether you know how you can utilise modern technology [videos] or whether it needs to be hard [paper] copy [they need]…' (PT3)

Additionally, the provision of tailored self-practice advice to empower stroke survivors/carers to self-manage/tailor treatment burden with confidence i.e. to 'find the best way for them' to engage successfully/positively in daily self-practice was another component of the EMPOWER intervention (Figure 15 in Chapter 3, Table 18 in Chapter 4). This self-tailoring to support participation in daily therapy was evident in different ways across transcripts in both these groups. Often stroke survivors/carers were seen to have the know-how they

needed to feel empowered and equipped to respond to fluctuating individual challenges such as fatigue by making adjustments to their daily therapy to cope better (i.e. by altering intensity (repetitions), session duration/frequency, pacing (staggering) of daily exercises, task order (e.g. most difficult first/last when fresher/movement efforts are warmed up) or by favouring easier/harder exercises on an individual day but not over the week, planning the best timing in a day to maintain focus/motivation or actively choosing to miss a day to maintain overall wellbeing i.e. for a valid reason).

> ‘Yeah, well it [setting a shared lower and higher daily intensity goal with the therapist] gave you a goal every day. Some days…you are a wee bit tired or…you just weren't on the ball, so you done a wee bit less…and other days you felt a wee bit more, perkier, you done a bit more…So, every day was different like.’ (P2)

> ‘[I got involved in the trial as it] gives you ownership and a purpose…because, you know, I'm the other half of the duo…every day [you would] sit down at the table and, you know, get the clock out to do our routine…I think there’s flexibility in there [the guidance/limits suggested by the therapist to accommodate individual needs]…[the therapist said] you don't have to do it in one 45 minute block, you could…do it in 10 minute blocks…shorter blocks [didn’t work for us] because I don't think…[her] focus [was as good]…it wasn't the quality [we wanted]…where as if we were doing it like in…[one] session, the focus was definitely there. And…later on in the day she…just seemed to have that brain fog…so we just concentrated, it [therapy participation] was a morning session and it was one session [that worked best for us]…it [trial therapy] definitely gave [us] a definitive action, that I could be involved with and…more ownership…because I could say to her right yesterday we done 35 minutes, we done a total of 140 [repetitions] so we’re gonna aim to beat that…’ (P5’s carer)

Planning and scheduling of competing daily commitments (e.g. rest, usual care therapy, visiting) to manage fatigue and self-practice therapy was also noted across all groups to be important to support self-tailoring and an individual’s ability to maintain positive participate.

> ‘…we didn't really want to ask [the usual NHS therapists] too much…when the [usual NHS] physio [was] going to be [coming to do my therapy]…But I think sometimes it was just when people [therapists] had availability…they would come and do some NHS stuff with him…if he had a big [usual NHS therapy] session coming up, we would just try and put a gap in between [it and the trial therapy]…because different things fatigue him…and [the research

> physiotherapist] kind of said you do have to prioritise [balance rest and rehabilitation, ward therapy and the trial therapy to self-manage your recovery] and things like that. So, I think we've tried our best to do it. And I think…that's improved over time, and it's just become easier…But sometimes you [as a carer] come in [to support his trial therapy] and that would be exactly when he would be going for [usual care] physio…So the scheduling kind of was the hardest thing.' (P7's carer)

> '…[if the trial therapy was introduced into NHS practice] we would just need to work it out from a therapy point of view [to support stroke survivors to self-manage their recovery and fatigue]…making sure…it [trial therapy is] not overlapping the other therapies…maybe…They get the Saebo trial stuff in the morning or something like that…' (OT1)

Similar comments on the provision of tailored self-practice advice to empower stroke survivors/carers were not observed amongst therapists, perhaps reflecting the limited role therapists had delivering daily trial therapy in a self-management intervention largely led by stroke survivors and their informal carers.

Therapists shared effort to try to aid recovery: Trust and participation support provided by therapists appeared greatest when a collaborative 'in it together' relationship between the expert (therapist) and the stroke survivor/carer was apparent, with effort on both sides being evident to try to support stroke survivors to achieve goals they valued i.e. desired pre-stroke normality.

> 'I…just hoped it [trial therapy] would help me [recover]…You don't quite realise until this has happened to you what a hand [does], you know how complicated this [a hand] is. You take it for granted, like tying up your shoe laces and putting on your trousers and buttoning up your shirt like…[so] I have been…putting that glove on every day and doing the exercises like, ya know [trusting the experts advice],…She [the research physiotherapist] puts her heart [effort]…into it [giving him the information/guidance/support he needs to try to help him recover] like so I've got to meet her…half way' (P2)

> 'Yeah [trial therapy benefited him in non-physical ways]…again it is just going back to [his therapist at reviews] involving him [in the review process]…[guiding him with identifying and] setting his [personal/valued] goals, involving his wife…showing his family what he's doing [supporting his carer(s) to support him to achieve his goals]…I think that [involving stroke survivors and carers at reviews helps recovery as] if it is something that the patient is really…invested in [values] and their family member or carer can be involved or

invested in [to support it them]…again it's all about the motivation' (PT1)

5.5 Discussion

5.5.1 Summary of findings

This study has examined qualitative feedback from stroke survivors, carers, occupational and physiotherapists on their experience of the EMPOWER Help for Hands self-management intervention when used in conjunction with routine NHS care. Emergent themes relating to support felt to moderate, or influence, intervention fidelity were identified to inform interpretation of outcomes in the RCT in Chapter 4 and the transfer of findings to other settings.

There were four key findings/themes:

Key themes

1. Rehabilitation is hard work
2. Stroke severity heightens the rehabilitation challenge and support required
3. More meaningful upper limb therapy is needed/wanted
4. The EMPOWER intervention is acceptable and HELPs support engagement

Themes 1-3 are factors that relate to support felt to moderate, or influence, fidelity in any rehabilitation after stroke including the EMPOWER Intervention and the fourth applies to the EMPOWER Intervention only (Figure 15 in Chapter 3, Table 18 in Chapter 4).

Theme 1 highlights that rehabilitation after stroke, regardless of the intervention or context, is perceived to be hard work physically (e.g. due to the need for sustained physical effort often in the presence uncertain recovery) and emotionally (e.g. as having a stroke is upsetting, and trying and failing in rehabilitation is feared). Additionally, although rehabilitation is primarily a physical process, an increased prevalence of emotional rehabilitation demands was identified across transcripts (Interviewees/groups: 17/4 versus 16/4) which may be an indicator that they present an equivalent or even greater challenge.

Theme 2 highlights that a greater severity (range and magnitude) of stroke symptoms heightens the physical and emotional demand to engage in

rehabilitation and the need for external support, and this was particularly true for post-stroke fatigue.

Theme 3 highlights that all groups believed that a stroke survivors' motivation, perseverance, and personal effort to engage in upper limb therapy, despite challenges encountered, were fuelled by the belief that more therapy and more meaningful therapy tasks would optimise recovery potential i.e. normality.

Central to the perceived need/want for more therapy was the belief that rehabilitation, and therefore recovery, in hospital and community settings in both Health Boards was limited by limited NHS resources and an associated perceived need to divert resources to other competing rehabilitation priorities (e.g. to progress independence in mobility, activities of daily living without regaining use of the affected upper limb or stroke survivors with less severe impairment who were felt more likely to be faster progressors, to protect therapists time to address these perceived priorities by transferring upper limb rehabilitation responsibilities to stroke survivors, carers and support workers or by making it a small and/or passive part of another intervention (e.g. upper limb weight bearing during stepping or ADL practice)). This resource diversion was often felt to be required to facilitate swift discharge home.

Contributing to the perceived need/want for more meaningful therapy tasks for stroke survivors to engage in was the belief that engagement in these tasks was limited in routine NHS therapy as such tasks were limited in availability. This was felt to be particularly true for stroke survivors with more severe impairment as they were often perceived to have insufficient movement to engage in meaningful therapy tasks that were available.
Interestingly, three of the four groups with this perceived need/want (not physiotherapists) expressed that the limited function required in hospital meant that the true value of participating in meaningful therapy tasks earlier only became evident around discharge when more complex functional tasks were introduced.

Thus, to successfully support fidelity/engagement after stroke (in general), Theme 1 suggests a need for complex interventions to identify and respond to the emotional and physical demands of individual stroke survivors, with efforts

needed to instil belief/hope that participation is worthwhile. Theme 2 suggests that interventions will support engagement best if they proactively consider post-stroke severity and the additional challenges it may bring and take steps to ensure sufficient support is provided on an individual basis. Additionally, the findings in Theme 3 highlight that upper limb therapy engagement and perseverance is likely to be improved after stroke by interventions that are resource efficient and offer more and earlier meaningful therapy tasks, especially when impairment is severe.

Theme 4 highlights that all interviewees unanimously felt that the EMPOWER Help for Hands Intervention was acceptable and responsive to the perceived physical and emotional rehabilitation support needs of stroke survivors summarised in Themes 1-3. Prior to commencing the intervention it instilled hope of improved recovery as it seemed plausible that help provided at therapy reviews and self-practice sessions (SaeboGlove and carer if/when required) could better support stroke survivors with hand opening difficulties to access and engage more easily in therapy they valued.

Once started, this hope was realised as interviewees made a direct link between stroke survivors' physical participation in the Intervention and meaningful progress using their affected hand/arm during self-practice and everyday life. This provided much needed emotional support as ongoing efforts to engage were felt to be easier and worthwhile. The intervention structure itself provided emotional support as it was felt to enable self-monitoring that evidenced such links further instilling motivation to engage (e.g. graded exercises including glove weaning, recording movement repetitions against an intensity target, and comparing movement quality against take-home instruction highlighted progress made).

Furthermore, help provided from the SaeboGlove, carer (if/when required) and therapist was felt to help manage the rehabilitation challenge encountered as it provided the means for stroke survivors to participate with less personal effort and perseverance, or to problem solve to overcome difficulties encountered (e.g. post-stroke fatigue). Physical support from the SaeboGlove appeared to make it easier for stroke survivors to move more or in more familiar or

meaningful ways which in turn was felt to increase confidence/belief that recovery hoped for was possible and, to some degree, within their control. While physical support from carers appeared to make it easier for stroke survivors to don/doff the glove, do their exercises or locate and complete their self-management booklets which in turn was felt to provide emotional support as the responsibility and effort to engage was shared. Additionally, support from carers was often felt to be important to encourage stroke survivors to 'put the required work in' and highlight daily progress made as it occurred to make efforts invested, and progress made feel 'worthwhile'.

Similarly, the therapist's input at review visits was felt to be key to ensure positive ongoing engagement, with efforts to manage emotional demands being particularly prominent. Their previous rehabilitation/recovery experience instilled trust that the therapist had the knowledge stroke survivors needed both to make sense of their own rehabilitation/recovery experiences and to aid their overall recovery. This trust was felt to be elevated when therapy started as a collaborative 'in it together' relationship between the therapist and the stroke survivor was established as the therapist demonstrated her shared effort to join stroke survivors in their quest for improved normality.

Additionally, expert information/guidance was felt to reduce personal challenges encountered (e.g. a lack of belief that recovery was possible or that participation was worthwhile) as it nurtured hope and motivation, essential for maintain ongoing participation. Such efforts typically centred around the provision of much needed reassurance and validation of efforts and progress made being 'right' i.e. 'worthwhile' and/or regaining focus by linking therapy tasks to a meaningful endpoint.

Tailored guidance from the therapist for exercise provision was also felt to be essential to maintain positivity, coping and ongoing engagement (e.g. by selecting the 'right' difficulty level, intensity level i.e. repetition target/target range and linking to normality) and take-home instructions (i.e. content and format) to accommodate individual abilities and preferences. The provision of tailored advice to stroke survivors to help them self-manage/tailor their daily self-practice to accommodate fluctuating daily challenges with confidence appeared to be empowering and was similarly important (e.g. by altering

intensity (repetitions performed), session duration/frequency, pacing/staggering of daily exercises, task order (e.g. most difficult first/last when fresher/movement efforts are warmed up) or by favouring easier/harder exercises on an individual day while not avoiding any over the week, planning the best timing in a day to maintain focus/motivation or actively choosing to miss a day to maintain overall wellbeing i.e. for a valid reason).

The participants also offered guidance that they felt may be useful to help manage treatment burden and optimise successful engagement of stroke survivors in the EMPOWER Intervention on an individual basis for deviant cases anticipated. This guidance related to the level of support, primarily emotional support, required from carers and/or the SaeboGlove to successfully engage. For example, greater carer support was perceived to be needed for stroke survivors when they themselves perceived more to be needed, when stroke survivors' patience was felt to be limited (e.g. when personality or stressors meant that treatment burden was felt to be less well tolerated), when stroke survivors were felt to be less willing to seek help from staff to support their self-practice (e.g. to get the glove on), when the treatment burden associated with recording repetitions was perceived to be high, or when it was not possible to stagger the intervention start with other competing life challenges such as imminent discharge preparations/discharge home or the commencement of other therapies.

Most of the stroke survivors interviewed had stopped using the SaeboGlove during the six week intervention as the supporting therapist felt it was no longer physically required for ongoing progress to be made. This limited six week (maximum) timeframe of glove use was also felt by interviewees to be long enough as use was no longer felt to be needed to continue progress and stopping use was therefore felt to mark further progress. Additionally, this limited availability of glove use was felt to be advantageous as it fuelled motivation and perseverance to use the glove while it remained available. However, one stroke survivor who stopped using the glove around 4.5 weeks associated his glove use with rapid progress he had made. This man highlighted that the provision of exercises at this point that clearly built on progress he had made before glove use had stopped had been important to maintain his ongoing therapy satisfaction

to continue his engagement. He expressed that this approach may be useful to maintain therapy engagement in other motivated individuals who similarly felt emotionally attached to the glove for the same reason.

Additionally, one carer suggested that to maintain satisfaction (i.e. emotional wellbeing) it may be reasonable to extend use of the SaeboGlove by a couple of weeks beyond the six week treatment period for individuals who, on occasion, felt that this would be beneficial to make further progress.

Thus, the findings in this study highlight that despite the hard work of rehabilitation (Theme 1) and the heightened challenge and need for greater external support in stroke survivors with severe stroke symptoms (Theme 2), the EMPOWER Intervention was perceived to be acceptable in the context it was evaluated. The subthemes within Theme 4 help to clarify reasons for this. For example, the intervention was felt to offer hope of new opportunity for improved access to meaningful therapy engagement, support and progress valued (Theme 3), the SaeboGlove itself was easy to use after initial instruction/demonstration and sometimes without help after a period of familiarisation, the intervention was felt to be progressive in daily self-practice therapy and in the restoration of normality in everyday life, utilise a structure that helped to highlight progress made, provide tailored and patient-centred support from the SaeboGlove, carer and therapist, impart information to empower stroke survivors to organise their care and develop coping strategies and to fulfil or even exceed initial hopes/expectations.

Consequently, the findings of this study suggest that the EMPOWER Intervention successfully supported stroke survivors with reduced upper limb function, severe hand impairment including reduced or absent active digital extension to engage in functional, guideline-based tasks that they perceived to be meaningful.

Relationship to published literature: There are many findings in this qualitative study that resonate with, and add support to, the existing stroke literature summarised in Chapter 1.

Rehabilitation is hard work

Consistent with this study, there is widespread recognition of the huge physical

and emotional rehabilitation demand experienced after stroke (Gallacher *et al*. 2013; Gallacher *et al*. 2018; Stroke Association 2018; Meads *et al*. 2020).

Stroke severity heightens the rehabilitation challenge and support required

A heightened rehabilitation challenge and need for support due to a greater severity of stroke symptoms including post-stroke fatigue, and negative personal attributes (e.g. impatience, poor resilience) has also been evidenced (Gallacher *et al*. 2018; Meads *et al*. 2020; Levy *et al*. 2022).

More meaningful upper limb therapy is needed/wanted

Furthermore, therapy time is known to be highly valued by stroke survivors in their quest for normality, with many stroke survivors believing that more meaningful therapy engagement and perseverance will lead to more recovery (Luker *et al*. 2015; Meads *et al*. 2020). Likewise, in usual care, limited therapy provision (Barker and Brauer 2005; Royal College of Physicians 2019; Meads *et al*. 2020; Intercollegiate Stroke Working Party 2023) and availability of meaningful and accessible upper limb therapy tasks ((Barker and Brauer 2005; Stockley *et al*. 2019; Meads *et al*. 2020), and a greater focus on lower limb rehabilitation (Bernhardt *et al*. 2004; Lang *et al*. 2009; Meads *et al*. 2020) and upper limb compensation (Meads *et al*. 2020) by therapists, often to facilitate swift discharge home, are all noted as factors that negatively influence upper limb recovery.

The EMPOWER intervention is acceptable and HELPs support engagement

Similarly, there are several features of the EMPOWER Intervention that supported engagement in it and aligned with recommendations made in the existing stroke literature. Hope that upper limb recovery was possible appeared to be nurtured by the intervention and has previously been highlighted as a critical factor to drive therapy engagement (Meads *et al*. 2020; Levy *et al*. 2022). Similarly, the following were all perceived to be important in the intervention to reduce treatment burden and drive ongoing therapy engagement and have also consistently been advocated in the stroke literature; assessing individual rehabilitation demands/needs and using this to inform the tailoring of meaningful goals and support to negate challenges anticipated/encountered (Gallacher *et al*. 2013; Gallacher *et al*. 2018; Meads *et al*. 2020), noticing progress to merit ongoing efforts and using self-monitoring strategies (e.g. comparing movement number and skill against goals set) to highlight progress (Langhorne *et al*. 2011; Gallacher *et al*. 2013; Sugavanam *et al*. 2013; Luker *et al*. 2015; Gallacher *et al*. 2018; Meads *et al*. 2020), arranging physical and emotional support from care givers and a trusted therapeutic alliance that fulfils informational needs (Gallacher *et al*. 2013; Gallacher *et al*. 2018; Meads *et al*. 2020; Levy *et al*. 2022).

However, there are several findings in the stroke literature relating to usual care delivery (Luker *et al*. 2015; Abrahamson and Wilson 2019) that contrast the findings on the support provided in the EMPOWER Intervention (Theme 4). A recent international systematic review of qualitative studies that included stroke survivors with a range of upper limb impairments varying from no upper limb functional use to some functional use highlights some shortcomings in support provision in usual care upper limb therapy (n>131, 3 months to ≥16 years post-stroke, evidence quality moderate to high) (Meads *et al*. 2020). Stroke survivors in this review often expressed feeling that there was an inadequate focus on their emotional rehabilitation needs because therapy was perceived to be unmotivating as therapy goals were often therapist and compensatory driven, staff attitudes around upper limb recovery were often negative, information was felt to be confusing, insufficient and disempowering, progress was felt to be lacking and hope that upper limb recovery was possible was low which was felt to contribute to feelings of hopelessness and depression (Meads *et al*. 2020).

Additionally, engaging the affected hand/arm was felt to be too physically challenging which led to frustration and fatigue, further increasing the emotional demand to engage in therapy (Meads *et al*. 2020). Consistent with this finding in the review, stroke survivors have previously reported the greatest barrier to their upper limb recovery to be them "not having enough movement to work with" (Barker and Brauer 2005). Similarly, although around 25-50% of stroke survivors experience severe movement impairment (Parker *et al*. 1986), UK therapists report providing only passive and non-functional rehabilitation activities with no evidence-base for functional recovery to stroke survivors with severe proximal upper limb weakness (Stockley *et al*. 2019). While the Graded Repetitive Arm Supplementary Programme (GRASP) (Harris *et al*. 2009) and Constraint Induced Movement Therapy (CIMT) (Scottish Intercollegiate Guidelines Network 2010; Intercollegiate Stroke Working Party 2023) are active, functional, and evidence-based for improving upper limb function in stroke survivors with partial active hand opening, these were not used in this group. Furthermore, evidence on strategies to enable stroke survivors with severe hand impairment including absent active digital extension have yet to be identified (Veerbeek *et al*. 2014b; Kwakkel *et al*. 2015a).

Thus, collectively the stroke literature suggests that conventional rehabilitation does not successfully engage stroke survivors with upper limb movement problems physically in more functional, meaningful, and guideline-based interventions, particularly when impairment is severe. It also suggests that this unmet physical rehabilitation need contributes significantly to the perceived unmet emotional needs of stroke survivors (Meads *et al*. 2020), and this may, in part, explain why around 50% of stroke survivors with initial motor impairment have no function 6 months after their stroke occurred (Broeks *et al*. 1999).

However, the findings in Theme 4 (and the higher upper limb therapy engagement reported in the Intervention findings in the RCT in the SaeboGlove group (Chapter 4, Section 4.4.4)) contrast with this narrative. Theme 4 highlights that the EMPOWER Intervention can successfully engage stroke survivors in meaningful, functional, guideline-based therapy early after stroke even if stroke survivors have severe hand impairment including reduced or absent active digital extension, shoulder, elbow, or wrist movement. Thus,

unlike conventional therapy, the EMPOWER Intervention appears to fulfil the physical and emotional rehabilitation support needs. This is a novel contribution to the stroke literature and may help to improve upper limb outcomes in a sizable and hard to engage group.

5.5.2 Limitations

This qualitative study had some limitations. Although a diverse sample of stroke survivors, carers and clinical occupational and physiotherapists was sought to aid the transferability of the findings, the study was only conducted in two health boards in Scotland for feasibility reasons (NHS GGC and Lanarkshire). Additionally, less stroke survivors ended up being recruited to the RCT from NHS Lanarkshire (5/39 (13%) versus 34/39 (87%)) largely because Covid-19 led to more prolonged restrictions in research activities there. Consequently less interviewees were selected from NHS Lanarkshire to better represent stroke survivors recruited to the RCT from each board (stroke survivors 1/7 (14%), carers 1/6 (17%), and therapists 2/8 (25%) versus 6/7 (86%), 5/6 (83%) and 6/8 (75%) respectively). Thus, although data from both boards aligned with the main themes and represent the two largest health boards in Scotland adding strength to transferability, the involvement of more interviewees from NHS Lanarkshire or additional health boards in and out with Scotland would further improve it.

No stroke survivors with a race and ethnicity other than white and Scottish were included as none had been recruited to the RCT during the timeline available for interviews. Consequently, we cannot be confident that the findings represent, and are transferable to, stroke survivors with a different race and ethnicity. Similarly, the late introduction of stroke survivors with an ARAT of 29-46 in the RCT (7/39=18%) (Chapter 4) meant that no interviewees had experience using the intervention with this level of ability. This was because only one was recruited within the available interview timeline but was not invited for interview as this was not felt to be appropriate as she had fallen and broke her affected upper limb soon after the intervention had finished. Additionally, while a small proportion of stroke survivors in the RCT were considered by researchers to have predominantly mild, but also some moderate, cognitive and language impairment, interviewers retrospectively considered such impairments in stroke survivors interviewed to be nil to mild. Thus, it is possible that the

findings do not accurately represent the therapy support needs stroke survivors in these two small groups (ARAT 29-46, moderate cognitive and/or language deficits).

Therapists interviewed observed the EMPOWER intervention and, in some cases, supported aspects of it daily (e.g. donning the SaeboGlove), and the findings indicate that they favoured accessing it in usual practice. However, limited clinical therapy resources prevented them delivering therapy reviews in the EMPOWER Intervention. Thus, while therapists would have experience supporting self-management in therapy reviews as part of routine guideline-based stroke care (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2023) it is possible that some support needs specific to the EMPOWER Intervention were not captured as they were unanticipated.

Additionally, the intervention was supported by only one therapist, the stroke specialist research physiotherapist who is also the author of this thesis (JA). Thus, the research physiotherapists involvement in this programme of research is likely to mean that she had high motivation to make the intervention work. Thus, the transferability of therapist support reported in the findings in this study to other therapy settings, likely required to replicate the outcomes reported in Chapter 4, cannot be assumed in other therapy settings (Pfadenhauer *et al.* 2017).

The research physiotherapist who delivered all the therapy reviews also carried out some interviews (8/18 (44%)) after the intervention ended due to limited resources. Thus, it is possible that her occupational preconceptions, academic aspirations, or prior relationship with interviewees may have biased the findings by influencing data collected or analyses made. However, efforts were made to reduce this bias. The therapist declared her motivations to interviewees to centre around gaining new knowledge to improve upper limb recovery outcomes after stroke at the interview outset. Additionally, another researcher (CS) with no previous stroke experience or relationship with interviewees conducted the majority of the interviews performed (10/18 (56%)) and data were compared and consistent across both sets of interviews. Furthermore, as the findings underwent peer debriefing with two additional researchers (JD, LK) who did not

have a relationship with interviewees this gives reassurance that any bias present is likely to be minimal.

The small number of interviewees included in this study could be viewed as a limitation. However, the purpose of qualitative research is not to generalise findings to a large population (Al-Busaidi 2008; Bryman 2008). Instead it is to explore context in a diverse sample in depth to aid transferability judgements to other settings (Al-Busaidi 2008; Bryman 2008). Thus, along with the detailed description of the sample selected in this work, this number is typically considered sufficient in the field of qualitative research to inform such judgements (Francis *et al*. 2010).

Although the views of key stakeholders were sought, interviews were only carried out at one point in time shortly after the intervention was completed (a median (IQR, range) of 9.5 (24.5, 21-51) days after) and it is possible that repeating subsequent interviews may have offered additional insights into the supported self-management needs surrounding the intervention. However, this would necessitate additional research resources beyond those available to this project.

5.5.3 Strengths

The main strength of this study relates to the rigorous and well-established methods used to optimise stakeholder acceptability and usefulness of findings (Section 5.3.1.7).

Four strengths of this study relate to the meaningful contributions that the findings make to the stroke rehabilitation literature. The findings:

- highlight the considerable physical and emotional demands associated with engaging in any rehabilitation after a stroke, especially when symptoms are more severe, and provide an indicator that the emotional demands encountered may present stroke survivors with the greatest rehabilitation challenge,

- provide an insight into the information stroke survivors need to feel empowered to take an active role in their rehabilitation and recovery when engaging in the EMPOWER Intervention and this may be useful to inform support offered in other stroke rehabilitation interventions.

- identify an intervention that:

    - can successfully engage stroke survivors in meaningful, functional, guideline-based therapy early after stroke even if they have severe hand impairment including reduced or absent active digital extension, shoulder, elbow, or wrist movement. This finding is novel and likely to generate research interest in the use of environmental rehabilitation aids, including dynamic hand orthoses, to optimise support and improve poor outcomes in this sizable and hard to engage group (Parker *et al*. 1986; Nakayama *et al*. 1994; Broeks *et al*. 1999; Kwakkel *et al*. 2003).

    - fulfils the support needs of this group who have severe hand impairment it is likely to do so for individuals with less severe hand impairment who also have reduced upper limb function and active digital extension.

5.5.4 Implications for practice

This research suggests that meaningful upper limb therapy tasks and objects should be used in stroke in clinical practice, and ideally earlier (i.e. before imminent discharge home), to optimise therapy motivation, engagement, and upper limb recovery.

A high level of acceptability for the EMPOWER intervention was observed in this qualitative study. This is likely to have contributed to the enhanced upper limb therapy engagement reported in Chapter 4 (Section 4.4.4).

If utilised in other settings, to ensure replicability of the findings in this qualitative study, likely essential to achieve this superior treatment effect reported in Chapter 4, the following recommendations are made:

- The proposed intervention detail which was well received is adhered to (Figure 15 in Chapter 3, Table 18 in Chapter 4) (Alexander *et al*. 2021b).

- Staff introducing possible use of the intervention to stroke survivors should have sufficient clinical expertise with the target population and intervention to set realistic hopes and expectation around what therapy engagement and recovery involves (i.e. the SaeboGlove is an aid to enable hard physical work and the practice of meaningful tasks and better meaningful recovery is more likely if they can work hard in this way).

- Prior to commencing the intervention, efforts should be made to identify and fulfil the physical and emotional support needs of each individual stroke survivor, with an equivalent, or even greater, emphasis being placed on the latter. For example, any physical support needed (e.g. to don/doff the glove, do exercises provided or complete therapy diaries) and any emotional support needed (e.g. to support/encourage positive engagement and highlight progress) should reliably be established including how clinical teams will aim to manage carer gaps. This is likely to be particularly important in stroke survivors with a greater severity (range and magnitude) of stroke symptoms including post-stroke fatigue, and negative personal attributes (e.g. impatience, poor resilience) as these factors are perceived to heighten the rehabilitation challenge. It is recommended that therapy reviews are conducted by stroke specialist therapy staff prior to them training rotational staff and overseeing their delivery of the intervention as this is likely to ensure that support needs are met.

- Therapists should proactively demonstrate a shared effort in stroke survivors' quest for more normality to increase trust that their input will be valuable to them, and should strive to have expertise in the provision of:

    - General information/guidance on how rehabilitation and recovery typically work (i.e. what normally happens, what challenges are normally encountered and what strategies normally help manage them) and validation around efforts and progress made to engage

in these processes being ‘right’ i.e. worthwhile in their quest for improved normality

- Tailored exercises (i.e. set at right difficulty level, intensity level i.e. repetition target/target range and with a clear link to the restoration of the individual’s normality) and take-home exercise instructions (content and format) to accommodate individual abilities and preferences and enable self-monitoring of meaningful progress

- Tailored information/guidance on self-practice (i.e. to encourage stroke survivors to work at a higher/lower intensity range, session duration/frequency or exercise pace, alter task order or time of day or without avoiding any exercise over the week select more difficult/easy exercises on a particular day) to manage progress and fluctuating daily challenges encountered, and instil self-management

- The SaeboGlove should routinely be utilised for a maximum of six weeks as this period is likely to be sufficient to continue progress in functional-based rehabilitation without it after this time. However, on occasion, use could be extended by a couple of weeks if this can be justified to maintain therapy satisfaction and ongoing engagement. Similarly, if glove use is stopped before six weeks as the therapist no longer feels it is needed exercises that clearly build on progress made with the glove should be provided to maintain therapy satisfaction, particularly in stroke survivors who demonstrate an emotional attachment to the glove.

- The intervention content without the SaeboGlove could be utilised beyond six weeks to build on progress made and as a framework for usual care to help maintain therapy motivation and engagement (as the programme is evidence-based in theory and was received well)

5.5.5 Implications for research

To inform the successful implementation of this intervention in other settings in the group studied and to further increase confidence that the self-management support needs surrounding it have been captured, if possible, future research should:

- Interview some therapists who have experience delivering the therapy reviews as well as supporting and/or observing daily therapy to ensure that a range of views on the self-management support needs encompassing review delivery are captured.

- Include interviews with stroke survivors differing in race/ethnicity, with an ARAT of 29-46 and stroke survivors, informal carers, and therapists from other health boards, ideally out with Scotland.

- Consider repeating interviews with stroke survivors, informal carers, and therapists later (e.g. ≥4 weeks after the initial interview but <12 weeks after completion) to offer additional insights into how the supported self-management needs surrounding the intervention may change over time.

To reduce bias, if resources allow, further research should avoid interviewers and interviewees having any prior knowledge of each other.

Additionally, if the intervention is utilised in other settings, to ensure replicability of the findings in this study recommendations are made. These have already been listed in the previous section ‘Implications for practice’ and can be viewed there.

The high level of acceptability of this intervention in a severely affected group highlights the potential value of using environmental aids to better manage the physical and emotional challenges inherent in stroke rehabilitation participation. Thus, it is recommended that future research proactively explores the use of environmental aids, particularly in harder to reach groups, to evaluate their role in countering therapy burden after stroke and empowering therapists to better support and engage stroke survivors in meaningful therapy participation. This

may include exploring the possibility of using a SaeboGlove to evaluate other interventions that are evidence-based in stroke survivors with partial active hand opening (e.g. GRASP, CIMT) but have not previously been accessible to stroke survivors lacking such movement/strength in the group studied.

Furthermore, to extend the evidence-base and potential accessibility of the EMPOWER Help for Hands intervention and better represent people with hand impairment including reduced active digital extension after stroke the acceptability of the intervention in this study now justifies work to:

- Assess the impact of extending the intervention without the SaeboGlove beyond six weeks (e.g. by four more weeks) on the treatment effect.

- Assess the feasibility of using the intervention in a similar group but later after stroke (i.e. beyond 60 days post-stroke as an inpatient or beyond two weeks of discharge home) or in individuals who lack capacity either in a self-management format if reliable carer support is available or in a 1:1 therapy setup. To optimise successful engagement, such work should be guided by key stakeholders including therapists, stroke survivors and carers.

- Assess the effectiveness of using the intervention in individuals with less severe hand impairment (Fugl Meyer Hand score >7/14) who also have reduced upper limb function and active digital extension.

Additionally, the EMPOWER Help for Hands intervention is underpinned by core rehabilitation principles (neuroplasticity (Kleim and Jones 2008; Intercollegiate Stroke Working Party 2023), patient-centred health care (Department of Health 2005a; Intercollegiate Stroke Working Party 2023) and health behavioural change (Parke *et al*. 2015)). These core principles are shared in rehabilitation across many patient groups (e.g. in Parkinsons Disease (Keus *et al*. 2014; National Institute for Health and Care Excellence 2017) or Multiple Sclerosis (National Institute for Health and Care Excellence 2022). Thus, the perceived benefit of all components in the EMPOWER Help for Hands programme in this study to therapy engagement in a hard to reach group suggests that the intervention could be evaluated much more widely e.g. by tailoring it for use in groups with reduced

active hand opening due to other long term conditions or in stroke survivors or groups with other long term conditions to support rehabilitation and recovery of other clinical problems (e.g. balance, mobility, falls).

5.6 Conclusions

This process evaluation complements the RCT in the SUSHI trial. The Intervention findings reported in the RCT (Chapter 4, Section 4.4.4) suggest that upper limb therapy engagement was higher in the SaeboGlove group. This qualitative study highlights that engaging in rehabilitation early after stroke is hard work physically and emotionally with the EMPOWER Help for Hands intervention being no exception. Despite such rehabilitation challenges, the self-management intervention was acceptable, and all components in it were felt to support and motivate engagement in stroke survivors with severe hand impairment including reduced or absent active digital extension.

The intervention itself provided additional upper limb therapy and more meaningful therapy tasks that were felt to be wanted/needed and representing a welcome opportunity for this group to try something new that had the potential to improve their upper limb recovery. It was felt to be progressive in therapy and in everyday life tasks and its structure highlighted this. Additionally, help provided by the SaeboGlove, carers (if required) and therapists were key to reducing treatment burden and maintaining positivity and motivation required for ongoing engagement in it.

This qualitative process evaluation offers valuable insights into factors that may be critical to successfully support people to engage well in rehabilitation, regardless of impairment severity and even in a self-management context. Understanding and implementing these factors is therefore likely to be key to transform stroke rehabilitation and recovery outcomes.

Replicating the qualitative findings in other settings will depend on the ability of implementers to successfully replicate the delivery of all intervention components as they were in the SUSHI trial. Ensuring sufficient external support and expert information will likely be key to doing that. A process evaluation involving a descriptive quantitative analysis of implementation data collected

during the conduct of the RCT in Chapter 4 is therefore needed and will be conducted out with this thesis.

Chapter 6

Conclusions

6 Chapter 6: Conclusions

6.1 Summary of research rationale

This thesis began by introducing readers to the scale and nature of stroke, key stroke recovery mechanisms, stroke rehabilitation principles, the magnitude and gravity of post stroke upper limb problems and rehabilitation challenges that negatively influence stroke upper limb outcomes.

Common challenges involving upper limb rehabilitation highlighted included factors that relate to *stroke presentation* (e.g. insufficient active movement to access meaningful and recommended rehabilitation activities that fulfil neuroplasticity/recovery principles (i.e. functional-based rehabilitation, self-practice opportunities and intensive/repetitive training), learned non-use, flexor spasticity, secondary complications). Other challenges centred around *upper limb rehabilitation itself* i.e. the complexity and variety of upper limb movements that must be relearned, *rehabilitation service provision* (e.g. inadequate therapy availability in general, reduced upper limb rehabilitation prioritisation (1:1 and self-practice)), and *individual factors that influence rehabilitation behaviours/choices/motivations* (e.g. post stroke fatigue).

Stroke survivors with severe motor impairment, including reduced/absent active digital extension were highlighted as a particularly sizable but relatively under-researched group with the poorest prognosis and greatest challenge to recover upper limb function.

Non-robotic dynamic hand orthoses (DHOs) were introduced as novel rehabilitation devices that offer sustained and dynamic graded wrist and digital extension assistance. The assistance such devices provide was proposed as having the potential to counter many of the rehabilitation challenges highlighted even in the presence of more severe motor impairments, including reduced/absent active digital extension.

6.2 Summary of research objectives

A programme of original research that aimed to appraise and progress the existing evidence base and theory on the use of non-robotic DHOs to improve upper limb recovery after stroke was presented.

The existing evidence base was appraised by conducting two literature reviews; a scoping review to map the existing research on the use of non-robotic DHOs in stroke rehabilitation (Objective 1a) and a systematic review with meta-analysis of the Randomised Controlled Trials (RCTs) identified in the scoping review to synthesise the evidence on the effects of using non-robotic DHOs on upper limb recovery (as no systematic review was identified) (Objective 1b).

Learning gained prior to commencing this thesis (Chapter 1, Figure 8) through an existing complex non-robotic dynamic hand orthosis (DHO) intervention that the author developed, delivered, and successfully piloted (i.e. tested) (The EMPOWER Help for Hands Programme, Pilot version, (Alexander and Dawson 2019)) was summarised along with views of key stakeholders on the pilot study design and intervention (Chapter 3, Appendix F).

Together, learning from this development work (pre-doctorate) and the two reviews conducted early in this doctorate were utilised to inform and progress the existing evidence base on non-robotic DHOs in stroke rehabilitation (Figure 8, Chapter 1). The previously piloted intervention and study design (Alexander and Dawson 2019) underwent minor refinement (Chapters 4 and 5) and evaluation (Chapters 4 and 5) during this doctorate following the Medical Research Council framework for developing and evaluating complex interventions (Skivington *et al*. 2021).

The evaluation involved an outcome assessment of upper limb function (Objective 2a, Chapter 4) that compared the effectiveness of:

1. Usual care plus the EMPOWER Help for Hands Programme (self-directed, repetitive functional-based upper limb practice supported using a DHO and four upper limb therapy progress reviews) (Intervention or SaeboGlove group), with

2. Usual care plus additional upper limb usual care (therapy input based on National Clinical Guidelines i.e. self-directed and repetitive functional-based practice (as able) supported using four upper limb therapy progress reviews) (Control or Usual Care group)

The evaluation also involved a process evaluation of the EMPOWER Help for Hands self-management programme to complement the outcome evaluation in Chapter 4 by aiding the interpretation of outcomes and their transfer to other settings. It explored and described factors relating to support that moderate, or influence, intervention implementation from a stroke survivor, carer and therapist perspective (Objective 2b, Chapter 5).

The main findings addressing each research objective will now be summarised. Thereafter, the principal challenges encountered in this programme of work will be highlighted along with areas recommended by the author for future development.

6.3 Summary of key findings

6.3.1 Identifying the current evidence base on the use of non-robotic DHOs after stroke

All research objectives (1a-b and 2a-b, Chapter 1) in this thesis were fulfilled.

6.3.1.1 Scoping review

The scoping review mapped the existing research conducted on the use of non-robotic DHOs and identified that the evidence base was lacking due to:

1. An absence of any systematic reviews

2. A shortage of RCTs (n=4), and a shortage of research in general that:

    a. reported certain participant characteristics (e.g. race/ethnicity and in some cases age, gender, recruitment time post stroke, cognition and quantification of upper limb functional capacity severity), intended and actual intervention delivery (setting e.g.

clinic or home, format e.g. 1:1 or self-practice, carer help and discipline of supporting healthcare professional), including factors perceived to influence implementation/engagement of the intervention as it is intended, adverse events and stakeholder involvement of any kind

b. included stroke survivors with moderate to severe upper limb functional capacity in the acute/subacute phase of recovery

c. was high in design quality (e.g. key factors reducing design quality included a lack of - samples representative of the target population, adequate power to establish effectiveness, long term follow-up, multiple recruitment sites, outcomes on Activities of Daily Living (ADL) and instrumental ADL, an evaluation of factors influencing intervention engagement or inclusion criteria that do not unnecessarily restrict the participation of stroke survivors with impaired cognition and/or language)

6.3.1.2 Systematic review

The systematic review with an accompanying meta-analysis included the four RCTs identified in the scoping review. The research gaps identified were consistent with those in the scoping review. No safety concerns were reported. Heterogeneity was low and a positive effect in favour of the use of non-robotic DHOs after stroke was observed in comparison to usual care, and usual care plus placebo regarding upper limb function and dexterity (primary outcomes) but not impairment (secondary outcome).

A high risk of bias was observed in the four RCTs included, largely due to poor methodological reporting and a lack of good quality, multi-site, adequately powered RCT(s) with long term follow up. Consequently, there was uncertainty around the positive effects observed in relation to the use of a non-robotic DHO intervention after stroke.

6.3.2 Progressing the evidence base on the use of non-robotic DHOs after stroke

6.3.2.1 Evaluation of the effectiveness of The EMPOWER Help for Hands programme in the SUSHI Trial

A total of 275 stroke survivors were identified. 188 were excluded without consent or formal screening based on information gained by identifiers (clinical/Stroke Research Network staff). 87 were consented; 9 were excluded and 78 were randomised (39 in each group). Attrition was acceptable but slightly higher in the Usual Care group due to an increase in dropouts at the time of group allocation (unblinding) due to allocation disappointment (n=3 versus n=0).

Differences in baseline demographics, stroke characteristics, upper limb clinical measures, other clinical measures, and baseline upper limb rehabilitation between the two intervention groups were not considered sufficient to bias the study findings.

During the intervention period, therapist-reported delivery of usual care upper limb therapy on weekdays was slightly higher in physiotherapists than occupational therapists but was balanced by discipline between groups. Stroke survivor-reported upper limb therapy contact time with a therapist appeared balanced between groups over the entire 14 week intervention and follow-up period upper limb therapy time.

However, although Usual Care group participants reported spending *more* upper limb therapy contact time with a therapist during the intervention period (weeks 1-6) they reported spending considerably *less* upper limb therapy time without a therapist and with/without a therapist during both the intervention period (weeks 1-6) and the intervention and follow up period combined (weeks 1-14).

The proportion of participating stroke survivors with the same outcome assessor and the proportion of outcome assessors retaining their blinded status was high, especially at the six week primary outcome visit.

The proportion of missing data for all assessments was small. A total of 71 (71/78; 91.0%) and 68 (68/78; 87.2%) out of 78 stroke survivors were included in

the six and 14 week outcome visits respectively. At the six week visit, the primary outcome (upper limb function) Action Research Arm Test (ARAT) Total score and three of the four ARAT subscores (Grasp, Grip and Pinch) were significantly improved in the SaeboGlove group compared to the Usual Care group (Table 32). The between group change in the remaining ARAT subscore (Gross) was not significant (Table 32).

In terms of secondary outcomes, the change in the Fugl Meyer Upper Extremity (FMUE) Motor Total and Hand scores at the six week visit were also both statistically significantly improved in the SaeboGlove versus Usual Care group (Table 32). All other secondary upper limb and other clinical measures at the six and 14 week visits were not significantly different between groups (Table 32 and 33).

Thus, the significant findings recorded at the six week primary outcome visit (Primary outcomes: ARAT Total, Grasp, Grip and Pinch, Secondary outcomes: FMUE Total and Hand) were not sustained at the 14 week visit and the between group difference for all other measures at both outcome visits remained non-significant. Additionally, as the significant improvement in ARAT Total, Grasp, Grip, and Pinch and FMUE Total and Hand observed at six weeks in the SaeboGlove group cannot be explained by an increase in upper limb therapist contact time it is likely to have occurred due to a difference in intervention content.

The Mean Minimum Clinically Important Difference was within the 95% CI for some secondary outcomes that did not reach statistical significance (the ARAT Total, FMUE Motor Hand Total, SIS Hand subscore and EQ-5D-5L total (Tables 32 and 33). This was the case for these measures at both the 6 and 14 week visits (Tables 32 and 33). Thus, this may be an indicator that these differences were clinically meaningful, or that they may be statistically significant in a future trial with adequate statistical power to be able to detect it.

SAEs considered related/theoretically related to the SaeboGlove intervention (SADEs) were similar in both groups suggesting that there was no obvious difference in safety in terms of the interventions delivered. However, there were more SAEs in the Usual Care group considered to be unrelated to the

intervention due to an increase in the number of hospital admissions/extended hospital admissions related to medical issues/illness (four versus one). This increase in SAEs in the Usual Care group may reflect attention bias e.g. less 1:1 contact time, support, or reassurance in this group from a therapist and/or carer as they carried out less self-directed therapy and therefore less self-directed therapy under their support.

6.3.2.2 Exploration of factors relating to support that moderated implementation/engagement (fidelity) of The EMPOWER Help for Hands programme in the SUSHI Trial from a stroke survivor, carer and therapist perspective

Factors relating to support that moderated, or influenced, intervention fidelity of the EMPOWER Help for Hands self-management programme in the SUSHI trial were described from the perspective of 18 interviewees selected purposively: seven stroke survivors from the SaeboGlove group, and five and six supporting carers and therapists (Tables 41 and 42) respectively. Two stroke survivors had follow-up interviews to seek clarity on interpretation.

Four main themes were identified (Themes 1-4) (Chapter 5, Section 5.2.4.3). Themes 1-2 highlighted that rehabilitation participation after stroke, in general, was perceived to be:

- Hard work physically and emotionally (Theme 1: Rehabilitation is hard work)

- More physically and emotionally demanding with the need for more external support when the severity of stroke symptoms (range and magnitude), including post-stroke fatigue, are heightened (Theme 2: Stroke severity heightens the rehabilitation challenge and support required)

Theme 3 highlighted that more upper limb therapy, particularly meaningful upper limb therapy such as that provided through the EMPOWER Help for Hands programme, was wanted/needed as it was valued to help restore normality for stroke survivors but was felt to be limited. Factors felt to be contributing to limited meaningful upper limb therapy included limited *therapy resources* such

as time, staff, and meaningful treatment options. *Therapy resource diversion* was also felt to contribute as more time was felt by interviewees to be diverted to the lower limb/mobility or recovery of independence in activities of living without use of the affected upper limb. Similarly, upper limb therapy time was felt by interviewees to be given less priority, especially when upper limb impairment was more severe, as it was often perceived to become a small and/or passive part of another intervention or to be relegated to stroke survivors, support workers or family rather than being performed with a therapist)).

Theme 4 highlighted that the EMPOWER Help for Hands Programme was acceptable as the EMPOWER therapy principles were perceived to successfully support stroke survivors to engage with it. Four key support mechanisms embedded in the intervention were identified to nurture engagement and were summarised by creating and using the HELP acronym: **H**ope to recover normality is instilled and expectations are fulfilled, **E**fforts are rewarded through meaningful progress and structure, the intervention **L**ends sufficient physical and emotional support during daily practice, and **P**hysiotherapist experience, expertise, and alliance provides much needed physical and emotional support (Theme 4: The EMPOWER intervention is acceptable and HELPs support engagement).

Thus, despite the physical and emotional demands of rehabilitation (in general), the findings suggest that the EMPOWER Help for Hands Programme filled an identified gap in clinical services and successfully met the therapy support needs of stroke survivors with reduced upper limb function, severe hand impairment including reduced/absent active digital extension, wrist, elbow and shoulder movement.

6.4 Summary of main challenges encountered

6.4.1 Challenges encountered identifying the current evidence base on the use of non-robotic DHOs after stroke

Two reviewers screened all abstracts and full texts and extracted data for all included RCTs in the scoping and systematic review, however only one reviewer

did this for non-RCTs in the scoping review due to resource limitations. Thus, despite thorough search efforts, it is possible that relevant non-RCT papers or data extracted from them may have more easily been missed.

Poor reporting, particularly of methods used and the population and intervention involved in studies included in the scoping and systematic review with meta-analysis limited the author's ability to identify and summarise the current evidence base on the use of non-robotic DHOs after stroke. Additionally, there was a lack of research representing stroke survivors with moderate to severe upper limb functional capacity who were in the acute/subacute phase of recovery. Consequently, generalisability and research replicability of the review findings in these areas to other settings are made more challenging.

Similarly, poor design quality in the studies included in both reviews limited the knowledge gained from them on recovery/aspects of recovery, outcome durability, research relevance and generalisability.

The lack of precision due to the small number of studies with small sample sizes included in the systematic review and meta-analysis, and the high risk of bias due, largely, to poor methodological reporting means that there is uncertainty over the positive effects observed.

6.4.2 Challenges encountered progressing the evidence base on the use of non-robotic DHOs after stroke

6.4.2.1 Evaluation of the effectiveness of The EMPOWER Help for Hands programme in the SUSHI Trial

Challenges relating to therapy interventions – More complex and time consuming yet less resourced

Compared with medical research, managing multisite RCTs of complex rehabilitation interventions is typically more complex and time consuming to deliver and evaluate (Hoffmann *et al*. 2014; Moore *et al*. 2015; Kwakkel *et al*. 2017; Skivington *et al*. 2021). There are additional, well recognised challenges that must be managed to identify and reduce bias (Negrini *et al*. 2019; Arienti *et al*. 2022). For example, successfully recording and reporting usual care therapy data and ensuring that therapy (e.g. upper limb therapy reviews) is conducted as

planned by usual care therapists to maintain treatment balance is challenging and has historically been poor (Negrini *et al*. 2019; Arienti *et al*. 2022). Consistent with this, in the SUSHI trial these research tasks required considerable planning, time and a huge effort to conduct which is unlikely to be feasible in many settings and likely accounts for the poor recording and reporting documented in rehabilitation research (Hoffmann *et al*. 2014; Negrini *et al*. 2019; Negrini *et al*. 2020; Arienti *et al*. 2022).

Managing blinding in stroke rehabilitation research is challenging, often doesn't happen, isn't reported, or is planned but without success being measured (Arienti *et al*. 2022). Like other rehabilitation trials (Rodgers *et al*. 2019) it wasn't possible to blind stroke survivors, carers, or therapists to treatment allocation in the SUSHI trial which inevitably led to allocation disappointment and a slightly higher attrition in the control group.

Blinding of outcome assessors was planned, measured, and reported to be excellent in SUSHI, particularly at the primary outcome visit. However, maintaining the blinding of outcome assessors required considerable planning. Clinical teams, stroke survivors and carers required ongoing education on the importance of outcome blinding, alternative secure storage was required for blinded documents (CRFs, clinic and taxi bookings), a phone line out with the main research base separate from outcome assessors was primarily used, two electronic diaries were set up for blinded and unblinded study visits/staff schedules and the research physiotherapist and therapy equipment needed to be relocated away from the research base. Additionally, despite using the electronic diary systems there were occasions where outcome assessors arrived unexpected in areas where the research physiotherapist had therapy review appointments scheduled which created an additional challenge.

In SUSHI, only one of the six participating sites (the coordinating site) (one of two Health Boards) had a dedicated therapy research team that ran in parallel with the clinical team. It included a full-time physiotherapist and a part time nurse, support worker and administrator to conduct and coordinate all day-to-day trial activities over all participating sites. This dedicated therapy research team were experienced and had good, well-established contacts with clinicians on all sites and the management of trial activities with this resource across

participating sites was expected to increase trial management complexity (e.g. greater organisation and the pulling of staff/resources over multiple sites).

However, four additional Scottish Health Boards (Forth Valley, Lothian, Fife, and Tayside) and three English Trusts (Newcastle, North East and North Cumbria, and Leicestershire), some accounted for in prestart recruitment plans, made contact to express interest in becoming recruiting sites. Although these Health Boards all had a dedicated medical research staffing resource, only one English Trust had limited therapy research resources. It was not felt feasible to open English sites with the resources available. Great effort was made by interested clinical teams and the coordinating site to facilitate involvement at the Scottish sites – additional funding for staff involvement was secured, outcome and therapy kits were sourced, laundering arrangements were made, and an amendment to permit a lower therapy resource option in the control group delivered by clinical therapy teams was prepared and approved by the Research Ethics Committee. Standardised outcome and therapy video training resources were also created to support this wider involvement. Despite high levels of interest and support, lack of therapy staff and clinic space to conduct research activities meant that participation by these Health Boards was not feasible. Consequently, recruitment was impacted.

Challenges relating to Covid disruptions

Many Covid disruptions were inevitable but negatively impacted recruitment and trial management complexity. For example, all research activities were ceased for four months at the initial lockdown with cessation continuing in sites out with the coordinating health board. Wards, stroke survivors, carers and therapists frequently needed to be isolated. Precautionary restrictions were regularly imposed on the movement of research staff and carer hospital visiting, and a change in the target population occurred laterally due to an increase in morbidity felt to be related to Covid-19. Covid-19 regulations meant that additional trial activities needed managing. For example, there was a regular need to check the changing Covid regulations with ward managers, PIs, Research and Development departments on different sites and to implement the changing need for stroke survivors, carers, and research staff to isolate while also rearranging appointments, clinic space and taxi bookings.

Without any notice the dedicated research therapy space planned for the four recruiting sites in NHS Greater Glasgow and Clyde, based at the coordinating site, was converted into a discharge lounge in August 2020 to aid Covid management just as recruitment re-opened after the initial lockdown. This created the need to rely more on clinic space that was prioritised for clinical work (e.g. stroke clinics). Although these clinics were not routinely utilised on certain days they were routinely booked and therefore were not made available for stroke rehabilitation research purposes. Attempts to overcome this challenge were unsuccessful. Arranging clinic space in the Clinical Research Facility was initially complex, requiring much more documentation than for the medical trials run within the same department, took time to get established and using it either required this disabled group to walk a much greater distance or staff to move between three buildings from their base to collect a wheelchair to then meet participating stroke survivors (all while maintaining blinding). Thus, a shortage of clinic space, particularly for potential recruits identified around discharge, prevented recruitment of several stroke survivors.

The SaeboGlove group had more protocol deviations primarily involving delayed face to face measures for the 14 week outcome visit due to there being a higher number of recruits in this group at the onset of the pandemic when research activities were ceased which may have imparted some bias on the study findings.

Many logistical challenges encountered were anticipated, some related to clinical factors (i.e. uncertain discharge timing and locations, accurately anticipating the feasibility of stroke survivors being able to return for therapy reviews safely post discharge, securing appropriate carer involvement and carer and therapy staff availability) and some related to research factors (i.e. moving between sites, protocol timelines, coordinating the availability of outcome assessors or stroke survivors with them and their clinical teams). Unfortunately, the added complexity due to Covid-19 on top of challenges already anticipated in the planning of the trial meant that recruitment was much lower than originally planned and achieving the power originally anticipated in the timeframe available for the project was no longer possible.

6.4.2.2 Exploration of factors relating to support that moderated implementation (fidelity) of The EMPOWER Help for Hands programme in the SUSHI Trial from a stroke survivor, carer and therapist perspective

Many trial design features were included to optimise the transferability of the findings to other settings (e.g. *stroke survivors* - differing in health board (Greater Glasgow and Clyde, Lanarkshire), gender (male, female), age (≤65 years, >65 years), time since stroke (≤1 month, >1 month), severity of upper limb disability (ARAT 0-10, 11-28) and informal carer support (informal carer/no informal carer), and with a range of cognitive and language abilities and carer support permitting, *carers* – with experience supporting stroke survivors differing in the characteristics sampled and *therapists* - differing in health board (Greater Glasgow and Clyde, Lanarkshire), discipline (occupational/physiotherapist) and experience (post seniority: band 5 rotational, band 6 rotational, band 6 stroke specialist).

A small proportion of stroke survivors with a race and ethnicity other than white and Scottish, with less upper limb disability (ARAT of 29-46) and judged to have sufficient carer help and moderate cognitive and/or language impairment plus capacity were included late in the RCT. However, these stroke survivors were not available to be interviewed within the study timeline. Additionally, limited clinical therapy resources meant that only the research physiotherapist delivered therapy reviews, not the therapists who were interviewed. Such factors were unavoidable but do reduce confidence that the support offered by therapists in other settings will successfully meet stroke survivors' support needs, particularly in these groups unrepresented in the interviews conducted.

Similarly, many design features were incorporated to optimise trustworthiness (Table 40, Chapter 5) and control/report bias that may result from the research physiotherapist's (and author's) involvement in interviews, data collection and interpretation (e.g. effort made for clinical therapists to deliver therapy reviews, included researcher reflexivity, the majority of the interviews were performed by a different researcher (CS) with no previous stroke experience or relationship with interviewees, data from interviews from both researchers were compared and found to be consistent, peer debriefing utilised). However, it is possible that some bias may still have been imparted.

Interviews were only conducted at a single time point which may have limited insights gleaned into the supported self-management needs surrounding the intervention.

This was the author's first time conducting qualitative research which may have slowed the data analysis process. However, consistent with other sources (Al-Busaidi 2008; Bryman 2008), the rigorous process adopted to try to ensure that the findings truly reflected the data was very time consuming.

6.5 Future directions

To progress stroke rehabilitation going forward, the considerable challenges encountered managing the SUSHI trial should be considered by the stroke rehabilitation and stroke research communities.

6.5.1 Successful implementation of the EMPOWER Help for Hands Programme

A process evaluation involving a descriptive quantitative analysis of implementation data collected during the conduct of the RCT in Chapter 4 (e.g. dose, content etc) and a cost effectiveness analysis is outstanding (and planned) prior to wide spread implementation.

However, the EMPOWER Help for Hands intervention is a safe intervention. Additionally, in comparison to the Usual Care group it led to superior engagement in upper limb therapy, and it is more efficient in terms of therapist time, recovery time and upper limb functional recovery immediately post intervention. Thus, the intervention should be utilised in clinical practice if a SaeboGlove is available to do so.

As is likely with any self-management intervention, some clinical challenges were present implementing the intervention in the SUSHI trial. However, the majority of the challenges encountered were research based. To reproduce (or improve) the clinical benefits observed in the SUSHI trial clinical teams will need to proactively manage the relevant challenges documented (Section 6.4.2, above) and successfully replicate (or better) the intervention engagement reported in Chapter 4 (Section 4.4.4). Similarly, replicating the intervention as it

was implemented in the SUSHI trial will also be key to reproduce the findings when implementation data are available (e.g. dose, content).

6.5.2 Progressing the existing evidence-base on non-robotic DHOs: Stroke and non-stroke groups and other self-management contexts

Future research involving non-robotic DHOs in stroke rehabilitation should aim to optimise research use by using trial conduct and reporting guidelines (Equator Network 2023) to help improve research design (e.g. by using larger samples representative of the target population studied, adequate statistical power required in definitive effectiveness trials, long term follow-up, multiple recruitment sites, outcomes on ADL and instrumental ADL, an evaluation of factors influencing intervention engagement and inclusion criteria that do not unnecessarily restrict the participation of stroke survivors with impaired cognition and/or language) and reporting (particularly on adverse events, race/ethnicity, intended and actual intervention delivery and stakeholder involvement of interventions and trial design).

A further adequately powered and resourced effectiveness trial involving the EMPOWER Help for Hands programme and a similar design is recommended to determine if the results in the SUSHI trial can be reproduced. Ideally, such a trial should attempt to address limitations in the SUSHI trial. For example, accelerometery or video observation could be utilised to optimise participation accuracy in conjunction with self-recording/monitoring of dose, involvement from other sites could be secured ahead of the trial commencing, sites out with Scotland could be involved, the intervention could be delivered within clinical services, interviews could be repeated at multiple time points and without any involvement from a treating therapist or interviewers with previous knowledge of interviewees, and the support needs of groups in the target population who were not represented in interviews could be explored (i.e. stroke survivors with a race and ethnicity other than white and Scottish, less upper limb disability (ARAT of 29-46) and who are judged to have moderate cognitive and/or language impairment plus capacity and sufficient carer help).

The identification of an intervention that successfully enables this group with severe hand impairment, including reduced or absent active digital extension, wrist, elbow, or shoulder movement to engage in meaningful, repetitive, functional-based rehabilitation, particularly in a self-practice context, is a novel finding (Kwakkel *et al*. 2003; Veerbeek *et al*. 2014b; Kwakkel *et al*. 2015b; Teasell *et al*. 2020; Stroke Foundation 2022; Intercollegiate Stroke Working Party 2023). Consequently, it is suggested that the EMPOWER Help for Hands programme also be evaluated in research in different formats in the target population to identify optimal delivery (e.g. support offered - beyond 6 weeks but without a SaeboGlove, with 1:1 delivery from an occupational or physiotherapist, in conjunction with adjunctive evidence-based interventions e.g. vagus nerve stimulation (Intercollegiate Stroke Working Party 2023).

Using a unified upper limb therapy approach for all severities of upper limb motor deficits would help to improve knowledge on upper limb recovery potential after stroke. The accessibility of the EMPOWER Help for Hands intervention makes this possible for stroke survivors with minimal active digital flexion only throughout the upper extremity. Thus, to improve this knowledge the intervention should be used in an RCT involving stroke survivors with all levels of upper limb functional deficits, possibly with baseline imaging (Chapter 4, Section 4.5.5, above), with or without the SaeboGlove depending on whether active digital extension is complete or not.

An exploration of the potential use of the EMPOWER Help for Hands intervention out with this population is also highly recommended with the SaeboGlove if active digital extension is lacking or without the SaeboGlove if it is not (e.g. in stroke survivors or other groups who have full active digital extension but other upper limb rehabilitation needs but without a SaeboGlove, in stroke survivors lacking capacity but in a 1:1 set up, in other patient groups who have reduced upper limb function due to neurological conditions (e.g. stroke survivors in the chronic phase of recovery or people with Multiple Sclerosis, brain, and spinal cord injuries).

Similarly, *the EMPOWER rehabilitation principles that* underpin the intervention were felt to successfully support intervention engagement and progress through four key support mechanisms illustrated through *the HELP acronym*. These

principles are based on the principles of neuroplasticity (Kleim and Jones 2008; Intercollegiate Stroke Working Party 2023), patient-centred health care (Department of Health 2005a; Intercollegiate Stroke Working Party 2023) and health behavioural change (Parke *et al*. 2015), core principles shared in rehabilitation across many patient groups (e.g. in Parkinsons Disease (Keus *et al*. 2014; National Institute for Health and Care Excellence 2017) or Multiple Sclerosis (National Institute for Health and Care Excellence 2022).

Thus, rehabilitation research communities either in stroke and upper limb rehabilitation or out with these areas who are studying interventions that share these core rehabilitation principles should consider the potential merit of using such *acronyms* to develop interventions that are engaging and progressive. In stroke, this may include interventions targeting balance or walking (e.g. The EMPOWER Help for Balance Programme after Stroke or The EMPOWER Help for Walking Programme after Stroke respectively etc) (Intercollegiate Stroke Working Party 2023).

6.5.3 Progressing stroke rehabilitation research in general

6.5.3.1 Stakeholder involvement

The success of complex rehabilitation interventions depends as much on the behaviours of stroke survivors/carers and therapists as the intervention design itself (Skivington *et al*. 2021) yet none of the trials included in the reviews in this thesis (Chapter 2) reported that they were informed in any way by them. Thus, to optimise the relevance of rehabilitation research and expedite the advancement of rehabilitation provision, involvement of such key stakeholders should be prioritised and front and centre of the design of trials piloting and evaluating such interventions (National Institute for Health and Care Research 2022). This will require increased commitment and collaborative working from leaders in rehabilitation and research throughout the stroke community (Stroke Association 2023).

6.5.3.2 Improved rehabilitation research resources to help fulfil traditional methodological standards

The challenges encountered in the programme of work in this thesis further highlight the complexities of managing stroke rehabilitation research and improving evidence-based upper limb rehabilitation in clinical settings (recording and reporting, fulfilling traditional methodological expectations including maintaining blinding and involving multiple sites and countries and meeting recruitment targets, all with a negligible dedicated rehabilitation research resource).

Rehabilitation specific reporting guidelines are now recommended to improve the replicability and applicability of research results (Hoffmann *et al*. 2014; Kwakkel *et al*. 2017). However, currently they do not acknowledge the additional time and resources required to collect such data in a rehabilitation trial so that the traditional methodological standards needed to produce high quality evidence can be met. Nor do they acknowledge or address the lack of therapy specific resources in many NHS stroke services in the UK currently available for it. The need for academic researchers in the rehabilitation field to consider how such challenges can realistically be managed to advance rehabilitation research has previously been highlighted (Negrini *et al*. 2020). This need for increased research time and therapy involvement without dedicated research resources is further emphasised by experiences encountered managing the SUSHI trial. Additionally, this need is felt by the author of this thesis to be the greatest factor impeding therapy advancement.

The establishment of integrated clinical and research therapy teams with research funding and core research training where this is lacking, like that utilised in medicine, is needed, and would likely alleviate all of these challenges. A rotational system where designated senior therapy staff in the clinical team rotate into a role with an integrated research component in their daily workload may be most feasible and beneficial to both clinical and research services. The system should incorporate peer therapy research support. In the temporary absence of rehabilitation research trials, therapists could be involved in medical research to broaden their academic/research knowledge and share their clinical expertise, essential in the design of rehabilitation trials, with the

academic community. Stroke rehabilitation and research leaders are urged to work collaboratively to reflect on barriers and facilitators to create such a system. The accessibly and availability of clinics and clinical research facilities required for study visits should be considered and supported. The Stroke Rehabilitation and Research Roundtable are urged to give this serious consideration and prioritisation in their global effort to 'bring major breakthroughs for people living with stroke' (International Stroke Recovery and Rehabilitation Alliance 2022). A degree of cross site working within Health Boards would likely be beneficial/needed, particularly by outcome assessors to successfully maintain assessor blinding in their local sites.

The SUSHI trial identified the EMPOWER Help for Hands Programme as the first evidence-based intervention for improving upper limb function in stroke survivors with reduced upper limb function and severe hand impairment including reduced or absent active digital extension. The intervention was found to be acceptable, motivating, progressive and supportive in this group. The study demonstrates for the first time that the effects of upper limb functional-based rehabilitation are not restricted to stroke survivors who have some active digital extensor control at baseline. Thus, the EMPOWER Help for Hands intervention is highlighted as an intervention with the potential to improve the lives of stroke survivors with severe hand impairment including those with reduced or absent active digital extension, a sizable group most in need of help to recover lost function.

Appendices

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Appendix A – Published papers

Systematic review paper
Article removed due to copyright issues

This is an Accepted Manuscript of an article published by Taylor & Francis in Journal of Topics in Stroke rehabilitation on 31 January 2021, available online: https://www.tandfonline.com/doi/full/10.1080/10749357.2021.1878669

Supplemental materials

PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 and 3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	3
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3 and 4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	3 and 4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplement
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	3 and 4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4 and 5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3, 4 and 5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	4
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	4
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	4 and 5

Search strategy

The search strategy is shown below for MEDLINE. It was adapted for the other nine bibliographic databases:

1 Orthotic Devices/ (6251)

2 Splints/ (8592)

3 (dynamic or functional or outrigger or dorsal or extended or extension or soft or saebo or dynsyst).mp. (2174459)

4 (splint* or orthos* or orthotic or device* or glove*).mp. (500897)

5 3 and 4 (60896)

6 upper extremity/ or arm/ or elbow/ or forearm/ or hand/ or fingers/ or thumb/ or metacarpus/ or wrist/ or shoulder/ (149083)

7 (upper adj3 (limb* or extremit*)).mp. (54302)

8 (arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder*).mp. (880053)

9 6 or 7 or 8 (906705)

10 1 or 2 (14707)

11 3 and 10 (3098)

12 exp stroke/ (125564)

13 cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebrovascular trauma/ or exp intracranial arterial diseases/ or intracranial arteriovenous malformations/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or vasospasm, intracranial/ (276948)

14 exp brain infarction/ (35716)

15 (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc* or cva* or apoplex* or SAH).mp. (391020)

16 ((brain* or cerebr* or cerebell* or intracran* or intracerebral) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus*)).mp. (150266)

17 ((brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)).mp. (88805)

18 12 or 13 or 14 or 15 or 16 or 17 (573337)

19 Hemiplegia/ (11354)

20 exp Paresis/ (7779)

21 (hemipleg* or hemipar* or paresis or paretic or impair* or weakness).mp. (765846)

22 19 or 20 or 21 (766756)

23 5 or 11 (60896)

24 9 and 18 and 22 and 23 (396)

25 limit 24 to yr="2000 -Current" (378)

26 limit 25 to english language (370)

27 25 not 26 (8)

Characteristics of included studies

Study / setting	**Participants** **Number recruited / analysed post intervention** **Inclusion** **Exclusion**	**Intervention**	**Comparison**	**Outcomes of interest**
Barry 2012[1] / USA, NR - assume rehabilitation clinic	22 / 19 Inclusion: ≥ 6 months post stroke, ≥ 21 years, AROM ≥ 15° shoulder elevation, ≥ 15° elbow flexion, ≥ 25%, PROM ≥ 15° wrist extension with fingers straight Exclusion: Ability to grasp/release a 7.6-cm diameter ball, botulinum toxin injections UL ≤ 12 weeks, swan neck deformities, prone to skin breakdown, severe aphasia, or cognitive impairment (MMSE < 17/30).	6 weeks - Task specific motor training activities wearing a DHO in different formats (1:1 with a therapist (1 hour, 1/week) and self-practice +/- carer assistance (20 reps of 6 exercises twice daily, 4 days/week)) with preparatory stretches	6 weeks - Task specific motor training activities in different formats (1:1 with a therapist (1 hour, 1/week) and self-practice (20 reps of 6 exercises twice daily, 4 days/week)) with preparatory stretches	ARAT, BBT, SIS – arm ability, SIS - % recovery, Grip strength, occurrence of DHO discomfort, SIS – strength domain
		Adherence: 1:1: 84% attended 6/6 (100%) visits, 16% attended 5/6 visits (83%), Self-practice: Only 8/19 (42%) diaries returned therefore not analysed		
Huang 2019[2] / China, NR - assume rehabilitation clinic	10 / 10 Inclusion: > 6 months post stroke, ≥ 20 years, UL weakness, proximal Brunnstrom stage IV, distal Brunnstrom stage III to IV, able to understand / follow orders, MMSE > 24 Exclusion: UL deformity / contracture, unable to commit to trial	4 weeks - Task specific motor training activities wearing a DHO in different formats (1:1 with a therapist (30 mins, 2/week) and self-practice (30 mins, 5/week, unclear if carer involved) with preparatory stretches 2 weeks follow up - self-practice with DHO (30 mins, daily)	4 weeks - Task specific motor training activities in different formats (1:1 with a therapist (30 mins, 2/week) and self-practice (30 mins, 5/week) with preparatory stretches 2 weeks follow up - self-practice (30 mins, daily)	BBT, Grip strength, Lateral pinch, Palmar pinch
		Adherence: 1:1: 100% attended 8/8 (100%) visits, Self-practice: Weeks 1-4: NR, 2-week follow-up: Mean (p value) Intervention 56.8 mins daily, Comparison 26.2 mins daily (0.019)		

Characteristics of included studies (continued)

Study / setting	**Participants** **Number recruited / analysed post intervention** **Inclusion** **Exclusion**	**Intervention**	**Comparison**	**Outcomes of interest**
Jeon 2012[3] / Republic of Korea, rehabilitation hospital, assume clinic	15 / 10 Inclusion: > 6 months post stroke, UL weakness, AROM ≥ 10° shoulder elevation, ≥ 10° elbow flexion/extension, ≥ 30 PIP or 20° DIP joint flexion with wrist/fingers straight, MMSE (Korean) ≥23 Exclusion: Nil reported	4 weeks - Task specific motor training activities wearing a DHO in a 1:1 format with a therapist (1 hour, 5/week) plus usual care (undefined) (1 hour, 5/week)	4 weeks – Placebo (Same quantity and type of elbow/shoulder movements as intervention group but no grasp/release), wearing a DHO in a 1:1 format with a therapist (1 hour, 5/week) plus usual care (undefined) (1 hour, 5/week)	ARAT, BBT, FMUE, resultant velocity of movement smoothness
		Adherence: 1:1: NR		
Lannin 2016[4] / Australia, inpatient rehabilitation	9 / 9 Inclusion: Acute inpatient with first stroke, ≥18 years, UL weakness, <6 on item 6 or 7 of the Motor Assessment Scale, AROM ≥ 10° shoulder elevation, ≥ 10° elbow flexion/extension, MMSE ≥21, follow one step commands Exclusion: Able to grasp/release tennis ball 10 times, deformity / contractures / hypermobility.	8 weeks - Task specific motor training activities wearing a DHO in different formats (1:1 with a therapist (45 mins, 5/week) and self-practice +/- carer assistance (≤45 mins, daily) plus usual care (comparison group therapy minus group sessions (permitted, not used).	8 weeks - Task specific motor training activities plus FES as appropriate in different formats (1:1 with a therapist (≥45 mins, 4/week), self-practice (undefined intensity) and in a group (45 mins, 3/week))	BBT, SIS – arm ability, SIS - % recovery, SIS – strength domain (UL only), Grip strength, Occurrence of problems with circulation, skin and joint pressure, MAS
		Adherence: Intervention 1:1: ≥ 45 mins, 5/week (n=2 (40%): 20-30 mins, twice/day, n=3 (60%): 45-60 mins once/day), Self-practice: NR. Usual care: NR, Comparison: NR.		

AROM: Active Range of Movement. PROM: Passive Range of Movement, UL: Upper Limb, MMSE: Mini Mental State Examination, DHO: Dynamic Hand Orthosis, ARAT: Action Research Arm Test, BBT: Box and Block Test, SIS: Stroke Impact Scale, FMUE: Fugl Meyer Upper Extremity score, FES: Functional Electrical stimulation, MAS: Motor Assessment Scale.

Characteristics of included participants

Study	Number of participants randomised	Age: Mean (SD)	Gender (M / F)	Stroke type (I / H)	Time since stroke (months): Mean (SD)	Side Affected (L / R), Dominant side affected	Measures of severity
Barry 2012[1]	Intervention: 11	52.7 (16.1)	4 / 6	6 / 4	49.2 (27.6)	5/5, 5	**MMSE: Mean (SD)** 27.6 (2.6) **Arm involvement (Moderate/Severe)*** 6/4
	Comparison: 11	50.3 (7.5)	6 / 3	5 / 4	61.2 (68.4)	5/4, 4	**MMSE: Mean (SD)** 26.2 (4.5) **Arm involvement (Moderate/Severe)*** 3/6
Huang 2019[2]	Intervention: 5	59.6 (8.0)	5 / 0	NR	51.6 (41.7)	3 / 2, NR	**MMSE: Mean (SD)** 27.8 (0.5) **FMUE: Mean (SD)** 30.6 (12.4)
	Comparison: 5	56.6 (7.9)	4 / 1	NR	49.6 (26.0)	4 / 1, NR	**MMSE: Mean (SD)** 28.0 (0.7) **FMUE: Mean (SD)** 31.4 (12.3)
Jeon 2012[3]	Intervention: 7	51.0 (13.5)	3 / 2	NR	29.6 (9.2)	3 / 2	**MMSE: Mean (SD)** 28.8 (1.8) **Brunnstrom's stage: Mean (S)** 3 (1.0)
	Comparison: 8	51.2 (12.5)	4 / 1	NR	27.6 (16.5)	2 /3	**MMSE: Mean (SD)** 29.2 (1.8) **Brunnstrom's stage: Mean (SD)** 2.8 (0.8)
Lannin 2016[4]	Intervention: 5	63.0 (10.4)	5 / 0	NR	2.5 (1.7)	2 /3	**Motor weakness (Mild/Significant)*** 2 / 3
	Comparison: 4	51.0 (21.2)	2 / 2	NR	4.7 (6.1)	3 / 1	**Motor weakness (Mild/Significant)*** 1 / 3

SD: Standard Deviation, M / F: Male / Female, I / H: Ischaemic / Haemorrhagic, L / R: Left / Right, MMSE: Mini Mental State Examination, *: Not defined, NR: Not Reported, FMUE: Fugl Meyer Upper Extremity score

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This is an Accepted Manuscript of an article published by Taylor & Francis in Journal of Topics in Stroke rehabilitation on 31 January 2021, available online: https://www.tandfonline.com/doi/full/10.1080/10749357.2021.1878669

Protocol paper

Check for updates

Study Protocol

EUROPEAN STROKE JOURNAL

European Stroke Journal
0(0) 1–9
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DOI: 10.1177/23969873211036586
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SAGE

SaeboGlove therapy for upper limb disability and severe hand impairment after stroke (SUSHI): Study protocol for a randomised controlled trial

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Abstract

Background: Impaired active digital extension is common after stroke, hindering functional rehabilitation, and predicting poor recovery. The SaeboGlove assists digital extension and may improve outcome after stroke. We recently performed a single group, open, pilot trial of the SaeboGlove early after stroke which demonstrated satisfactory safety, feasibility and acceptability. An adequately powered randomised clinical trial is now needed to assess the clinical effectiveness of the SaeboGlove.

Methods: SUSHI is a pragmatic, multicentre, parallel-group, randomised controlled trial with blinded outcome assessment, and embedded process and economic evaluations. Adults, 7–60 days post-stroke, with upper limb disability and severe hand impairment, including reduced active digital extension, will be recruited from NHS inpatient stroke services in Scotland. Participants will be randomised on a 1:1 basis to receive 6 weeks of self-directed, repetitive, functional-based practice involving a SaeboGlove plus usual care, or usual care only. The primary outcome is upper limb function measured by the Action Research Arm Test (ARAT) at 6 weeks. Secondary outcomes will be measured at 6 and 14 weeks. A process evaluation will be performed via interviews with 'intervention' participants, and their carers and clinical therapists. A within-trial cost-effectiveness analysis will be performed. 110 participants are required to detect a difference between groups of 9 in the ARAT with 90% power at a 5% significance level allowing for 11% attrition.

Discussion: SUSHI will determine if SaeboGlove self-directed, repetitive, functional-based practice improves upper limb function after stroke, whether it is acceptable to stroke survivors and whether it is cost-effective.

Keywords

Stroke, upper limb, rehabilitation, dynamic hand orthosis, randomised controlled trial

Date received: 22 March 2021; accepted: 14 July 2021

Background

Stroke is the third leading cause of disability worldwide.[1] Upper limb motor impairment contributes significantly to the burden experienced by stroke survivors. It affects around 80% of people with stroke[2] and approximately 50% of them have no improvement in upper limb function six months post-stroke.[3] Long-term upper limb impairment is associated with increased disability[4] and reduced quality of life.[5]

Impaired active digital extension is the most common upper limb motor impairment after stroke.[6] It reduces hand opening essential for upper limb function[7] and predicts poor upper limb recovery.[8] Repetitive, functional-based rehabilitation and

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self-practice activities are advocated by national clinical guidelines[9,10] and systematic review evidence.[11–13] However, lack of active digital extension can prevent people accessing guideline-based activities, both in clinical[14,15] and research[16] settings, and no evidence-based interventions have been identified to improve this.[3,13,17] This may account for the particularly poor upper limb prognosis experienced after stroke.

The SaeboGlove is a CE marked mechanical hand orthosis already used in some health services. It consists of a glove, fixed using velcro inside a wrist splint (Figure 1),[18] and offers digital extensor assistance using tensioner bands which span between hooks over weak joints to enable hand opening.[18] Consequently, it improves access to repetitive, functional-based upper limb rehabilitation and self-practice opportunities,[19] regardless of extensor weakness severity. This might promote engagement in recommended rehabilitation activities and improve long-term recovery; addressing key priorities in stroke care.

We recently completed a single-group pilot trial of four weeks of SaeboGlove self-directed, repetitive, functional-based practice in people with reduced active digital extension early after stroke (n = 12, mean (range) 27 (4–80) days post).[19] The intervention was found to be safe, feasible and acceptable. We used the revised, standardised[20] and validated[21] version of the original ARAT by Lyle[22] (scale 0–57) which does not specify time limits. As this test has been historically described as a measure of upper limb function, a term that aligns with upper limb activity capacity within The International Classification of Functioning, Disability and Health model, this manuscript will continue to use this terminology. ARAT scores improved by a mean (SD) of 18.8 (13.5) points.[19] This improvement is nearly double that observed in historical controls (10 (15) points)[23] but the absence of a control group limits interpretation.

In this protocol paper, we describe the SUSHI trial. The primary objective of the SUSHI trial is to assess the clinical effectiveness of SaeboGlove self-directed, repetitive, functional-based practice plus usual care when compared to usual care alone in people with upper limb disability and severe hand impairment, including reduced active digital extension after recent stroke. We hypothesise that upper limb function (ARAT) will be significantly greater in the intervention group immediately post intervention.

Methods

Trial design

The SUSHI trial is a pragmatic, multicentre, parallel-group, RCT comparing self-directed, repetitive, functional-based practice with a SaeboGlove plus usual care, to usual care alone. The trial includes blinded outcome assessments with embedded process and economic evaluation. Follow-up for primary and secondary outcomes will occur at 6 and 14 weeks post randomisation. A further follow-up will be performed at 6 months to inform assessment of long-term benefits and economic evaluation. Figure 2 provides an overview of the SUSHI trial. The study is presented according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[24] and a summary is provided in Table 1.

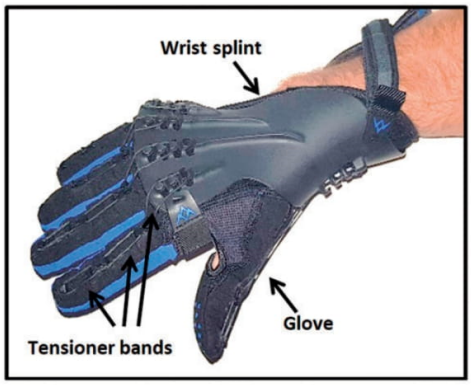


Figure 1. The SaeboGlove. The SaeboGlove consists of a glove velcroed inside a wrist splint, and bands of different size that offer variable extensor assistance. This assistance increases hand opening when it is limited, improving access to recommended rehabilitation activities.

Trial setting

Participants will be recruited within NHS Inpatient Stroke Services in Scotland.

Trial status

The study is registered on ClinicalTrials.gov (NCT04007315, 5 July 2019). Participant recruitment started in November 2019 (protocol version 2.0, 15th July 2019, current 3.0, 14th April 2020). Recruitment was suspended in March 2020 due to Covid-19 after 16 participants were randomised. Enrolment began again in July 2020 and is expected to close in July 2022.

Ethical/regulatory approval

The study sponsor is the NHS GG&C Health Board. The study will be performed in line with the Declaration of Helsinki. Ethical approval was granted by the West of Scotland Research Ethics Committee (REC) 1 in August 2019 (19/WS/0097). NHS Board

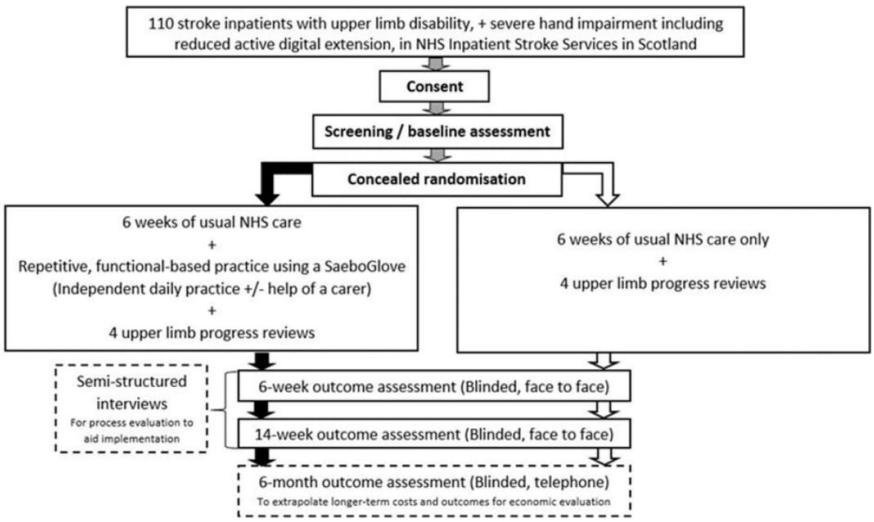


Figure 2. Overview of methods used for RCT, and process and economic evaluations.

approvals were granted by NHS GG&C (GN19ST318) and NHS Lanarkshire (L19046) in November 2019. At the time of writing approval from other sites is awaited. The Principal Investigator at each site will be notified of protocol amendments. The SaeboGlove is CE marked for use as a rehabilitation device so prior regulatory approval from the MHRA is not required.

Eligibility criteria

Participants aged 18 years or older with a new clinical stroke diagnosis that occurred 7–60 days prior to enrolment will be included in the study if they have upper limb disability (ARAT $\leq$46) and severe hand impairment (Fugl Meyer Upper Extremity scale (FMUE) hand sub-section $\leq$7, and reduced active digital extension). The ARAT range was based on feasibility data and the limited function in this group.[25] A full list of the inclusion and exclusion criteria are listed in Table 2.

Case ascertainment, consent and screening

Potential participants will be identified by clinical care teams. Once identified, site personnel will provide a patient information leaflet and discuss study requirements with potential participants. To check eligibility, a screening assessment will then be performed (Table 1). Eligibility will be re-confirmed at the baseline assessment if it takes place >48 hours after initial screening or if the assessor has any concerns over a change in eligibility since it was initially checked (Table 1).

Baseline assessments

The baseline assessment will be carried out by trained site personnel, and will include assessing upper limb impairment (FMUE), perceived habitual functional upper limb use (Motor Activity Log (MAL)), degree of disability or dependence (modified Rankin Scale (mRS)), activities of daily living (Barthel Index (BI), quality of life (Stroke Impact Scale (version 3.0, UK) (SIS), EuroQuol (EQ-5D-5L), upper limb pain intensity (visual analogue scale (VAS)), NHS and social services resource use pre-stroke and current upper limb treatment (Table 1). Details on each measure are given in the online Supplementary material.

Randomisation

A central online randomisation service will be used, developed and maintained by the Robertson Centre for Biostatistics, University of Glasgow. Participants will be allocated, on a 1:1 basis, to receive 6 weeks of SaeboGlove self-directed, repetitive, functional-based practice plus usual NHS care or 6 weeks of usual NHS care. A minimisation algorithm (with a small random element) will be applied, designed to maintain balanced allocations with respect to study site, time since stroke ($\leq$1 month, >1 month) and severity of upper limb function (ARAT 0–10, 11–28, 29–46). When randomised, only nominated unblinded site personnel will be emailed with group allocation details to progress blinded tasks.

Table 1. Standard protocol items.

	Study period					
	Enrolment	Baseline assessment (≤48 hr after screening)	Intervention	Outcome assessments		
Trial activity	Pre week 0	Week 0	Weeks 1–6	Week 6	Week 14	Month 6
Written informed consent	X					
Contact details	X					
Demographics	X					
Stroke details	X					
Relevant comorbidities	X					
Hand + Wrist movement (Active, and passive (contractures + spasticity)	X					
Hand impairment (Hand sub-section of Fugl Meyer upper extremity scale)	X	*				
Upper limb function (Action Research Arm Test)	X	*		X*	X	
Screening check list	X					
Current upper limb treatment		X				
Upper limb impairment (Fugl Meyer upper extremity scale)		X		X	X	
Habitual functional use (Motor Activity Log)		X		X	X	X
Degree of disability (Modified Rankin Scale)		X		X	X	X
Activities of daily living (Barthel Index)		X		X	X	
Quality of life						
(EQ-5D-5L)		X		X	X	X
(Stroke Impact Scale)		X		X	X	
Upper limb pain intensity (Visual analogy scale)		X		X	X	
NHS and social services resource use questionnaire		X			X	X
Randomisation		X				
Adverse events			X	X	X	
SaeboGlove therapy plus usual care			X (Intervention group)			
Usual care**			X (Control group)			
Rehabilitation booklet completed, weekly telephone reminder			X	X		
Usual care recorded			X			

Recommendations for Interventional Trials (SPIRIT): Schedule of enrolment, interventions, assessments and visits. EQ-5D-5L: EuroQol with 5 Dimensions and 5 Levels, UL: Upper limb.

*Hand sub-section and ARAT only repeated if baseline assessment occurs >48 hours after the screening assessment or if it occurred <48 hours ago and assessor is concerned that eligibility may have changed. * represents the primary outcome. ** Optional 6 weeks of SaeboGlove therapy offered after 14 week outcome visit is completed.

Interventions

Usual care. All participants will receive usual NHS care. Usual care involves an evidence-based approach tailored to each individual's needs, and is based on National Clinical Guidelines that recommend a minimum of 45 minutes of physiotherapy and occupational therapy, five days per week.[9,10] Therapy teams will be asked to record the usual care they provide during the intervention period on a study specific form (content, dose (time/movement repetitions), achievement of recommended 45-minute duration).

Intervention group. First use of the SaeboGlove should be within 48 hours of randomisation and must be within one week of the baseline assessment.

Participants in the intervention group will be given a SaeboGlove to use for 6 weeks. A therapist (physiotherapist/occupational) from the study team, trained in how to measure, fit and use the SaeboGlove will train participants and any assisting carers (informal or Health Care Worker) how to don/doff the glove and establish an individualised self-directed, repetitive, functional-based practice training programme involving grasping/releasing. A detailed description of the

Table 2. Inclusion and exclusion criteria.

Inclusion criteria
1. New clinical stroke diagnosis that occurred 7–60 days (inclusive) prior to randomisation
2. Age ≥18 years
3. ARAT ≤46 and FMUE hand sub-section ≤7 due to stroke
4. Capacity to consent to study participation with or without aphasia
5. Identified during stroke index admission with consent, baseline assessment and randomisation occurring as an inpatient or within 2 weeks of discharge home
6. Considered eligible to use a SaeboGlove at consent/baseline assessment:
■ Reduced active range of digital extension with wrist held passively in full extension at consent/baseline
■ At least 5° passive wrist extension with fingers held passively in full extension
■ Nil to minimal digital contractures (5–10° accommodated)
■ Some initiation of gross active digital flexion (crude estimate ≥2 cm in thumb plus ≥1 other digit, using the tips of these digits as a reference)
■ Modified Ashworth Scale ≤2 in wrist/fingers and considered to have consistent hand opening / closing with SaeboGlove on to enable grasp / release despite tone present
7. Considered able to don/doff a SaeboGlove and engage in independent rehabilitation with or without the help of a willing carer
8. Considered able to comply with the requirements of the protocol, including questionnaires with or without help from proxy
Exclusion criteria
1. Swelling of the paretic hand considered severe enough to cause discomfort when glove is worn
2. Other significant upper limb impairment e.g. fixed contracture, fracture within last 6 months, frozen shoulder, severe arthritis, amputation
3. Diagnosis likely to interfere with rehabilitation or outcome assessments e.g. registered blind or terminal illness
4. Participant in another intervention trial

ARAT: Action Research Arm Test; FMUE: Fugl Meyer Upper Extremity scale.

intervention used is shown using the Template for Intervention Description and Replication (TIDieR) Checklist[26] provided in the Supplement. All therapists will have observed at least one SaeboGlove therapy session with a therapist with over 3 years' experience in its use. Therapists will encourage participants to carry out their training programme daily and will provide a review session during 4 of the 6 weeks to assess progress and re-define their individualised upper limb treatment plan. Participants and their therapist will agree shared intensity goals for their daily practice (number of hand opening movements to aim to perform) at each review. If a participant is discharged during the intervention period, they will travel back to their local hospital to attend remaining review appointments. If this is not possible then advice will be provided by telephone.

Control group. Control participants will also receive a review with a therapist (physiotherapist/occupational) during 4 of the 6 weeks to assess progress and re-define their usual care individualised upper limb treatment plan and goals.

After the week 14 outcome assessment is completed, usual care participants will be offered 6 weeks of SaeboGlove self-directed, repetitive, functional-based practice. This is to minimise attrition in the control group. Data collected during this 6 week period will not be a part of the formal efficacy analysis.

Hand and arm rehabilitation booklets. All participants will be given a Hand and Arm rehabilitation exercise booklet to encourage self-management by recording and monitoring active upper limb therapy time during weeks 1–14 (Table 1). Site personnel will explain the booklets to them and phone them weekly to remind them to complete their rehabilitation booklet.

Outcome assessments

Assessments will be performed at 6 and 14 weeks (range 5–9 weeks and 13–17 weeks respectively) after randomisation (Table 1) by trained site personnel. These assessments will include measures with established validity and reliability. As upper limb functional recovery is a recognised research priority for stroke survivors,[12] the primary outcome is upper limb function measured by the ARAT at 6 weeks post randomisation. The secondary outcomes are ARAT at 14 weeks post randomisation, and FMUE, VAS, MAL, BI, mRS, SIS (full, plus hand domain only) and EQ-5D-5L at 6 and 14 weeks. Resource use will be recorded at 14 weeks also.

At 6 months a telephone follow-up will occur. This will include the EQ-5D-5L, MAL, mRS and resource utilisation. These are exploratory outcomes for economic evaluation.

All outcome assessors will receive training on the assessment before conducting any assessments.

This will include face to face training, provision of an accompanying training manual and independent co-scoring of each outcome measure a minimum of 3 times with a researcher with over 5 years' scoring experience.

Blinding and masking of treatment allocation

Outcome assessments will be conducted by a blinded assessor. They will be asked to record if they have been unblinded at each outcome visit to enable potential bias to be reported. Given the interventions involved, it is not possible to conceal group allocation from participants or their therapist. Participants, therapists and the clinical team will be asked not to let outcome assessors know which treatment group participants are allocated to.

At the baseline assessment all participants will be given an identical small therapy box with a cardboard insert weighing the same as a SaeboGlove, and a Hand and Arm rehabilitation booklet specific for control participants (Table 1). The box will have a note in it thanking them for their participation in the SUSHI trial, asking them to bring the box with their Hand and Arm Therapy Booklets to their future study visits and to not discuss the contents of the box or the treatment group they are placed in with outcome assessors.

When participants in the intervention group are given a SaeboGlove, it will be left in their therapy box in exchange for the cardboard insert which their therapist will remove. The Hand and Arm rehabilitation booklet previously provided will also be swapped for a booklet specific for the intervention group (Table 1). All therapy booklets look identical from the outside and would need to be opened and studied to reveal group allocation. Regardless of group allocation, therapy booklets, and all case report forms used for the recording of usual care and upper limb therapy reviews will appear identical externally and will not reveal group allocation unless opened and studied. These measures will help keep outcome assessors blinded.

After the week 14 visit, SaeboGlove therapy can be offered to eligible controls, but outcome assessors should remain blinded.

Statistical analysis

The Robertson Centre for Biostatistics within the Glasgow Clinical Trials Unit will provide statistical support to the trial. A statistical analysis plan will be agreed and made available before completion of enrolment.

Analysis will be performed on an intention to treat basis. All efficacy measures will be compared between randomised groups using linear regression (or other appropriate regression method), adjusting for the baseline value of the outcome, and minimisation variables. If statistical models fail to converge, then a reduced level of adjustment may be applied. Data may be transformed prior to analysis to satisfy statistical modelling assumptions. If no suitable regression model can be identified, then groups will be compared using a stratified Wilcoxon test (van Elteren test).[27]

Missing data

Missing data will not be imputed for the main statistical analyses. The sensitivity of analysis results may be assessed under alternative assumptions regarding missing data, and/or through the use of multiple imputation techniques.

Sample size calculation

A mean change in ARAT score of 10 points is assumed in the control group.[23] A mean difference between groups of 9 points is being used for our sample size calculation based on our pilot data where participants improved by 19 points (standard deviation 13.5 points).[19] A sample size of 49 per group will detect this difference with 90% power at a 5% significance level. Allowing for 11% attrition, we will randomise up to 110 participants to achieve this number with a 6-week outcome measure.

Safety monitoring and analysis

Predicted adverse device effects will include discomfort in the upper limb considered to be device related. The safety of SaeboGlove self-directed, repetitive, functional-based practice and usual care will be evaluated by examining the occurrence of all adverse device events (ADEs), serious adverse events (SAEs), serious adverse device events (SADEs) and unexpected serious adverse device events (USADEs) until the 14 week visit.[28] The occurrence of all such events will be checked at all study visits. Additionally, participants will be encouraged to report them between visits. Participants undergoing SaeboGlove therapy who have upper limb discomfort of a degree sufficient to compromise function will have study therapy stopped. Such participants will be allowed to resume therapy should they wish and if their upper limb discomfort improves, provided this is within the planned 6-week intervention period.

Economic analysis

A within-trial cost-effectiveness analysis will be performed from the perspective of NHS and Social Services resource use. Costs will be calculated using

routine data sources and data from a resource use questionnaire administered at baseline, 14 weeks and 6 months (further detail available in Supplement). Health outcomes will be expressed as quality adjusted life years using population tariffs and responses to the EQ-5D-5L at baseline, 6 and 14 weeks and 6 months (Table 1).

Process evaluation

To aid implementation an embedded process evaluation will be performed involving the two currently approved NHS Health Boards. Semi-structured interviews will be performed with a purposive sample of at least six participants in the intervention group, four carers and four therapists (two physiotherapists and two occupational therapists) from each Board (further detail available in Supplement).

Data management and clinical monitoring

All personal information will be collected, stored and processed in accordance with the General Data Protection Regulation (2018). Each person will be identified on case report forms only by their study number. Site personnel will record data on paper source forms and enter data into an electronic database.

A trial steering committee and a patient and carer research advisory group has been convened and will meet annually. Further details on these groups can be found in the Supplement. A Data Monitoring Committee has not been convened.

This study will be audited by designated representatives of the Sponsor, NHS GG&C, according to their audit processes.

Dissemination

The results of this trial will be presented at research conferences and be published in peer-reviewed journals. A lay summary will be given to those participants who wish to receive it (participants will be asked at their last study visit). Anonymised data will be stored on a research repository called Enlighten for 10 years from the time of last data access and will be shared with other organisations or universities to carry out research to improve scientific understanding.

Discussion

Impaired active digital extension is the most common motor impairment after stroke. It reduces hand opening, hindering participation in self-directed and repetitive functional-based rehabilitation recommended in national clinical guidelines, predicts poor upper limb recovery and may contribute significantly to the poor upper limb prognosis experienced after stroke. Evidence-based interventions for this group have yet to be identified. The SaeboGlove is a rehabilitation aid that assists hand opening, enabling greater access to self-directed, repetitive, functional-based practice and has been found to be a safe, feasible and acceptable intervention early after stroke. A high-quality definitive trial is now needed to assess the effectiveness and role of the SaeboGlove in the treatment of the stroke affected hand and arm in the NHS. SUSHI is a multicentre RCT to determine whether self-directed, repetitive, functional-based practice involving a SaeboGlove improves upper limb function early after stroke when compared to usual NHS care. The results from the trial will provide evidence on the clinical and cost effectiveness of SaeboGlove self-directed, repetitive, functional-based practice.

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Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Saebo Ltd who make the SaeboGlove loan SaeboGloves to the study. Saebo Ltd have no other involvement in the study. OW has received consultancy fees from Bayer, Lupin, Takeda and Freeline, and a research grant from Novo Nordisk. The other authors declare no other conflicts of interest.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This project is an investigator led study funded by the Chest Heart and Stroke Scotland (ResFell19/173); and the Chief Scientist Office (TCS/19/14). Saebo Ltd will loan some of the SaeboGloves for the duration of the trial and will have no other contribution.

Ethical approval

Ethics approval for this study was obtained from the West of Scotland REC 1 (19/WS/0097).

Informed consent

Written informed consent was obtained from all subjects before the study.

Guarantor

JD.

Contributorship

All authors were involved in the study design. JD is the Chief Investigator. JA manages the trial and leads the SaeboGlove therapy. JA and JD drafted the manuscript. LK, OW and AM lead on the process evaluation, health economics and the statistical analysis respectively. All authors have contributed to and approved the final manuscript.

Acknowledgements

We would like to thank:

1. The clinical teams, and the Stroke Research Network within participating NHS Stroke Services for identifying potential participants, performing and recording upper limb reviews in control group participants and recording usual NHS care.
2. The SUSHI coordinating team based at the Queen Elizabeth University Hospital in NHS GG&C for their valuable help to coordinate the study.
3. Members of the trial steering committee and the patient and carer research advisory group for help with study management.

Data availability statement

The authors confirm that the data supporting this manuscript are available within the article and/or its Supplementary materials.

Trial registration

ClinicalTrials.gov: NCT04007315.

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Supplemental material

Supplemental material for this article is available online.

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Supplemental materials

Template for Intervention Description and Replication (TIDieR) Checklist for the SUSHI trial intervention treatment

Item	Intervention
1. **Brief name:** Provide the name or a phrase that describes the intervention.	Help for Hands EMPOWER Programme
2. **Why:** Describe any rationale, theory, or goal of the elements essential to the intervention.	The Help for Hands EMPOWER Programme involves SaeboGlove self-directed, repetitive, functional-based practice. Rationale for this therapy: National guidelines advocate repetitive, functional-based practice and self-practice activities[1, 2]. Research shows that in order to improve brain function and regain the ability to perform every day movements after stroke, hundreds of challenging movement repetitions[3-8], specific to a given every day task[9, 10] must to be practiced. Systematic review evidence shows that after stroke 1) increased intensity of repetitive, functional-based rehabilitation is known to improve functional outcomes (dose > 20 hours)[11] and 2) self-directed interventions that involve repetitive functional-based practice can improve upper limb function and independence in activities of daily living[12]. Research on dynamic hand orthoses after stroke (including the SaeboGlove[13, 14]) consists of small feasibility studies involving between 1-20 participants with moderate and severe upper limb impairment using RCT[15-18] and non-RCT[13, 14, 19-35] designs). This preliminary evidence suggests that such devices are safe, feasible and acceptable, and enable this group to perform higher numbers of functional-based movement repetitions[13, 21, 22, 34], even when self-directed[13, 21, 22, 34]. Positive trends in upper limb recovery are observed in the acute-subacute[13, 14, 24, 32-34] and subacute-chronic[15-23, 25-31, 35] phases of recovery. Essential elements of this intervention include: • SaeboGlove device • Increased access to repetitive, functional-based practice • Increased access to self-practice opportunities • Increased intensity of training (> 100 movement repetitions daily where possible)[8]
3. **What - Materials:** Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The **SaeboGlove** is used[36]. It consists of a glove velcroed inside a wrist splint and tensioner bands of different size/strength which span between hooks, on the SaeboGlove, over weak joints to enable variable hand opening support, essential for self-directed, repetitive, functional-based practice (Figure 1). **Hand and Arm rehabilitation exercise booklets** are used to encourage self-management[37, 38] and record active upper limb therapy time daily. Booklets provided to the intervention group will also include a paragraph highlighting the need for intensive (> 100 movement repetitions daily[8]), repetitive functional-based practice to optimise recovery, and will

	record intensity goals agreed at each review, and encourage participants to record the number of hand opening movements they perform daily during their individualised self-directed, repetitive, functional-based training programme. A **written copy of all exercises** will be provided to participants. Additionally, therapists can **video** participants performing the exercises provided on their own / their carers mobile phone / video camera if participants feel this would be helpful.
4. **What - Procedures:** Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	**Self-practice:** Intervention group participants will receive a SaeboGlove for 6 weeks to carry out self-directed, functional-based hand and arm exercises daily, independently with or without support of a carer. They will aim to fulfil a daily intensity goal agreed with their therapist (number of hand opening movements to aim to perform). **Progress reviews:** A therapist will supervise and support participants (and carers) by providing a progress review during 4 of the 6 weeks to: i) assess/reassess their ability, define/redefine their treatment plan and set shared intensity goals for their daily practice ii) administer them with an individualised self-directed, repetitive, functional-based practice training programme where all exercises provided involve grasping /releasing (where possible grasping should involve an object, alternatively it should involve opposition) iii) train them on the intervention, specifically on how to don/doff the SaeboGlove, and on how to perform any exercises given and log daily self-practice activity (number of hand opening repetitions and minutes of active practice) against their agreed goal in their booklet iv) remind them of the ultimate goal and need to increase use of their affected hand, out with therapy exercises, in everyday tasks between each review. **Rehabilitation booklet:** Site personnel will try to phone participants each week to remind them to complete their rehabilitation booklet daily. **The EMPOWER principles will be followed:** **E**quip with the tools needed to carry out meaningful exercise involving everyday tasks (e.g. eating, drinking, self-care) - a **SaeboGlove**, and **written or videoed exercises** involving everyday objects whenever possible. **M**otivate by setting shared intensity goals and logging / monitoring daily self-practice activity. Identify and overcome barriers to doing daily exercises. **P**rogress review every 1-2 weeks so exercises remain challenging and progressive. **O**ptimise self-management support at reviews by coaching independence in exercises, progression

	and tailoring. **W**ean from SaeboGlove bands and glove for some / all exercises as able. **E**ngage carer support whenever possible. **R**emind of ultimate goal and need to increase use of stroke affected hand in everyday tasks.
5. **Who provided:** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	The intervention will be carried out by participants with support from 1) a trained therapist (physiotherapist or occupational therapist) and 2) a trained carer if needed. The therapist is a clinical specialist in stroke care, will receive training on the intervention, be provided with an accompanying therapy guidance document and observe at least one SaeboGlove Therapy session with a therapist with over 3 years' experience in the delivery of SaeboGlove Therapy. All supporting carers will be encouraged to attend review sessions with participants where they will receive training on the intervention, specifically on how to don/doff the glove, assist with the performance of any exercises and record self-practice activity. Participants and carers will be encouraged to contact their therapist for further advice if they have questions/concerns.
6. **How:** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Typically, 1:1 face-to-face delivery, though on occasion, for participant convenience by telephone.
7. **Where:** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	For 1:1 delivery: at bedside or clinic room in NHS hospital facilities. By telephone: in NHS hospital facilities if inpatient, or at home if discharged.
8. **When and how much:** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Over the 6 week intervention period: • Participants will be encouraged to fulfil their individualised, shared intensity goal daily. • A progress review with a therapist will be provided every 1-2 weeks (4 occasions) at a mutually suitable time that also allows flexibility depending on anticipated rate of progress. • SaeboGlove self-directed, repetitive, functional-based practice will be in addition to usual NHS care. It is assumed that usual care is based on National Clinical Guidelines[1, 2]. Therapy teams will be asked to ensure that participants receive 45-minutes of physiotherapy and occupational therapy daily for as long as required and will be asked to record the usual care they provide on a study specific form.
9. **Tailoring:** If the intervention was planned to be	Programs will be set at 1 of 3 levels:

personalised, titrated or adapted, then describe what, why, when, and how.	**Level 1:** 1-2 exercises involving grasping / releasing (with or without wrist movement). **Level 2:** Level 1 **plus** a lower arm movement (supination/pronation or elbow flexion/extension) involving grasping / releasing. **Level 3:** Level 2 **plus** an upper arm movement (any shoulder movement) involving grasping / releasing. Participants will start at the highest level according to their ability. The difficulty level and number of exercises performed will be reduced / increased according to ability but all participants must be able to carry out at least one level 1 exercise with or without the help of a carer in order to participate in the trial. As participants move from levels 1 to 3, exercises will become progressively more difficult because each increment will involve movement of more upper limb segments and joints, and this will require greater strength to lift the weight of an increased number of body segments up against gravity[39], the ability to coordinate movement over increasing numbers of joints, and the generation of higher torque forces (T) as the length of the moment arm (r) i.e. perpendicular distance between the joint (axis) e.g. wrist, elbow, shoulder and the hand carrying a given object or force (F)) in a task is gradually increased ($T = F \times r$)[40]. Exercises selected will be functional-based movements identified as being meaningful to participants. Participants will be encouraged to learn the best way for them to achieve their daily intensity goal e.g. doing exercises all at once, or spreading exercises out separated by breaks, doing more challenging exercises first before tiring, or last after warmed up. They will also be encouraged to increase the use of their affected hand in a varying number and type of everyday tasks between each review depending on ability and preference. If the therapist feels that the SaeboGlove is no longer needed for some/all of the exercises, participants will continue to carry out an individualised self-directed, repetitive, functional-based practice training programme involving grasping/releasing based on level 3 with/without a SaeboGlove according to their changing ability. Similarly, the design of the SaeboGlove will enable assistance from tensioners to be increased / decreased according to individual ability.
10. **Modifications:** If the intervention was modified during the course of the study, describe the changes (what, why, when, and	To date there have been no modifications.

how).	
11. **How well - Planned:** If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Therapists will complete a Case Report Form after each review to document adherence at sessions. Participants will complete a Hand and Arm rehabilitation booklet to record the number of hand opening movements and minutes of self-practice they carryout daily. Data from booklets will be studied by therapists at reviews to monitor intervention adherence and take steps to optimise it.
12. **How well - Actual:** If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Unable to describe until study completion

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Outcome measures

The Fugl-Meyer Upper Extremity scale (FMUE) – The FMUE[41] is a stroke-specific assessment which measures upper limb impairment using three subscales (passive range of upper limb movement and pain during passive upper limb movement (24 items, 0-48), active movement impairment (33 items, 0-66) and sensory impairment (6 items, 0-12). Each item is rated on a 3-point ordinal scale (0=cannot perform, 1=performs partially and 2=performs fully) with a higher score representing a higher performance i.e. less impairment.

Action Research Arm Test (ARAT)—The ARAT[42] measures upper limb function and dexterity in people with hemiparesis. It scores 19 items grouped into four subscales (grasp, grip, pinch and gross movements) using a 4-point ordinal scale (0-3). Items within each subscale are arranged hierarchically, such that some items may be skipped if earlier items score 0. The final score ranges from 0-57, with 57 representing the best function i.e. normal function.

A rigorous and validated approach to ARAT assessment was followed. The original ARAT by Lyle (1981) is ambiguous with little instructions for scoring[42]. Consequently, a revised standardised[43], and validated[44] version with very high inter-rater and test-retest reliability[44] was used to increase precision of scoring.

Self-Report Measures Motor Activity Log (MAL-14)—The MAL-14 [45] is a structured interview used to assess self-perceived performance (Amount of use (AOU) and quality of use (QOU)) in 14 real-world UE activities. AOU and QOU are both rated using a 6-point scale (0-5). The mean for each scale is calculated and the final score ranges from 0-5 for each scale, with 5 indicating that the affected arm is used as much (AOU) and as well (QOU) as before the stroke. There are different versions of the MAL; MAL-14, MAL-30, MAL-28, MAL-14, MAL-45, LF-MAL, Grade 4/5 MAL and Turkish, Brazilian and German versions[46]. MAL-14 will be used as it has been studied earlier after stroke, during the subacute phase[47], and has less items and therefore a smaller burden.

Stroke Impact Scale (SIS) — The SIS[48] is a two-part stroke-specific questionnaire that measures health status after stroke. Part 1 scores 59 items grouped into eight subscales (strength, hand function, ADL/IADL, mobility, communication, emotion, memory and thinking, and participation/role function) using a 5-point Likert scale. Scores for each subscale range from 0-100, with the final score for part 1 ranging from 0 to 800. The hand function and ADL/IADL are most useful for measuring health in relation to upper limb recovery. Part 2: An overall recovery score (0- 100) is also included. A higher score reflects better health in both parts.

Barthel Index (BI) – The BI[49] measures performance in activities of daily living across 10 items of activities of daily living (feeding, bathing, grooming, dressing, bowel control, bladder control, toileting, chair transfer, ambulation and stair climbing). Items are rated in terms of whether individuals can perform activities independently, with some assistance, or are dependent. Scores for each item vary between 0-1, 0-2 or 0-3 with the overall score ranging from 0-20. A higher score represents a higher performance.

The Euroquol (EQ-5D-5L™) – The EQ-5D-5L™[50] is a self-reported questionnaire for the generic measurement of health. It scores five health dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) using a five-level response (1-5, with 1 representing the best health). The responses from each dimension make a 5-digit health state profile which is combined into a single utility index value using population tariffs. An EQ-5D-5L index score of 1 represents full health.

Modified Rankin Scale (mRS) – The mRS[51] is a stroke-specific tool that measures degree of new disability/dependence after stroke using a subjective 6-point ordinal global outcome scale. Disability/dependence is rated based on an individual's independence in relation to pre-stroke activities (0=no stroke symptoms at all, 5= Severe disability due to stroke: bedridden, incontinent, and requiring constant nursing care and attention). Higher scores reflect greater disability/dependence.

Visual analogue scale for pain (VAS)[52] – A VAS is a tool often used to measure pain intensity. Individuals are asked to rate their pain intensity at a specified time (in the SUSHI trial this is the average intensity of their pain over the previous week) using an 11-point scale displayed on a 10 cm line, ranging from 0=No Pain to 10=Unbearable Pain. Higher scores reflect greater pain intensity.

All outcomes selected are widely used and accepted (FMUE[53], ARAT[53], MAL[53], SIS[54], BI[55], EQ-5D-5L[55], mRS[55], VAS[56, 57]), and have robust psychometric characteristics (FMUE[44, 58-61], ARAT[44, 60-63], MAL[45, 47], SIS[48, 64], BI[65, 66], EQ-5D-5L[67, 68], mRS[69], VAS[52, 56, 57]) in people with stroke.

However, it should be noted that while VAS is a reliable and valid measure in populations outwith stroke[70, 71], and intra-rater reliability is good in a stroke population[52], a large systematic bias has been found between raters[52]. Use of training and standardised assessment procedures have been recommended to overcome such differences[52]. Furthermore, stroke literature currently lacks a gold standard pain measure in patients with higher cortical (cognitive and visuospatial) deficits [56]. Data suggests that the validity in this group is improved using a vertical visual analogue scale [57, 72]. Thus, like all measures used, training and standardised assessment procedures will be utilised along with a training manual, a vertical scale will be used to measure upper limb pain intensity and the same assessor will assess repeated outcomes whenever possible.

Furthermore, while the MAL-14 has been found to be a reliable and valid post stroke measure[45, 47], data on the MAL is limited during the acute phase after stroke (< 1 month)[45, 47]. As SUSHI will include acute and subacute stroke patients, and acute stroke patients are likely to be inpatients with more limited opportunity to carry out everyday activities in a hospital environment, three additional upper limb activities (open a bottle or jar, tie lace, hobbies e.g. reading, cards etc) routinely accessible at a hospital beside will be scored in addition to the MAL-14 as per our pilot trial[13].

NHS and social services resource use questionnaire – The questionnaire is an adaptation of the Client Services Receipt Inventory by Beecham and Knapp (1992)[73-76]. Individuals are asked questions about the NHS and social services resources they use. This includes resources used in primary NHS care (e.g. general practice, nursing, therapy visits and prescription costs), secondary NHS care (e.g. inpatient stays and outpatient visits), social care (residential care home, nursing home and home care), and health related benefits.

Trial Management

Trial steering committee
This comprises an independent chair, two other independent members, the Chief Investigator, the co-investigator/lead physiotherapist and two other investigators. This committee shares the overall scientific responsibility of the study with the Chief Investigator and Sponsor, contributing expertise, oversight and guidance for the study duration.

Patient and carer research advisory group
This comprises two stroke survivors, two carers and the lead physiotherapist. The role of this group is to offer advice / feedback on any issues arising throughout the trial including any publications,

represent the wider views of people affected by reduced upper limb function after stroke and contribute to decision making and clinical implementation planning where relevant.

Process evaluation

The purposive sample used in the process evaluation represents more than 20% of the intervention group. Final numbers will be determined by saturation of themes (where no new themes in the data arise)[77] and resources permitting. Interviews will be designed to explore the views and experiences of participants having a stroke and receiving both usual NHS stroke rehabilitation and SaeboGlove Therapy. In order to enhance sample variation participants who provide written consent to be invited at study enrolment, will be selected to ensure representation of participants differing in age, time since stroke, severity of upper limb disability and those with and without supporting carers. Similarly, therapists will be selected to ensure representation of differing experience levels. Interviews will be conducted by a trained researcher at an agreed time and place (typically at the participants local hospital / therapists place of work), audio-recorded, and transcribed in an anonymous format. To minimise participation burden, some interviews may be carried out by telephone. Interviews will be analysed using thematic analysis[78].

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Appendix B - Prospero protocol

PROSPERO
International prospective register of systematic reviews

NHS National Institute for Health Research

UNIVERSITY of York
Centre for Reviews and Dissemination

Systematic review

1. * Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

Dynamic hand orthoses for the recovery of hand and arm function in adults after stroke. A systematic review of randomised controlled trials

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.
01/09/2019

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.
31/07/2020

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.
Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.
This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

The review has not yet started: No

PROSPERO
International prospective register of systematic reviews

NHS National Institute for Health Research

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

6. * Named contact.

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Jen Alexander

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Jen

7. * Named contact email.

Give the electronic mail address of the named contact.

jen.alexander@nhs.net

8. Named contact address

Give the full postal address for the named contact.

ICAMS, Stroke Research Unit \ Office Block, Ground Floor, Zone 0.01, Office M0.08 (Glasgow University)\

Queen Elizabeth University Hospital\ 1345 Govan Road, Glasgow, G51 4TF

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

Tel: 0141 451 5870 / 5871

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

University of Glasgow / NHS GGC

Organisation web address:

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country are**

now mandatory fields for each person.

Ms Jen Alexander. University of Glasgow / NHS GGC
Professor Jesse Dawson. University of Glasgow / NHS GGC
Professor Peter Langhorne. University of Glasgow / NHS GGC

12. * Funding sources/sponsors.

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

Chest Heart and Stroke Scotland

Grant number(s)

ResFell 19/173

13. * Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country are now mandatory fields for each person.**

15. * Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

Do dynamic hand orthoses improve the recovery of hand and arm function in adults after stroke?

16. * Searches.

State the sources that will be searched. Give the search dates, and any restrictions (e.g. language or publication period). Do NOT enter the full search strategy (it may be provided as a link or attachment.)

Sources: MEDLINE, Embase, Amed, CINAHL, Cochrane Database of Systematic Reviews, Cochrane Central Register of Clinical Trials (CENTRAL), PEDro, OT Seeker, CSP Catalogue, RehabData, ClinicalTrials.gov, EThOS (British Library), Web of Science (Core Collection, Conference Proceedings). The reference list of all included studies and any review papers will also be searched to help identify other eligible studies.

Search dates: 2000 - 27/09/19

Restrictions: From year 2000 onwards only

17. URL to search strategy.

Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies), or upload your search strategy.Do NOT provide links to your search results.

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Functional recovery of the stroke affected hand and arm

19. * Participants/population.

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion

- Adults (?18 years)

- Clinical stroke diagnosis including ischaemic, intracerebral haemorrhage or subarachnoid haemorrhage and any anatomical location, as defined by WHO's definition "rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours.."

- Upper limb impairment due to stroke

- Mixed group of participants involving other neurological conditions where ?50% have a stroke diagnosis

- Receiving care in any "usual care" setting (e.g. hospital, community, home)

Exclusion

- Children (18 years)

- No clinical stroke diagnosis

- No upper limb impairment due to stroke

- Mixed group of participants involving other neurological conditions where 50% have a stroke diagnosis

N.B. PICOS adapted from: Coupar F, Pollock A, Legg LA, Sackley C, van Vliet P. Home-based therapy programmes for upper limb functional recovery following stroke. Cochrane Database Syst Rev. 2012;2012(5):CD006755. Published 2012 May 16. doi:10.1002/14651858.CD006755.pub2

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

Inclusion

- A dynamic hand orthosis was used

- A dynamic hand orthosis was the only upper limb intervention or the only intervention over and above usual care.

- The main goal of intervention was to improve functional upper limb recovery after stroke

- Intervention was provided / supervised by a healthcare professional

Exclusion

- A dynamic hand orthosis was not used

- A dynamic hand orthosis was not the only upper limb intervention or the only intervention over and above usual care.

- The main goal of intervention was not to improve functional upper limb recovery after stroke

- Intervention was not provided / supervised by a healthcare professional

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Inclusion

- Comparison group receives either i) placebo or no intervention or ii) usual care

Exclusion

- No comparison group

- Comparison group does not receive either i) placebo or no intervention and ii) usual care

- The second phase of any cross-over studies were excluded to avoid learning effects

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion

- Randomised control trials where one group fulfilled the criteria for the intervention and one group fulfilled the criteria for the comparison group

Exclusion

- Non randomised trials

- Randomised control trials where one group did not fulfilled the criteria for the intervention or one group did not fulfilled the criteria for the comparison group

23. Context.

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

Inclusion

Primary outcomes:

1. Functional movement of the upper limb (such as measures of active movement, co-ordination, dexterity, manipulation and grasp/grip/pinch).

Common measures: ARAT, MAS-UE or combined arm, Frenchay Arm Test , WOLF, Upper Extremity Function Test, Functional Test of the Hemiparetic Upper Extremity, BBT, Upper Extremity Performance Test for the Elderly, Chedoke Arm and Hand Activity Inventory, Sodring Motor Evaluation of Stroke Patients - arm section, University of Mary land Arm Questionnaire for Stroke, MAL, MAS, Jebsen Hand Function Test, NHPT, Purdue Peg Test.

2. Performance in ADL (including feeding, toileting, dressing, bathing, grooming, continence, simple mobility and transfers).

Common measures: Barthel, Rivermead, Rivermead Motor Ability Scale, Rankin Scale, FIM, Katz Index of ADL, Rehabilitation Activities Profile.

Secondary outcomes:

1. Performance in extended ADL (including shopping and household tasks). Common outcome measures: Nottingham Extended ADL (Nouri 1987), Rivermead Extended ADL (Rossier 2001) and Frenchay Activites Index (Holbrook 1983).

2. Motor impairment of the upper limb (measures of general upper limb impairment, muscle strength and muscle tone).

Common measures: FM-UE, Motricity Index, Rivermead Motor Assessment(arm section), Motor Club Assessment, Ashworth Scale/Modified Ashworth Scale, MRC scale, dynamometer scores and Kinematic

Measures.

* Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Mean difference between groups

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state ‘None’ or ‘Not applicable’ as appropriate to the review

Inclusion

- Adverse events, such as death and pain

* Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Mean difference between groups

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Study selection

Three reviewers will be involved in applying the eligibility criteria and selecting studies for inclusion in the systematic review. One reviewer will upload and screen all database titles into Endnote software and remove any that are clearly not eligible for inclusion. Included titles will then be uploaded to Covidence software with their abstracts. In Covidence, two reviewers will then independently screen all abstracts for eligibility, rating them by selecting either "No", "Maybe" or "Yes". Studies will be considered ineligible if both reviewers select "No". Disagreements between individual judgements will be resolved through discussion, with the help of a third reviewer where appropriate. The full texts of all remaining studies will then be uploaded and two reviewers will independently screen them, rating them by selecting either "Include" or "Exclude". Studies will be considered ineligible if both reviewers rate the full text of a study with "Exclude". Once again disagreements between individual judgements will be resolved through discussion, with the help of a third reviewer where appropriate.

Data extraction

Two reviewers will independently extract the following data from included studies, where available - participant demographics and baseline characteristics including the inclusion / exclusion criteria,

experimental intervention characteristics (including description (e.g. movements, goals, support), frequency, duration, intensity (e.g. time / reps)), comparison intervention characteristics and outcomes. Disagreements between individual judgements will be resolved through discussion, with the help of a third reviewer where appropriate.

Data will be extracted onto a designed electronic form.

27. * Risk of bias (quality) assessment.

Describe the method of assessing risk of bias or quality assessment. State which characteristics of the studies will be assessed and any formal risk of bias tools that will be used.

The Cochrane risk of bias tool 1.0 will be used to assess risk of bias. This includes the assessment of selection, performance, attrition, detection and reporting bias, and any other bias.

Unfortunately due to the very visable nature of the intervention, participant and therapist blinding will not be feasible.

Two reviewers will independently assess study quality. Disagreements between individual judgements will be resolved through discussion, or with the help of a third reviewer where appropriate.

28. * Strategy for data synthesis.

Provide details of the planned synthesis including a rationale for the methods selected. This **must not be generic text** but should be **specific to your review** and describe how the proposed analysis will be applied to your data.

We will provide a narrative synthesis of the findings from the included studies, structured around the type of intervention, target population characteristics and type of outcome. Adverse events and safety data will be presented in a descriptive fashion.

A quantitative synthesis will also be performed for an outcome if more than two studies measured the same outcome. We hope to be able to include a measure of functional movement of the upper limb, performance in ADLs and motor impairment of the upper limb. RevMan Review Manager software will be used for all analyses.

Continuous data will be presented as the weighted mean difference with 95% confidence intervals (CIs) if the measure is consistent across trials. If the measure is not consistent, the results will be presented as the standard mean difference with 95% CIs. Calculations will be performed using a random-effects method. A p value = 0.05 will be considered statistically significant. Heterogeneity will be assessed using the inconsistency I^2 test. Values above 25% and 50% will be considered indicative of moderate and high

heterogeneity. Dichotomous data, such as clinically meaningful responses will be analysed using odds ratio and 95% confidence intervals. Sensitivity analysis will be performed if indicated.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

Time from stroke

Severity of upper limb functional impairment

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

Type of review

Cost effectiveness
No

Diagnostic
No

Epidemiologic
No

Individual patient data (IPD) meta-analysis
No

Intervention
Yes

Meta-analysis
Yes

Methodology
No

Narrative synthesis
No

Network meta-analysis
No

Pre-clinical
No

Prevention
No

Prognostic
No

Prospective meta-analysis (PMA)
No

Review of reviews
No

Service delivery
No

Synthesis of qualitative studies
No

Systematic review
Yes

Other

No

Health area of the review

Alcohol/substance misuse/abuse
No

Blood and immune system
No

Cancer
No

Cardiovascular
Yes

Care of the elderly
No

Child health
No

Complementary therapies
No

COVID-19
No

Crime and justice
No

Dental
No

Digestive system
No

Ear, nose and throat
No

Education
No

Endocrine and metabolic disorders
No

Eye disorders
No

General interest
No

Genetics
No

Health inequalities/health equity
No

Infections and infestations
No

International development
No

Mental health and behavioural conditions
No

Musculoskeletal
No

Neurological
Yes

Nursing

No

Obstetrics and gynaecology
No

Oral health
No

Palliative care
No

Perioperative care
No

Physiotherapy
Yes

Pregnancy and childbirth
No

Public health (including social determinants of health)
No

Rehabilitation
Yes

Respiratory disorders
No

Service delivery
No

Skin disorders
No

Social care
No

Surgery
No

Tropical Medicine
No

Urological
No

Wounds, injuries and accidents
No

Violence and abuse
No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.
English

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.
Scotland

33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with

The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

Give the link to the published protocol.

Alternatively, upload your published protocol to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

Do you intend to publish the review on completion?

Yes

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Systematic review, stroke, cerebrovascular event, upper limb function, dynamic hand orthosis, dynamic wrist orthosis, functional hand orthosis, functional wrist orthosis, splint, SaeboGlove.

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38. * Current review status.

Review status should be updated when the review is completed and when it is published. For newregistrations the review must be Ongoing.
Please provide anticipated publication date

Review_Ongoing

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

Extra detail has been added to field 28 as requested on 29/04/2020. This includes information specific to our review with further detail of our planned synthesis.

40. Details of final report/publication(s) or preprints if available.

This field should be left empty until details of the completed review are available OR you have a link to a

preprint.

Give the link to the published review.

Appendix C – Search strategy for systematic review

Database: Ovid MEDLINE(R) ALL <1946 to September 25, 2019>
Search Strategy:

---

1 Orthotic Devices/ (6251)
2 Splints/ (8592)
3 (dynamic or functional or outrigger or dorsal or extended or extension or soft or saebo Or dynsyst).mp. (2174459)
4 (splint* or orthos* or orthotic or device* or glove*).mp. (500897)
5 3 and 4 (60896)
6 upper extremity/ or arm/ or elbow/ or forearm/ or hand/ or fingers/ or thumb/ or metacarpus/ or wrist/ or shoulder/ (149083)
7 (upper adj3 (limb* or extremit*)).mp. (54302)
8 (arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder*).mp. (880053)
9 6 or 7 or 8 (906705)
10 1 or 2 (14707)
11 3 and 10 (3098)
12 exp stroke/ (125564)
13 cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebrovascular trauma/ or exp intracranial arterial diseases/ or intracranial arteriovenous malformations/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or vasospasm, intracranial/ (276948)
14 exp brain infarction/ (35716)
15 (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc* or cva* or apoplex* or SAH).mp. (391020)
16 ((brain* or cerebr* or cerebell* or intracran* or intracerebral) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus*)).mp. (150266)
17 ((brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)).mp. (88805)
18 12 or 13 or 14 or 15 or 16 or 17 (573337)
19 Hemiplegia/ (11354)
20 exp Paresis/ (7779)
21 (hemipleg* or hemipar* or paresis or paretic or impair* or weakness).mp. (765846)
22 19 or 20 or 21 (766756)
23 5 or 11 (60896)
24 9 and 18 and 22 and 23 (396)
25 limit 24 to yr="2000 -Current" (378)
26 limit 25 to english language (370)
27 25 not 26 (8)

****

Database: Ovid Embase Classic+Embase <1947 to 2019 Week 38>
Search Strategy:

---

1 orthosis/ or active support bandage/ (6902)
2 splint/ or arm splint/ or finger splint/ or wrist splint/ (10610)
3 (dynamic or functional or outrigger or dorsal or extended or extension or soft or saebo or dynsyst).mp. (2844510)
4 (splint* or orthos* or orthotic or device* or glove*).mp. (852254)

5 3 and 4 (104310)
6 upper limb/ or arm/ or elbow/ or forearm/ or hand/ or wrist/ or finger/ or hand joint/ or shoulder girdle/ or shoulder/ or clavicle/ or scapula/ or sternum/ (282060)
7 (upper adj3 (limb* or extremit*)).mp. (81978)
8 (arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder*).mp. (1286435)
9 6 or 7 or 8 (1334169)
10 1 or 2 (17281)
11 3 and 10 (4665)
12 cerebrovascular accident/ or cardioembolic stroke/ or lacunar stroke/ or brain infarction/ or cerebrovascular disease/ or cerebrovascular accident/ (297540)
13 brain ischemia/ or transient ischemic attack/ or carotid artery disease/ or traumatic brain injury/ or cerebral artery disease/ or brain embolism/ (230315)
14 brain hemorrhage/ or brain ventricle hemorrhage/ or cerebellum hemorrhage/ or brain vasospasm/ (110027)
15 (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc* or cva* or apoplex* or SAH).mp. (593744)
16 ((brain* or cerebr* or cerebell* or intracran* or intracerebral) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus*)).mp. (267523)
17 ((brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)).mp. (178877)
18 12 or 13 or 14 or 15 or 16 or 17 (844495)
19 hemiplegia/ (21880)
20 paresis/ (12387)
21 (hemipleg* or hemipar* or paresis or paretic or impair* or weakness).mp. (1311953)
22 19 or 20 or 21 (1311953)
23 5 or 11 (104310)
24 9 and 18 and 22 and 23 (734)
25 limit 24 to yr="2000 -Current" (709)
26 limit 25 to english language (685)
27 25 not 26 (24)

****

Database: Ovid AMED (Allied and Complementary Medicine) <1985 to September 2019>
Search Strategy:
---
1 orthotic devices/ (1878)
2 splints/ (136)
3 (dynamic or functional or outrigger or dorsal or extended or extension or soft or saebo or dynsyst).mp. (30513)
4 (splint* or orthos* or orthotic or device* or glove*).mp. (8253)
5 3 and 4 (2049)
6 arm/ or elbow/ or forearm/ or hand/ or fingers/ or thumb/ or shoulder/ or wrist/ (7081)
7 (upper adj3 (limb* or extremit*)).mp. (3945)
8 (arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder*).mp. (19265)
9 6 or 7 or 8 (20255)
10 1 or 2 (2007)
11 3 and 10 (519)
12 cerebral hemorrhage/ (78)
13 cerebral infarction/ or cerebral ischemia/ (390)
14 cerebrovascular accident/ or stroke/ (4801)

15 (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc* or cva* or apoplex* or SAH).mp. (10024)
16 ((brain* or cerebr* or cerebell* or intracran* or intracerebral) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus*)).mp. (812)
17 ((brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)).mp. (289)
18 12 or 13 or 14 or 15 or 16 or 17 (10495)
19 hemiplegia/ (1272)
20 muscle spasticity/ (1095)
21 (hemipleg* or hemipar* or paresis or paretic or impair* or weakness).mp. (14936)
22 19 or 20 or 21 (15727)
23 5 or 11 (2049)
24 9 and 18 and 22 and 23 (73)
25 limit 24 to yr="2000 -Current" (70)
26 limit 25 to english (66)
27 25 not 26 (4)

****

CINAHL

#	Query	Limiters/Expanders	Results
S1	(MH "Orthoses") OR (MH "Slings")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	6,086
S2	(MH "Splints")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	2,217
S3	dynamic or functional or outrigger or dorsal or extended or extension or soft or saebo or dynsyst	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	292,808
S4	splint* or orthos* or orthotic or device* or glove*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	132,530
S5	S3 AND S4	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	15,264
S6	(MH "Upper Extremity") OR (MH "Arm") OR (MH "Axilla") OR (MH "Elbow") OR (MH "Forearm") OR (MH "Shoulder") OR (MH "Hand") OR (MH "Fingers") OR (MH "Thumb") OR (MH "Wrist")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	35,385

S7	upper n3 limb* OR upper n3 extremit*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	17,804
S8	arm* or elbow* or forearm* or hand* or finger* or thumb* or wrist* or shoulder*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	224,271
S9	S6 OR S7 OR S8	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	234,589
S10	S1 OR S2	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	8,187
S11	S3 AND S10	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	2,005
S12	(MH "Stroke") OR (MH "Stroke, Lacunar")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	61,169
S13	(MH "Cerebrovascular Disorders") OR (MH "Cerebral Ischemia, Transient") OR (MH "Cerebral Ischemia") OR (MH "Cerebral Vasospasm")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	19,990
S14	(MH "Intracranial Hemorrhage") OR (MH "Hematoma, Subdural") OR (MH "Brain Injuries")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	25,110
S15	(stroke or poststroke or post-stroke or cerebrovasc* or cva* or apoplex* or SAH) OR cerebral vasc* OR brain vasc*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	118,038
S16	(brain* or cerebr* or cerebell* or intracran* or intracerebral) AND (ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*)	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	40,796
S17	(brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) AND (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	21,499

S18	S12 OR S13 OR S14 OR S15 OR S16 OR S17	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	161,678
S19	(MH "Hemiplegia")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	5,295
S20	(MH "Paralysis")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	2,503
S21	hemipleg* or hemipar* or paresis or paretic or impair* or weakness	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	159,038
S22	S19 OR S20 OR S21	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	161,137
S23	S5 OR S11	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	15,285
S24	S9 AND S18 AND S22 AND S23	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	216
S25	S9 AND S18 AND S22 AND S23	Limiters - Published Date: 20000101-20191231 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	210
S26	S9 AND S18 AND S22 AND S23	Limiters - Published Date: 20000101-20191231; English Language Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	203
S27	s25 NOT s26	Limiters - Published Date: 20000101-20191231; English	7

		Language Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	

Cochrane Database of Systematic Reviews – limited to Stroke Group

1. Title/Abstract/Keyword: splint* or orthot* or orthos* or device* or glove*
2. Title/Abstract/Keyword: arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder* or upper
3. Title/Abstract/Keyword: stroke or poststroke or post-stroke or brain* or cerebral* or cva* or apoplex* or SAH or cerebr* or cerebell* or intracran* or intracerebral or infarct* or thrombo* or emboli* or occlus* or ischaem* or ischem* or haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed* or hemipleg* or hemipar* or paresis or paretic or impair* or weakness*
4. Cochrane group: Stroke
5. Limit to 2000 – 2019 [“Word variations have been searched”]

Cochrane Central Register of Clinical Trials

1. **Title/Abstract/Keyword: splint* or orthot* or orthos* or device* or glove***
2. **Title/Abstract/Keyword: arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder* or upper**
3. **Title/Abstract/Keyword: stroke or poststroke or post-stroke or brain* or cerebral* or cva* or apoplex* or SAH or cerebr* or cerebell* or intracran* or intracerebral or infarct* or thrombo* or emboli* or occlus* or ischaem* or ischem* or haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed* or hemipleg* or hemipar* or paresis or paretic or impair* or weakness***
4. **Limit to 2000 – 2019 [“Word variations have been searched”]**

BL ETHOS

Splint / splints / orthotic / orthotics / orthoses / orthosis / device / devices / glove / gloves

arm / arms / elbow / elbows / forearm / forearms / hand / hands / finger / fingers / thumb / thumbs / wrist / wrists / shoulder / shoulders / upper

stroke / poststroke / post-stroke / brain / cerebral / cva / apoplexy / apoplexies / SAH / cerebral / cerebrovascular / cerebellum / intracranial / intracerebral / infarction / thrombosis / embolism / occlusion / ischaemic / ischemic / haemorrhage / haemorrhage / haematoma / hematoma / bleed / hemiplegia / hemiplegic / hemiparesis / paresis / paretic / impairment / weakness

Clinicaltrials.gov

Splint / splints / orthotic / orthotics / orthoses / orthosis / device / devices / glove / gloves

arm / arms / elbow / elbows / forearm / forearms / hand / hands / finger / fingers / thumb / thumbs / wrist / wrists / shoulder / shoulders / upper

stroke / poststroke / post-stroke / brain / cerebral / cva / apoplexy / apoplexies / SAH / cerebral / cerebrovascular / cerebellum / intracranial / intracerebral / infarction / thrombosis / embolism / occlusion / ischaemic / ischemic / haemorrhage / haemorrhage / haematoma / hematoma / bleed / hemiplegia / hemiplegic / hemiparesis / paresis / paretic / impairment / weakness

RehabData, CSP Catalogue, PEDro, OT Seeker

splint / orthotic / orthoses / orthosis / device / glove

arm / elbow / forearm / hand / finger / thumb / wrist / shoulder / upper

stroke / poststroke / post-stroke / brain / cerebral / cva / apoplexy / apoplexies / SAH / cerebral / cerebrovascular / cerebellum / intracranial / intracerebral / infarction / thrombosis / embolism / occlusion / ischaemic / ischemic / haemorrhage / haemorrhage / haematoma / hematoma / bleed / hemiplegia / hemiplegic / hemiparesis / paresis / paretic / impairment / weakness

Web of Science Core Collection database, in citations index: Conference Proceedings Citation Index- Science (CPCI-S) --1990-present.

Search 1 on splints etc was combined with arm etc and stroke etc to give search 3 below with 2557 hits between 2000-2019, language not specified.

# 3	2,557	**TOPIC:** (splint* or orthot* or orthos* or device* or glove*) *AND* **TOPIC:** (arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder* or upper) *AND* **TOPIC:** (stroke or poststroke or post-stroke or brain* or cerebral* or cva* or apoplex* or SAH or cerebr* or cerebell* or intracran* or intracerebral or infarct* or thrombo* or emboli* or occlus* or ischaem* or ischem* or haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed* or hemipleg* or hemipar* or paresis or paretic or impair* or weakness*) *Indexes=CPCI-S Timespan=2000-2019*	Edit
# 2	29,107	**TOPIC:** (splint* or orthot* or orthos* or device* or glove*) *AND* **TOPIC:** (arm or arms or elbow* or forearm* or hand or hands or finger* or thumb* or wrist* or shoulder* or upper) *Indexes=CPCI-S Timespan=1900-2019*	Edit
# 1	476,096	**TOPIC:** (splint* or orthot* or orthos* or device* or glove*) *Indexes=CPCI-S Timespan=1900-2019*	

Appendix D – Cochrane risk of bias scoring tool 1.0

Bias Domain	Judgement			Support for Judgement
	High	Low	Unclear	
Random sequence generation (selection bias)				
Allocation concealment (selection bias)				
Blinding of participants & personnel (performance bias)				
Blinding of outcome assessment (detection bias)				
Incomplete outcome data (attrition bias)				
Selective reporting (reporting bias)				
Other bias				

Reprinted with permission from Higgins, J.P.T. and Green, S. (2011) *(editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. (updated March 2011). The Cochrane Collaboration.*, available: www.handbook.cochrane.org [accessed 18/05/2020].

Appendix E – Cochrane criteria for judging risk of bias in the 'Risk of bias' assessment tool 1.0

RANDOM SEQUENCE GENERATION **Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.**	
Criteria for 'Low risk' of bias.	The investigators describe a random component in the sequence generation process such as: • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. *Minimization without a random element, and this is considered equivalent to random.
Criteria for 'High risk' of bias.	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
Criteria for 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.
ALLOCATION CONCEALMENT **Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.**	
Criteria for 'Low risk' of bias.	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for 'High risk' of bias.	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

BLINDING OF PARTICIPANTS AND PERSONNEL **Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.**	
Criteria for 'Low risk' of bias.	Any one of the following: • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for 'High risk' of bias.	Any one of the following: • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'; • The study did not address this outcome.
BLINDING OF OUTCOME ASSESSMENT **Detection bias due to knowledge of the allocated interventions by outcome assessors.**	
Criteria for 'Low risk' of bias.	Any one of the following: • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for 'High risk' of bias.	Any one of the following: • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'; • The study did not address this outcome.
INCOMPLETE OUTCOME DATA **Attrition bias due to amount, nature or handling of incomplete outcome data.**	
Criteria for 'Low risk' of bias.	Any one of the following: • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.

Criteria for 'High risk' of bias.	Any one of the following: • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
Criteria for 'Unclear risk' of bias.	Any one of the following: • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.
SELECTIVE REPORTING **Reporting bias due to selective outcome reporting.**	
Criteria for 'Low risk' of bias.	Any of the following: • The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for 'High risk' of bias.	Any one of the following: • Not all of the study's pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.
OTHER BIAS **Bias due to problems not covered elsewhere in the table.**	
Criteria for 'Low risk' of bias.	The study appears to be free of other sources of bias.
Criteria for 'High risk' of bias.	There is at least one important risk of bias. For example, the study: • Had a potential source of bias related to the specific study design used; or • Has been claimed to have been fraudulent; or • Had some other problem.
Criteria for 'Unclear risk' of bias.	There may be a risk of bias, but there is either: • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.

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Appendix F – Development of the EMPOWER Help for Hands Programme pre-doctorate

Development of the EMPOWER Help for Hands intervention pre-doctorate

1.1 Introduction

The intervention evaluated in this thesis involved using a non-robotic Dynamic Hand Orthosis (DHO) to try to improve outcomes in a large and challenging group after stroke - people with reduced active digital extension. It was developed by the author of this thesis based on the evidence presented in Chapter 1 which highlighted the potential merits of using a non-robotic DHO to improve access to guideline-based intensive, repetitive functional based and self-practice activities in this group early after stroke.

Prior to the work in this thesis, the intervention was piloted by the author in The SaeboGlove Evaluation Trial (T-SET) (Alexander and Dawson 2019). The results were then shared with stroke survivors from the target population to capture a patient-centred perspective on how future research should proceed. The intervention in this thesis is informed by T-SET and the views of these stroke survivors. Thus, both activities will now be summarised in this chapter (Chapter 2) briefly along with learning gained from them that has subsequently informed the outcome and process evaluation conducted in this programme of research.

1.2 Part 1: The SaeboGlove Evaluation Trial (T-SET)

1.2.1 The role of a pilot feasibility study

Preliminary research conducted before a future definitive trial is essential to the development of any intervention (Craig *et al*. 2008; Morgan *et al*. 2018; Skivington *et al*. 2021). It also plays a key role in providing sufficient knowledge of planned methods and any modifications required to optimise the usefulness of research and avoid fatal and costly design flaws in a larger-scale study (Craig *et al*. 2008; Morgan *et al*. 2018).

The terms "pilot" and "feasibility" in reference to studies carried out to inform definitive RCTs are not universally agreed upon in the research literature. While much literature makes no distinction between them (Craig *et al*. 2008; Thabane *et al*. 2010) this programme of research adopts the framework for defining pilot and feasibility studies described by Eldridge et al. (2016) which was developed using a Delphi survey and expert consultation (Eldridge *et al*. 2016). That is that

feasibility is considered an overarching concept concerned with whether some planned methodological components can be done, and that all studies carried out in anticipation of future definitive trials are referred to as feasibility studies (Eldridge *et al*. 2016). Whereas pilot studies are a specific subset of feasibility studies (pilot feasibility studies) that additionally involve conducting a future study, or portion of a future study, on a smaller scale to determine whether the components of the main study can all work together or need modified before the main study starts (Eldridge *et al*. 2016).

1.2.2 Objectives

To inform a larger-scale definitive, randomised controlled evaluation trial, the main objectives of T-SET, a pilot feasibility trial, were to assess criteria that relate to the feasibility of:

- The intervention (adherence, safety, acceptability to stroke survivors, cares, occupational and physiotherapists, and glove laundering turnaround time and durability)

- An evaluation trial design (recruitment, retention and outcome measure completion, and collection of clinical upper limb data to inform sample size calculations)

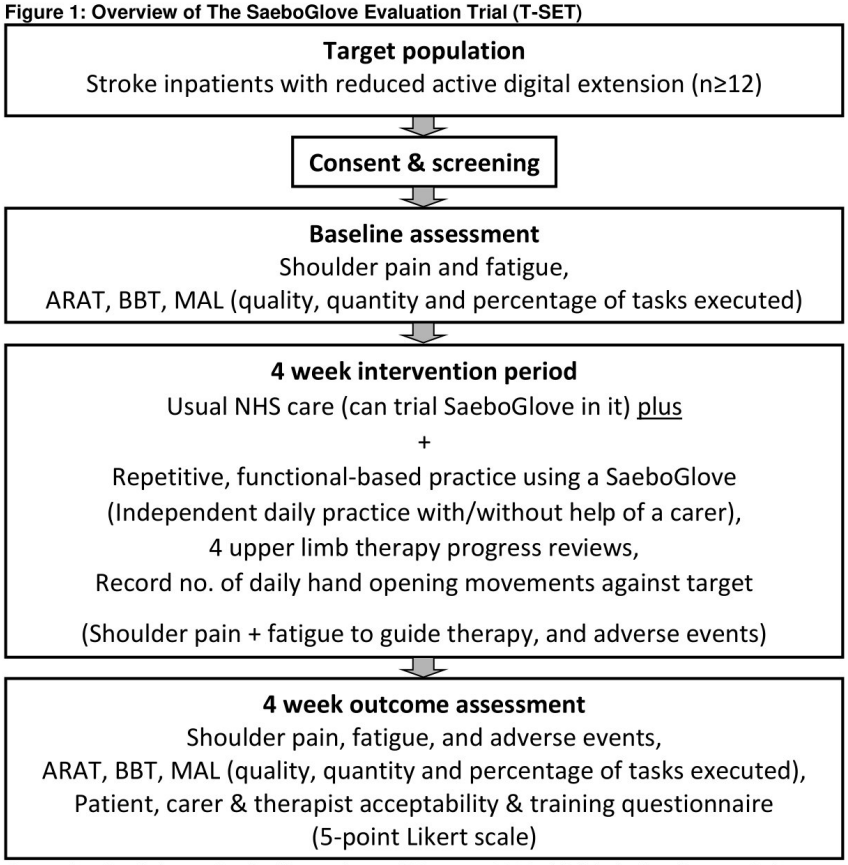
1.2.3 Method

1.2.3.1 Summary of study design & regulatory approvals

T-SET was a single site, open pilot feasibility trial with follow up at four weeks, immediately post intervention. Figure 1 provides an overview.

Stroke survivors were recruited from NHS Inpatient Stroke Services in Scotland (Queen Elizabeth University Hospital). Recruitment took place between 11 January and 31 October 2017. The study sponsor was the NHS Greater Glasgow and Clyde Health Board. The study was performed in line with the Declaration of Helsinki. The SaeboGlove is CE marked for use as a rehabilitation device so prior regulatory approval from the MHRA was not required. The study protocol

Figure 1: Overview of The SaeboGlove Evaluation Trial (T-SET)



Created using information in Alexander and Dawson 2019. ARAT: Action Research Arm Test, BBT: Box and Block Test, MAL: Motor Activity Log.

was approved by the North of Scotland Research Ethics Committee (REC) (16/NS/0112, 8 November 2016). NHS Board approvals were granted by NHS Greater Glasgow and Clyde (GN16ST162) on 11 January 2017. The study was registered on ClinicalTrials.gov (NCT03036033, 30 January 2017).

1.2.3.2 Population

Stroke survivors aged 18 years or older who were inpatients with a new clinical stroke diagnosis were included in the study if they had reduced active digital and/or wrist extension (i.e. reduced active range of digital extension with wrist held passively in full extension, a challenging position to generate extensor force which immediately highlights digital extensor weakness (active insufficiency)

(Schoenfeld 2002)). Inpatients were studied due to the potential merits of early upper limb rehabilitation, including the potential for heightened recovery and reduced risk of secondary complications associated with poorer outcomes (e.g. spasticity, contractures, learned non-use) highlighted in Chapter 1. In addition, the greater ease of monitoring a new self-management intervention in an inpatient environment also contributed to this decision.

As physical rehabilitation is an active process and successful engagement, particularly in a self-management context, requires insight into the existence and impact of an upper limb movement problem and an understanding of how active participation in rehabilitation could counter this, stroke survivors were required to be able to give informed consent. However, to optimise accessibility no specific limitations for language, cognition and perception were imposed if stroke survivors were considered able to don / doff the DHO, carry out exercises provided daily and comply with protocol requirements (e.g. complete outcomes/questionnaires) with or without the help of a supporting carer.

Stroke survivors needed to fulfil criteria specific for using a SaeboGlove DHO to engage successfully in functional-based (grasp/release) therapy recommended by the manufacturer (Table 1). This was to ensure comfort due to the physical limits imposed by the DHO. It was also to aid the establishment of grasp in the presence of the digital extensor assistance offered by it which opposing grasp and the establishment of release despite the emergence of mild to moderate flexor spasticity (Modified Ashworth Scale ≤2), most typical early after stroke (Wissel *et al.* 2010), which opposes release. One manufacturer recommendation, to exclude use if oedema was severe, was omitted from the eligibility criteria. This omission was made as severe hand swelling was anticipated in the target group and is caused by immobility and it was felt that the compression and physical assistance to generate increased movement offered by the SaeboGlove may reduce problematic swelling and aid better recovery. Additionally, it was felt that careful monitoring by stroke survivors with or without a carer as needed, should ensure safety. A full list of the inclusion and exclusion criteria are listed in Table 1.

Table 1: Inclusion and exclusion criteria

Inclusion criteria
1. Inpatient with new clinical stroke diagnosis
2. Age ≥18 years
3. Capacity to consent to study participation
4. Considered eligible to use a SaeboGlove at consent/baseline assessment: ▪ Reduced active range of digital and/or wrist extension at consent/baseline ▪ At least 10° passive wrist extension* ▪ Nil to minimal digital contractures (5-10° accommodated)* ▪ Some initiation of gross active digital flexion** ▪ Modified Ashworth Scale ≤2 in wrist/fingers***
5. Considered able to don/doff a SaeboGlove and engage in independent rehabilitation with or without the help of a willing carer 6. Considered able to comply with the requirements of the protocol
Exclusion criteria
1. Other significant upper limb impairment e.g. fixed contracture, fracture, frozen shoulder, severe arthritis, amputation
2. Diagnosis likely to interfere with rehabilitation or outcome assessments e.g. registered blind or terminal illness

ARAT: Action Research Arm Test; FMUE: Fugl Meyer Upper Extremity scale. Recommendation of manufacturer for comfort (*), to establish grasp (**), to establish release (***)

1.2.3.3 Intervention

A SaeboGlove was the non-robotic DHO chosen for the intervention (Figure 2).

Figure 2: A non-robotic dynamic hand orthosis (DHO)



The SaeboGlove (Saebo UK 2020). The orthosis consists of a glove velcroed inside a wrist splint, and elastic bands that offer variable extensor assistance. This assistance increases hand opening when it is limited, improving access to recommended rehabilitation activities.

This device was chosen because it is a relatively low-cost non-robotic DHO (approximately £270) (Saebo UK 2020) with a simple extensor assist mechanism (bands spanned between two hooks on dorsal aspect of glove/glove and splint) that was judged to be feasible for patients and carers to use in a self-management context and for clinicians to use in a busy clinical environment. Additionally, its lightweight design, without metal or springs, targets people

Images in Figure 2 used with copyright permissions (Left: Martijn Kaan, Right: Saebo UK).

with no, or mild to moderate wrist and digital spasticity (MAS ≤ 2), so before spasticity and secondary complications associated with poorer recovery have developed. Furthermore, a DHO with a lightweight design was considered a key priority when trying to facilitate movement recovery in a group with significant upper limb weakness.

The intervention was modelled based on the principles of stroke rehabilitation (assessment, problem solving and goal setting and a patient centred intervention to assist in goal achievement) (Langhorne *et al*. 2011) and the perceived physical rehabilitation needs of people after stroke (enhanced therapy provision, information & support, use of meaningful rehabilitation tasks, empowerment) (McKevitt *et al*. 2011; Luker *et al*. 2015; Stroke Association 2016; Abrahamson and Wilson 2019) presented in Chapter 1. In addition to usual care, all stroke survivors received a SaeboGlove to use for four weeks. A four-week period was chosen primarily based on resources (staffing and glove availability) and as this was felt to be long enough to allow stroke survivors to use the intervention and gain some familiarity with it. Additionally, this time frame was considered to be sufficient to observe potential progress. This is because a significant improvement in dexterous function (Box and Block Test) has been observed in other RCT feasibility interventional trials involving a 4 week non-robotic DHO intervention in individuals judged to have moderate to severe upper limb functional capacity (Alexander *et al*. 2021a) in the chronic phase of recovery (>6 months post stroke) (Jeon *et al*. 2012; Huang *et al*. 2019) when recovery is typically slower (Kwakkel *et al*. 2006; Langhorne *et al*. 2011). Due to resource limitation within the local NHS stroke service a physiotherapist from the study team, self-trained in how to measure, fit and use the SaeboGlove trained stroke survivors and any assisting carers (informal or Health Care Worker) how to don/doff the glove and established an individualised self-directed, repetitive, functional-based practice training programme involving grasping/releasing.

The physiotherapist encouraged stroke survivors to carry out a repetitive, functional-based practice training programme using a SaeboGlove independently daily with or without the help of a carer depending on need. The physiotherapist provided a weekly review session to assess progress and re-define their individualised upper limb treatment plan. Stroke survivors and the

physiotherapist agreed shared intensity goals for their daily practice (number of hand opening movements to aim to perform) at each review. Stroke survivors were asked to record the number of digital extension movements they carried out daily and this was examined at each review by the physiotherapist to guide intervention planning and optimise completeness. Additionally, shoulder pain and fatigue were recorded using a visual analogue scale (VAS) to guide therapy. If a stroke survivor was discharged during the intervention period, they travelled back to their local hospital to attend remaining review appointments. If this was not possible then advice was provided by telephone. The clinical occupational and physiotherapists were invited to use the SaeboGlove with stroke survivors during usual care therapy and training for them was encouraged and available on request.

A detailed description of the different components of the SaeboGlove self-directed, repetitive, functional-based practice intervention in T-SET, called The Help for Hands EMPOWER Programme (Pilot version), is shown using the Template for Intervention Description and Replication in Table 2.

Table 2: Template for Intervention Description and Replication (TIDieR) Checklist for the T-SET trial

Item	Intervention
1. Brief name: Provide the name or a phrase that describes the intervention.	Help for Hands EMPOWER Programme (Pilot version)
2. Why: Describe any rationale, theory, or goal of the elements essential to the intervention.	The Help for Hands EMPOWER Programme involved SaeboGlove self-directed, repetitive, functional-based practice. Rationale for this therapy: National guidelines advocate repetitive, functional-based practice and self-practice activities (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2016). Research shows that in order to improve brain function and regain the ability to perform every day movements after stroke, hundreds of challenging movement repetitions (Nudo and Milliken 1996; Carey *et al.* 2002; Kleim *et al.* 2002; Kleim *et al.* 2003; Luke *et al.* 2004; Monfils and Teskey 2004), specific to a given every day task (Perez *et al.* 2004; Boyd *et al.* 2010) must be practiced per session. Systematic review evidence shows that after stroke 1) increased intensity of repetitive, functional-based rehabilitation is known to improve functional outcomes (dose >20 hours) (Pollock *et al.* 2014) and 2) self-directed interventions that involve repetitive functional-based practice can improve upper limb function and independence in activities of daily living (Da-Silva *et al.* 2018). Research on dynamic hand orthoses after stroke (including the SaeboGlove (Alexander and Dawson 2019; Franck *et al.* 2019)) consists of small feasibility studies involving between 1-20 stroke survivors with moderate and severe upper limb impairment using RCT (Barry *et al.* 2012; Jeon *et al.* 2012; Lannin *et al.* 2016; Huang *et al.* 2019) and non-RCT (Davenport 2005; Barry *et al.* 2006; Butler *et al.* 2006; Farrell *et al.* 2007; Heise *et al.* 2010; Davenport *et al.* 2011; Gollega *et al.* 2012; Franck *et al.* 2013; Woo *et al.* 2013; Prange *et al.* 2014; Rickards *et al.* 2014; Stuck *et al.* 2014; Chang and Lai 2015; Chen *et al.* 2017; Semenko 2017; Doucet 2018; Alexander and Dawson 2019; Franck *et al.* 2019; Pooyania and Semenko 2014) designs). This preliminary evidence suggests that such devices are safe, feasible and acceptable, and enable this group to perform higher numbers of functional-based movement repetitions (Stuck *et al.* 2014; Chang and Lai 2015; Chen *et al.* 2017; Alexander and Dawson 2019), even when self-directed (Stuck *et al.* 2014; Chang and Lai 2015; Chen *et al.* 2017; Alexander and Dawson 2019). Positive trends in upper limb recovery are observed in the acute-subacute (Davenport *et al.* 2011; Rickards *et al.* 2014; Stuck *et al.* 2014; Semenko 2017; Alexander and Dawson 2019; Franck *et al.* 2019) and subacute-chronic (Davenport 2005; Barry *et al.* 2006; Butler *et al.* 2006; Farrell *et al.* 2007; Heise *et al.* 2010; Barry *et al.* 2012; Gollega *et al.* 2012; Jeon *et al.* 2012; Franck *et al.* 2013; Woo *et al.* 2013; Prange *et al.* 2014; Chang and Lai 2015; Lannin *et al.* 2016; Chen *et al.* 2017; Doucet 2018; Huang *et al.*

	2019; Pooyania and Semenko 2014) phases of recovery. Essential elements of this intervention included: • SaeboGlove device • Increased access to repetitive, functional-based practice • Increased access to self-practice opportunities • Increased intensity of training (aim >100 movement repetitions daily where possible) (Carey *et al.* 2002)
3. What - Materials: Describe any physical or informational materials used in the intervention, including those provided to stroke survivors or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The **SaeboGlove** was used (Saebo UK 2020) (Figure 2). It consists of a glove velcroed inside a wrist splint and tensioner bands of different size/strength which span between hooks, on the SaeboGlove, over weak joints to enable variable hand opening support, essential for self-directed, repetitive, functional-based practice. A **Hand and Arm rehabilitation exercise booklet** was used to encourage self-management (de Iongh *et al.* 2015; Parke *et al.* 2015). Booklets included a paragraph highlighting the need for intensive (>100 movement repetitions daily (Carey *et al.* 2002)), repetitive functional-based practice to optimise recovery, and were used to record intensity goals agreed at each review, and encourage stroke survivors to record the number of hand opening movements they performed daily during their individualised self-directed, repetitive, functional-based training programme. A **written copy of all exercises** was provided to stroke survivors.
4. What - Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	**Self-practice**: Intervention group stroke survivors received a SaeboGlove for four weeks to carry out self-directed, functional-based hand and arm exercises daily, independently with or without support of a carer. They aimed to fulfil a daily intensity goal agreed with their therapist (number of hand opening movements to aim to perform), typically 50 repetitions daily the first few days and increasing gradually towards 100 at the end of the first week if there was no reason not to (e.g. new hand pain or limiting fatigue). Stroke survivors were encouraged to keep track of repetitions using paper and pen to record tally marks. **Progress reviews**: A physiotherapist supervised and supported stroke survivors (and carers) by providing a weekly progress review to: i) Assess/reassess their ability, define/redefine their treatment plan and set shared intensity goals for their daily practice ii) Administer them with an individualised self-directed, repetitive, functional-based practice training programme where all exercises provided involve grasping /releasing (where possible grasping should involve an object, alternatively it should involve opposition)

	iii) Train them on the intervention, specifically on how to don/doff the SaeboGlove, and on how to perform any exercises given and log daily self-practice activity (number of hand opening repetitions) against their agreed goal in their booklet iv) Remind them of the ultimate goal and need to increase use of their affected hand, out with therapy exercises, in everyday tasks between each review **The EMPOWER principles were followed (Alexander *et al*. 2021b):** **E**quip with the tools needed to carry out meaningful exercise involving everyday tasks (e.g. eating, drinking, self-care) - a **SaeboGlove**, and **written exercises** involving everyday objects whenever possible. **M**otivate by setting shared intensity goals and logging / monitoring daily self-practice activity. Identify and overcome barriers to doing daily exercises. **P**rogress review every week so exercises remain challenging and progressive. **O**ptimise self-management support at reviews by coaching independence in exercises, progression and tailoring. **W**ean support offered by SaeboGlove bands as able. **E**ngage carer support whenever possible. **R**emind of ultimate goal and need to increase use of stroke affected hand in everyday tasks.
5. Who provided: For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	The intervention was carried out by stroke survivors with support from 1) a trained physiotherapist and 2) a trained carer if needed. The physiotherapist was a clinical specialist in stroke care who followed manufacturer's instructions on how to measure and fit a SaeboGlove and developed the EMPOWER Help for Hand intervention. All supporting carers were encouraged to attend review sessions with stroke survivors where they received training on the intervention, specifically on how to don/doff the glove, assist with the performance of any exercises and record self-practice activity. Stroke survivors and carers were encouraged to contact their therapist for further advice if they had questions/concerns.
6. How: Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Typically, 1:1 face-to-face delivery, though on occasion, for stroke survivor convenience after discharge by telephone, depending on stroke survivor convenience.

7. Where: Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	For 1:1 delivery: at bedside or clinic room in NHS hospital facilities. By telephone: in NHS hospital facilities if inpatient, or at home if discharged.
8. When and how much: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Over the four-week intervention period: • Stroke survivors were encouraged to fulfil their individualised, shared intensity goal daily. • A progress review with a physiotherapist was provided every one week at a mutually suitable time that also allowed flexibility depending on anticipated rate of progress. • SaeboGlove self-directed, repetitive, functional-based practice was delivered in addition to usual NHS care. It was assumed that usual care was based on National Clinical Guidelines (National Institute for Health and Care Excellence 2013; Intercollegiate Stroke Working Party 2016).
9. Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Exercises selected were functional-based movements identified as being meaningful to stroke survivors and aimed to progress the hand in isolation as well as with the lower and upper arm. Stroke survivors were encouraged to learn the best way for them to achieve their daily intensity goal e.g. doing exercises all at once, or spreading exercises out separated by breaks, doing more challenging exercises first before tiring, or last after warmed up. They were also encouraged to increase the use of their affected hand in a varying number and type of everyday tasks between each review depending on ability and preference. The design of the SaeboGlove enabled assistance from tensioners to be increased / decreased according to individual ability.
10. Modifications: If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	If stroke survivors wished, their exercises were videoed on their / their carers mobile phone to refer to later.
11. How well - Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	The physiotherapist completed a Case Report Form after each review to document adherence at sessions. Stroke survivors completed a Hand and Arm rehabilitation booklet to record the number of hand opening movements they carried out daily. Data from booklets were studied by the physiotherapist at reviews to monitor intervention adherence and take steps to optimise it.

12. How well - Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Mean (range, SD): 23.5 (10-28, 6.4) sessions / 28 days, 81.2 (14.8-144.3, 38.3) self-reported repetitions per session.

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1.2.3.4 Outcomes

Feasibility of the EMPOWER Help for Hands intervention

The feasibility of the intervention was determined by assessing:

Adherence: The number of reviews attended (face to face / telephone) as a proportion of the number of possible reviews, the number of self-reported training days performed as a proportion of the number of possible daily sessions (n=28) and the number of self-reported hand opening repetitions performed per session)

Safety: The number and type of adverse events / serious adverse events that occurred during the study that were probably or definitely related to SaeboGlove therapy, and a comparison of shoulder pain and fatigue measured using a visual analogue scale (VAS) pre and post intervention).

Acceptability: Stroke survivor, carer, and NHS stroke inpatient and/or community occupational and physiotherapist responses using a brief 5-point Likert scale bespoke questionnaire (strongly disagree, disagree, neither disagree or agree, agree, strongly agree) on the intervention and training provided. Utilisation of carer help to carry out the therapy (e.g. put glove on, do exercises) at the start and end of the intervention period and of the SaeboGlove by the usual care therapists (used in usual care therapy, not used but observed in trial therapy/review, reason for not using) were also collected to provide context for the acceptability questionnaires.

Glove laundering turnaround time and durability: While the hard splint of a SaeboGlove can be wiped down with a detergent wipe between stroke survivor use, the soft glove and staps cannot. To ensure that infection control standards were met without degrading of these components advice was sought from the manufacturers (Saebo Ltd), the Infection Control and laundry service within NHS Greater Glasgow and Clyde and Cathkin Clean, a UK wide laundering service used by the NHS for the laundering of specialist (e.g. small) items. The NHS Laundry service was unable to launder the gloves as they only have large industrial washing machines that are unsuitable for small items. Alternatively, Cathkin Clean was used. The method involved soaking the glove liners and

straps in a cold soak of 7% proprietary disinfectant solution for a minimum of 15 minutes then machine washing on a delicate cycle in a mix of water and antibacterial and anti-fungal detergent (compliant with BS EN1276 and EN1275) before being ambient dried (Cost £24.72 including VAT per glove). Soiled gloves were placed in a clear bag and marked for the attention of Cathkin Clean and uplifted twice weekly (Mondays, Wednesdays) when informed that gloves required laundering. Laundering turnaround time (days) and the durability (visible wear and tear) of a single glove and set of straps washed over ten washes was recorded to inform intervention feasibility.

Feasibility of an evaluation trial design

The feasibility of an evaluation trial design was determined by assessing:

Recruitment: The feasibility of recruitment was evaluated based on the number of stroke survivors recruited per month and the availability of SaeboGloves from one SaeboGlove Professional kit (Gloves: eight left and eight right with two extra small, two small, one medium, two large and one extra-large for each side, splint: eight left and eight right with two small, four medium and two large for each side). Detailed screening data were not recorded due to time and staffing constraints. However, barriers to enrolment were discussed at weekly team meetings.

Retention: The feasibility of retention was evaluated based on the percentage of stroke survivors starting therapy who completed the outcome visit.

Outcome measure completion: The feasibility of outcome measure completion was determined by calculating the number of stroke survivors who were able to have all clinical upper limb outcomes assessed pre and post intervention.

Clinical upper limb data to inform sample size calculations: Data on clinical measures were collected to inform sample size calculations needed to detect treatment effect**.** Clinical measures were upper limb function measured using the Action Research Arm Test (ARAT) (Lyle 1981), gross dexterity measured using the Box and Block Test (BBT) (Mathiowetz *et al*. 1985) and self-perceived performance (amount of use, quality of use and percentage of tasks executed with the affected upper limb) in 17 real-world activities using the Motor Activity

Log (Uswatte *et al*. 2005). All clinical measures have robust psychometric characteristics (Thomas Platz *et al*. 2005; Uswatte *et al*. 2005; Hammer and Lindmark 2010; Alt Murphy *et al*. 2015) and are widely used and accepted (Santisteban *et al*. 2016). A description of each measure is provided in Table 3.

Table 3: Description of clinical measures used at study assessments

Measure	Description
ARAT (Lyle 1981)	The ARAT measures upper limb function and dexterity in people with hemiparesis. It scores 19 items grouped into four subscales (grasp, grip, pinch and gross movements) using a 4-point ordinal scale (0-3). Items within each subscale are arranged hierarchically, such that some items may be skipped if earlier items score 0. The final score ranges from 0-57, with 57 representing the best function i.e. normal function. The revised, standardised (T. Platz *et al*. 2005a) and validated (T. Platz *et al*. 2005b) version of the original ARAT (Lyle 1981) without specific time limits was used.
BBT (Mathiowetz *et al*. 1985)	The BBT measures gross dexterity where stroke survivors are timed to transport as many 2.5cm blocks as they can over a barrier between two adjoined boxes in 1 minute.
MAL-14 (Uswatte *et al*. 2005)	The MAL-14 is a structured interview used to assess self-perceived performance (Amount of use (AOU) and quality of use (QOU)) in 14 real-world UE activities. AOU and QOU are both rated using a 6-point scale (0-5). The mean for each scale is calculated and the final score ranges from 0-5 for each scale, with 5 indicating that the affected arm is used as much (AOU) and as well (QOU) as before the stroke. There are different versions of the MAL; MAL-14, MAL-30, MAL-28, MAL-14, MAL-45, LF-MAL, Grade 4/5 MAL and Turkish, Brazilian and German versions (Canadian Partnership for Stroke Recovery 2020). MAL-14 was used as it has been studied earlier after stroke, during the subacute phase (Hammer and Lindmark 2010), and has less items and therefore a smaller burden. While the MAL-14 has been found to be a reliable and valid post stroke measure (Uswatte *et al*. 2005; Hammer and Lindmark 2010), data on the MAL is limited during the acute phase after stroke (<1 month) (Uswatte *et al*. 2005; Hammer and Lindmark 2010). As T-SET included acute and subacute stroke patients who are often likely to be inpatients with more limited opportunity to carry out everyday activities in a hospital environment, three additional upper limb activities (open a bottle/jar, tie lace, hobbies e.g. reading, cards etc) routinely accessible at a hospital beside were scored in addition to the MAL-14.

ARAT: Action Research Arm Test, BBT: Box and Block Test, MAL: Motor Activity Log, T-SET: The SaeboGlove Evaluation Trial

All outcome data were collected either during the intervention period by stroke survivors/carers and the research physiotherapist or immediately post intervention by an outcome assessor (Figure 1). All baseline and outcome assessments were carried out by the same trained assessor with >4 years' experience scoring upper limb outcomes.

Sample size and analysis plan: As pilot studies are not powered to assess effect no sample size calculation was made and analysis focused on descriptive statistics, not hypothesis testing (Lee *et al*. 2014). A minimum sample of 12 stroke survivors was considered to be an adequate number to assess the feasibility based on the time and number of gloves available for the study. Categorical and continuous variables were recorded as numbers, numbers with percentages or mean and standard deviation (SD) respectively. Parametric statistics were used for data that were normally distributed and non-parametric statistics were used for data that were not normally distributed.

1.2.4 Results

1.2.4.1 Population

A total of 14 stroke survivors were enrolled in the study. One subject did not fulfil the inclusion criteria as she was unable to engage in the rehabilitation activities as her hand was stuck in full digital extension as she had insufficient gross active digital flexion to establish grasp and one subject withdrew prior to therapy starting as they felt overwhelmed when they were advised they were being discharged home the following day. No assessments or therapy were carried out by these two patients. Consequently, 12 stroke survivors commenced SaeboGlove Therapy, mean (range, SD) age 62 (47-80, 9.4), days post stroke 27 (4-80, SD 25.0) and ARAT score 16/57 (0-44, 14.1). The majority of stroke survivors were males (92%). Full details of baseline characteristics are shown in Table 4.

Table 4: Baseline characteristics of stroke survivors

Baseline characteristics	Stroke survivors (n=12)
Gender	
Male n (%) Female n (%)	11 (92) 1 (8)
Age	
Mean (range, SD) years	61.6 (47-80, 9.4)
Time post stroke	
Mean (range, SD) days	27.0 (4-80, 25.0)
Stroke type	
Haemorrhage n (%) Infarct n (%)	3 (25) 9 (75)
Arm affected by the stroke	
Right n (%) Left n (%)	11 (92) 1 (8)
Dominant hand affected	
Yes n (%) No n (%)	6 (50) 6 (50)
ARAT score (Range 0-57: no-full function)	
Mean (range, SD)	15.9 (0-44, 14.1)

ARAT: Action research arm test

1.2.4.2 Feasibility

<u>EMPOWER Help for Hands intervention</u>

Adherence: Adherence for therapy review attendance was 100%. One review took place by telephone instead of being face to face as one stroke survivor expressed that he did not yet feel he needed changes to his existing programme and wanted to progress further with the existing programme. Usual review procedures were followed. Self-reported adherence for performing a daily training session was 85% (23.5/28 (10-28, 6.4). The number of self-reported hand opening repetitions performed per session was 81.2 (14.8-144.3, 38.3). Two stroke survivors (stroke survivors 8 and 12) self-reported adherence with performing a daily training session and number of hand opening repetitions they performed per session were much less than the other stroke survivors (43% and 36% of available days, 42.4 and 32.4 repetitions per session respectively). One of them had significant fatigue due to Multiple Sclerosis / post stroke fatigue and an increase in usual care therapy in preparation for discharge home. He also struggled to engage in usual care therapy. The other stroke survivor also had considerable fatigue. He also had significant hand oedema and experienced some discomfort wearing the SaeboGlove. Both of these factors contributed to

his reduced compliance. He also had very large hands and was using the largest glove liner manufactured so a larger glove could not be trialled.

Safety: In terms of safety, no related serious adverse events or adverse events occurred during the trial. There was a decrease in fatigue and increase in shoulder pain post intervention (Table 5). Although the mean post intervention fatigue score was comparable to those recorded at reviews with the physiotherapist, the mean post intervention pain score was higher than the scores recorded pre intervention and at therapy reviews.

Table 5: Change scores for fatigue and shoulder pain from baseline to end of treatment

Safety measure	Baseline Mean (SD)	Review 1-4 Mean (SD)				4 week visit Mean (SD)	Baseline to 4 week visit Change Mean (SD)
		1	2	3	4		
Fatigue* (VAS: 0-10)	5.5 (1.6)	4.3 (2.1)	4.3 (2.0)	3.3 (2.9)	4.0 (3.1)	3.6 (2.4)	-1.9 (2.2)
Shoulder pain* (VAS: 0-10)	0.6 (2.0)	1.1 (2.2)	1.2 (1.6)	0.8 (1.3)	1.4 (2.0)	4.1 (2.4)	3.5 (2.5)

VAS: Visual Analogue Scale, *Lower score is favourable

Acceptability: Table 6 shows the number (proportion) of stroke survivors who utilised help from a carer during their SaeboGlove therapy. Half of the stroke survivors utilised help from a carer at the start of the four-week treatment period. However, only a third of stroke survivors still utilised help from a carer at the end of the four-week treatment period. Thus, half of the stroke survivors carried out the therapy independent of a carer initially and this number increased over the intervention period to two thirds.

Table 6: Stroke survivors utilising carer help to do SaeboGlove therapy

Stroke survivors utilising carer help to do SaeboGlove therapy	Stroke survivors (n=12) n (%)
At start of therapy	6 (50)
At end of therapy	4 (33)

All stroke survivors (n=12), assisting carers (n=6) and observing carers (n=1) accepted their invitation to complete the acceptability questionnaire with a

researcher (outcome assessor) not involved in intervention design or delivery. The results of these questionnaires are summarised in Table 7 below.

Table 7 shows that the majority of stroke survivors and carers agreed or strongly agreed that stroke survivors enjoyed carrying out SaeboGlove therapy, benefited from carrying out the therapy, were able to get the glove on / off easily independently and were given enough training on how to get the glove on / off and on how to carry out upper limb rehabilitation exercises. It also shows that the majority of stroke survivors and carers agreed or strongly agreed that stroke survivors were able to carry out more therapy using the glove, found the therapy interesting, would recommend the SaeboGlove therapy program used to other stroke patients, enjoyed carrying out SaeboGlove therapy with their therapy team, benefited from carrying out the therapy with their therapy team and used their arm more daily because of the glove. This information suggests that patients and carers felt that one introductory training session and a once weekly session with the stroke specialist physiotherapist adequately equipped them to use a SaeboGlove, recognise its potential benefits and engage with it effectively.

The majority of stroke survivors and carers did not agree or strongly agree that the therapy was too difficult or too easy, suggesting that it was set at about the right level of difficulty. While the majority of stroke survivors and carers did not agree or strongly agree that the four-week program was too long the majority of carers and minority of stroke survivors agreed or strongly agreed that it was too short suggesting that there was an overall feeling that four weeks may not be long enough. A minority of stroke survivors and carers expressed that it may be too tiring (n=3 (25%) and n=3 (43%) respectively).

The two stroke survivors with the poorest adherence both agreed or strongly agreed that they enjoyed the therapy, benefited from it and felt able to carry out more therapy because of the glove. Thus, the severity of upper limb functional impairment they experienced (Baseline ARAT 16 and 0) was unlikely to have contributed to their reduced adherence.

Table 7: Results of acceptability questionnaire - stroke survivor and carer

Questions asked	n (%) who agree or strongly agree	
	Stroke survivor (n=12)	Carer (n=7)
The stroke survivor enjoyed using the SaeboGlove (with / without carer help)…	11 (91)	7 (100)
The stroke survivor benefited from using the SaeboGlove (with / without carer help)	11 (91)	7 (100)
The stroke survivor was able to get their SaeboGlove on easily him/herself (with / without carer help)	11 (91)	4 (57)
The stroke survivor was able to get their SaeboGlove off easily him/herself (with / without carer help)	12 (100)	5 (71)
The stroke survivor got enough training on how to get the SaeboGlove on / off him/herself (with / without carer help)	12 (100)	7 (100)
The stroke survivor got enough training on how to use the SaeboGlove to carry out upper limb rehabilitation exercises independently (with / without carer help)	10 (83)	7 (100)
The stroke survivor was able to carry out more therapy on his/her own (with / without carer help) because they had the SaeboGlove	11 (91)	7 (100)
The SaeboGlove Therapy was interesting…	11 (91)	7 (100)
I would recommend the SaeboGlove Therapy programme to other people who have had a stroke…	12 (100)	7 (100)
The stroke survivor enjoyed using the SaeboGlove with his/her therapy team…	12 (100)	7 (100)
The stroke survivor benefited from using the SaeboGlove with his/her therapy team…	12 (100)	7 (100)
The SaeboGlove helped the stroke survivor to use his/her arm more daily…	11 (91)	7 (100)
The SaeboGlove Therapy was too difficult…	0 (0)	0 (0)
The SaeboGlove Therapy was too easy…	0 (0)	0 (0)
The SaeboGlove Therapy was too tiring…	3 (25)	3 (43)
The 4 week SaeboGlove Therapy programme was too long…	1 (9)*	1 (14)
The 4 week SaeboGlove Therapy programme was too short…	4 (36)*	4 (57)

***Based on n=11 as data missing from one questionnaire**

Of all the usual care inpatient and/or community stroke occupational therapists (n=9) and physiotherapists (n=10) supporting stroke survivors during the intervention period, fourteen completed an acceptability questionnaire. Eight of these therapists had tried using the SaeboGlove with a stroke survivor in usual care therapy and six had observed a stroke survivor using the glove in trial therapy / review(s). The remaining five (23%) declined completing the questionnaire. The reasons why therapists declined the invitation to complete the questionnaire and the reasons why therapists completing the questionnaire hadn't used the SaeboGlove during usual care therapy are summarised in Table 8 below.

Interestingly 3/19 therapists who declined completing the questionnaire and 3/19 therapists who completed the questionnaire (32% of therapists) had not used the glove as they were focusing on priorities other than upper limb rehabilitation during the SaeboGlove intervention period and 2/19 therapists (11% of therapists) who completed the questionnaire but had not used the glove during usual care therapy felt the glove was beneficial and it allowed them to focus on other aspects of upper limb rehabilitation. This suggests that self-management strategies directed by a specialist, such as the SaeboGlove, may be essential to help therapists ensure that their patients fulfil their upper limb rehabilitation potential while allowing them to fulfil all other competing rehabilitation priorities with their patients.

Table 8: Utilisation of the SaeboGlove by the usual care therapists

Utilisation of the SaeboGlove by the usual care therapists	Number (%)
No. of therapists who declined to complete questionnaire (n=19)	5 (26)
Reason for declining (n=5):	
• Glove not used by therapist as focusing on other priorities i.e. not upper limb (e.g. discharge planning, seating and positioning, mobility)	3 (60)
• Patient moved between wards and home in quick succession and therapist unable to see patient in remaining treatment period	2 (40)
No. of therapists who completed questionnaire (n=19)	**14 (74)**
Experience of SaeboGlove use in therapists who completed questionnaire (n=14):	
• They tried using the SaeboGlove in usual care therapy	8 (57) (6 PT, 2 OT)
• They did not try using the SaeboGlove in usual care therapy but observed glove in use in trial therapy / review(s)	6 (43) (2 PT, 4 OT)
Reason therapists did not try using the SaeboGlove in usual care therapy (n=6:)	
▪ It seemed beneficial and allowed therapist to focus on other aspects of upper limb rehabilitation (e.g. proximal upper limb)	2 (33)
▪ Therapist focussing on other priorities i.e. not upper limb (e.g. discharge planning, seating and positioning, mobility)	3 (50)
▪ Aware patient and carer had some difficulty getting glove on due to significant swelling	1 (17)

PT: Physiotherapist, OT: Occupational Therapist

Table 9 shows that the majority of physiotherapists and occupational therapists agreed that stroke survivors were able to use a SaeboGlove safely independently (with / without carer help), carry out their SaeboGlove exercises independently (with / without carer help) and that they personally found the SaeboGlove therapy interesting and got enough training on how to use it with the stroke survivors in 1:1 therapy sessions.

The majority of physiotherapists and occupational therapists did not agree or strongly agree that the therapy was too difficult or too easy, suggesting that it was set at about the right level of difficulty. The majority of physiotherapists

Table 9: Results of acceptability questionnaire – physiotherapists and occupational therapists

Questions	Number (%) who agree or strongly agree		
	PT (n=8)	OT (n=6)	PT and OT (n=14)
I feel that the stroke survivor (with / without carer help) was able to use the SaeboGlove safely	8 (100)	4 (67)	12 (86)
I feel that the stroke survivor (with / without carer help) was able to use the SaeboGlove to carry out their exercises	7 (88)	4 (67)	11 (79)
I feel that the stroke survivor benefited from using the SaeboGlove with his / her therapy team	8 (100)	2 (33)	10 (71)
I feel that the stroke survivor was able to carry out more therapy movements because he / she had a SaeboGlove	8 (100)	2 (33)	10 (71)
The SaeboGlove helped the stroke survivor to use his / her arm more daily	5 (63)	2 (33)	7 (50)
The SaeboGlove Therapy was interesting for the stroke survivor	7 (88)	4 (67)	11 (79)
I was able to get the SaeboGlove on easily	3 (43)*	6 (100)	9 (69)**
I was able to get the SaeboGlove off easily	3 (43)*	6 (100)	9 (69)**
I got enough training on how to use the SaeboGlove with the stroke survivor during our 1:1 therapy sessions	7 (88)	6 (100)	13 (93)
The SaeboGlove Therapy was too difficult for the stroke survivor	0 (0)	2 (33)	2 (14)
The SaeboGlove Therapy was too easy for the stroke survivor	0 (0)	0 (0)	0 (0)
The SaeboGlove Therapy was too tiring for the stroke survivor	0 (0)	0 (0)	0 (0)
The SaeboGlove therapy was boring for the stroke survivor	0 (0)	2 (33)	2 (14)
The 4 week SaeboGlove Therapy programme was too long for the stroke survivor	1 (14)*	0 (0)	1 (8)**
The 4 week SaeboGlove Therapy programme was too short for the stroke survivor	0 (0)	2 (33)	2 (14)

PT: Physiotherapist, OT: Occupational Therapist, *Based on n=7 as question scored as "N/A" in one questionnaire as physiotherapist had not tried using glove, **Based on n=13 as question scored as "N/A" in one questionnaire as physiotherapist had not tried using glove

and occupational therapists did not agree or strongly agree that the SaeboGlove therapy was too tiring or too boring suggesting that they felt stroke survivors coped well with the therapy. They also did not agree or strongly agree that a four-week program was too long or that it was too short suggesting that both groups of therapists felt that four weeks is an acceptable duration for patients to participate in SaeboGlove therapy.

However, some variation in scores was observed in therapists for five questions (benefit, frequency of therapy movement and daily use for occupational therapists and ease of donning / doffing the glove for physiotherapists). Consistent with the stroke survivors and carers, while the majority of physiotherapists felt that the stroke survivors benefited from using the glove, carried out more therapy movements and used their arm more daily because they had the glove, the occupational therapists did not agree or strongly agree with these statements. In addition, while the majority of occupational and physiotherapists combined agreed / strongly agreed that the glove was easy to get on and off, the majority of physiotherapists did not agree or strongly agree that the glove was easy to get on / off, the majority of occupational therapists did agree with this statement. Four out of the six occupational therapists (66%) who completed the questionnaire had not used a SaeboGlove with stroke survivors in usual care therapy compared to 2/8 physiotherapists (25%) (Table 8) and the frequency of therapist use of the SaeboGlove in usual care therapy was not recorded. Thus, the limited practical use of the glove by occupational therapists or a limited frequency of use by therapists compared to stroke survivors and carers may have contributed to the indecision.

Glove laundering turnaround time and durability: The mean laundering turnaround time with twice weekly collections was 4.1 days. No obvious wear or tear was observed on any glove or straps following laundering including the glove and straps laundered 10 times.

Evaluation trial design

Recruitment: The recruitment rate was 1.3 stroke survivors/month with other competing medical and upper limb trials running. On one occasion recruitment was delayed a few days as a medium glove was required but was being laundered. However, as the intervention period was short, the limited

availability of glove sides/sizes never meant that recruitment of a potential stroke survivor was not possible.

Retention: All 12 stroke survivors who started the intervention completed the study.

Outcome measure completion: Clinical upper limb outcomes were collected in full in all 12 (100%) stroke survivors pre and post intervention. Data from the acceptability questionnaire was complete except for two questions missed for stroke survivor (1% of stroke survivors questions). Overall, outcome measure completion exceeded 99%.

Clinical upper limb data to inform sample size calculations: Clinical upper limb data needed to inform sample size calculations in an evaluation trial are presented in Table 10. The mean change in the ARAT score from the baseline to the four-week assessment was 18.8 (13.5).

Table 10: Change scores for clinical measures from baseline to end of treatment

Clinical measure	Baseline Mean (SD)	4 week visit Mean (SD)	Change Mean (SD)
ARAT* (0-57)	15.9 (14.1)	34.7 (20.9)	18.8 (13.5)
BBT* (No. blocks transferred in 1 minute)	28.9 (37.2)	65.4 (55.7)	36.5 (32.9)
MAL - QOU* (0-85)	5.6 (5.8)	28.5 (21.9)	22.9 (18.3)
MAL - AOU* (0-85)	6.3 (7.3)	30.3 (23.8)	24.1 (19.8)
MAL - % tasks executed* (0-100)	22.1 (20.9)	56.9 (30.8)	34.8 (24.3)

ARAT: Action Research Arm Test, BBT: Box and Block Test, MAL: Motor Activity Log, QOU: Quality Of Use, AOU: Amount Of Use, statistical significance with p <0.05, *Higher score = better performance

1.2.5 Discussion

1.2.5.1 Summary of findings

T-SET demonstrates that it appears to be feasible for people with reduced active digital extension to carry out a repetitive, functional-based practice training programme using a SaeboGlove daily independently, with or without the help of a carer, early after stroke. All 12 stroke survivors who started therapy attended all review sessions, reported carrying out a training session on the majority of available days and reported performing over 80 hand opening movements on average per session over and above their usual NHS care. This equates to a 250 – 350% increase in the number of repetitions delivered in usual care in subacute inpatients (23 and 32 repetitions respectively) based on data reported in a systematic review by Hayward (2015) that investigated functional-based upper limb training dose using observational methods during inpatient rehabilitation (Hayward and Brauer 2015). Although not conclusive due to the small sample utilised, the severity of upper limb functional impairment did not appear to influence adherence in the sample studied.

However, one stroke survivor withdrew prior to therapy starting as they felt overwhelmed when they were advised they were being discharged home the following day. Additionally, self-reported adherence was much lower in two stroke survivors compared to the others as one struggled to cope with increased usual care therapy delivered in preparation for discharge along with fatigue experienced due to a chronic condition (Multiple Sclerosis) and the other experienced discomfort and difficulty donning his glove as he had significant hand oedema and he could not be given a larger size as he was already using the largest size provided. Thus, severe hand oedema, and discharge timing / activities and their interaction with other comorbidities appeared to have the potential to influence the feasibility of recruitment and the intervention. Additionally, an enrolled stroke survivor failed the eligibility requirements to be able to use the intervention as despite being able to initiate active digital flexion her active digital flexion was insufficient to be able to engage in the rehabilitation activities in the trial as grasp could not be established.

The intervention was found to be acceptable to stroke survivors, carers and occupational and physiotherapists. However, the majority of carers and the minority of stroke survivors and therapists agreed or strongly agreed that four weeks was too short. No related serious adverse events or adverse events were reported during the trial suggesting that the intervention is safe.

Typically, shoulder pain is present in 70% of people early after stroke and is encountered during movement rather than rest (Lindgren *et al*. 2007). An increase in shoulder pain was observed between the last therapy review scored by the physiotherapist and the four-week visit scored by the assessor. Given its high prevalence, monitoring of shoulder pain in upper limb research involving novel interventions seems important. However, the increase in pain between these two time points was not felt to be concerning in T-SET as stroke survivors did not exhibit increased pain during their therapy reviews and no adverse events related to therapy were found. A systematic scoring bias between different users is a recognised limitation of the VAS with training to overcome inter-rater differences being recommended when different outcome assessors are utilised (Pomeroy *et al*. 2000). Thus, the increase observed between these two time points could be explained by the change in scorer used. Additionally, the increase may reflect the increased amount of upper limb use self-reported during the trial in everyday tasks in the MAL (Table 3) which may have made stroke survivors more aware of underlying pain, not often encountered prior to study participation due to insufficient movement.

The laundering method identified to fulfil NHS Infection Control procedures demonstrated excellent turnaround time and durability.

Outcome measure completion from stroke survivors pre and post intervention exceeded 99%. All five clinical measures of motor performance improved considerably. ARAT score improved by a mean (SD) of 18.8 (13.5) points in an acute to early subacute group (mean (SD) 27.0 (25.0) days post stroke). This improvement is nearly double that normally expected in controls (10.0 (SD 15.0) points) (Rabadi and Rabadi 2006). It also exceeds the minimum clinically important difference for the ARAT in chronic stroke patients (≥5.7 points based on stroke survivors ≥1 year post stroke) (van der Lee *et al*. 1999) and early subacute stroke patients (≥12 ARAT points if dominant affected limb, ≥17 ARAT

points if non-dominant affected limb based on stroke survivors ≤28 days post stroke) (Lang *et al*. 2008) based on standardised recovery time points recommended and previously defined (Chapter 1) (Bernhardt *et al*. 2017). Thus, this improvement suggests a promising improvement in upper limb function may be possible.

The recruitment rate observed is comparable to other stroke upper limb rehabilitation trials (Brkic *et al*. 2016; Held *et al*. 2019) and despite the early yet intensive intervention retention of stroke survivors who started therapy was 100%.

1.2.5.2 Limitations of study

T-SET provided evidence that it was feasible for the population studied to carry out the intervention. However, due to limited therapy resources within the NHS stroke service the intervention was not delivered within the NHS stroke service. Thus, although acceptability with NHS therapists was high, it is possible that the feasibility of the intervention could be reduced e.g. due to limitations in NHS staffing or transportation for outpatient appointments after discharge. Additionally, it would be useful to understand exactly how much this novel intervention increased baseline usual care training activities in this NHS setting, how many stroke survivors relied on study taxis to return to appointments after discharge and what the self-management support needs, barriers and facilitators for clinical implementation of this intervention are. However, unfortunately this information was not captured as this was beyond the scope of the study.

As T-SET was a single site study it is possible that the findings may not be replicable in other sites due to local differences e.g. staffing, expertise or organisational factors. Additionally, T-SET was a single group, open feasibility trial with a small sample size. Thus, the small sample size, confounding factors possible in a single group (i.e. uncontrolled, unrandomized) study and potential bias introduced as all parties were unblinded to the intervention mean that the improvement observed across all clinical measures must be interpreted with caution. Further, as T-SET was a feasibility study that did not comprise long term follow up and stroke is a condition with a similar incidence in men and women (annual global occurrence 47% versus 53% respectively) (World Stroke

Organization 2022) and the sample recruited in T-SET was predominantly male (92%), it cannot be assumed that the findings are durable longer term or representative of the true target stroke population.

1.2.5.3 Strengths of study

T-SET investigated a novel intervention early after stroke in people lacking active digital extension, a group where evidence-based interventions have yet to be identified. It had many elements of a well-designed clinical trial. The intervention was found to be safe, feasible and acceptable to stroke survivors and their carers and therapists. Additionally, retention was excellent, recruitment rate was comparable to other stroke upper limb studies (Brkic *et al*. 2016; Held *et al*. 2019) and data quality was good.

1.2.5.4 Implications for practice

Although the intervention was found to be safe, feasible and acceptable, the sample utilised was small and clinical effectiveness of the intervention was not evaluated. Thus, further research is required to see if these finding can be replicated and to evaluate clinical effectiveness prior to it being used as an adjunct to usual care.

1.2.5.5 Implications for research

An adequately powered, blinded randomised controlled evaluation trial should now be considered. To generate enough recruitment to achieve adequate statistical power and ensure generalisability of study findings to a real-life population a multi-site trial would be required. The control group could either be a placebo group (wearing the device without exercising) or attention-matched control. The advantages and disadvantages of these two options should be weighed up but feasibility will likely depend on the resources available (staff and gloves). As unblinding can lead to bias, it is recommended that systems are in place to minimise unblinding and that blinding success is recorded.

The recruitment, retention and high data completeness in T-SET provides useful information to guide the feasibility of future studies. However, involving local NHS therapists in therapy delivery was not possible due to resource constraints

and the study took place in a site where a specialist stroke rehabilitation research team were based. Thus, engagement with research was high and staff within the team already had the expertise and resources needed to coordinate study activities, conduct assessments and deliver therapy reviews. These factors may lead to an over-estimate of the feasibility of running similar studies in future out with such an environment.

If future studies are conducted, particularly out with a specialist stroke rehabilitation research setting, a research coordinator would be recommended to coordinate study activities. Care will also be required to ensure that those involved are able to fully commit to the trial and have dedicated time for it to ensure that all aspects of the trial are delivered as per protocol, and to achieve adequate levels of recruitment, retention, and completeness of data.

While the preference would be for NHS therapists to deliver the intervention so it is evaluated as it would be delivered in the NHS this was not feasible in T-SET. Given the limited therapy resource within the NHS this challenge is likely to remain unchanged. A mixed approach involving some NHS therapists, if possible, and some research therapists may offer a compromise in a multi-site trial. Cross site working and the sharing of gloves between sites could be considered to increase resource efficiency. Based on the recruitment rate in T-SET it is anticipated that two, 32 glove kits would be sufficient for three sites. However, sites would need to communicate to ensure availability prior to recruiting.

T-SET offers reassurance around the acceptability of the intervention. However, future studies should consider refining it slightly to further increase its acceptability by increasing the duration of the intervention. Incorporating a process evaluation to explore potential implementation barriers and facilitators anticipated by stakeholders (stroke survivors, carers, therapists) to provide a better understanding of how the intervention can be implemented successfully in different settings clinically if found to be effective is also recommended. Additionally, to optimise feasibility of recruitment and the intervention eligibility criteria should 1) include some flexibility for the timing of trial recruitment and activities to give potential recruits a reasonable chance to participate successfully/positively, particularly around discharge when other physical/emotional demands are high (e.g. to see how they settle in/gain

confidence at home before deciding to join study), 2) include improved clarity over the amount of active digital flexion that is likely to be required to establish grasp (likely ≥2 cm in thumb and ≥one finger based on the research physiotherapists experience) and 3) exclude people with hand swelling that is considered to be severe enough to cause discomfort when a glove is worn, particularly when a larger glove is not available.

Efforts should be made to record adherence to the intended EMPOWER Help for Hands Programme to aid interpretation of outcomes and usual care therapy dose and content of usual NHS therapy should also be recorded to permit group comparison and context.

The ARAT has historically been described as a measure of upper limb function, a term that aligns with upper limb activity capacity within The International Classification of Functioning, Disability and Health model (World Health Organisation 2001). It is well validated and appeared to offer a responsive measure to capture change. Thus, the ARAT should be considered as the primary outcome. Additionally, central training and the sharing of standardised assessment procedures / resources are recommended to assure reliable and repeatable results at different recruiting sites (Pomeroy *et al*. 2000; T. Platz *et al*. 2005a).

1.3 Part 2: Using patient and public involvement to further develop the intervention in T-SET in preparation for a future trial

To optimise the relevance of clinical research funders are increasingly expecting researchers to involve patients, carers, and members of the public in the planning of their research. Patient and public involvement (PPI) in research typically involves people with lived experience of a health condition being studied and is defined by The National Institute for Health Research (NIHR) as:

> "…research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them…[and]… an active partnership between patients, carers, and members of the public with researchers that influences and shapes research."

A priority of the work in this thesis was that it is patient-focussed. T-SET gathered useful information on the acceptability of the intervention and training provided in it from a stroke survivor, carer, and therapist perspective to inform the design of a future trial.

1.3.1 Objective

The objective of the PPI activity in that followed, reported in Part 2, was:

- to capture additional information on how future research could best proceed with optimal relevance for the target population

1.3.2 Method

Two stroke survivors from the target population who were involved in other rehabilitation trials within the stroke research department in the Queen Elizabeth University Hospital were invited to provide advice for the planning of a future trial. Both agreed to participate. They were then provided with a brief written summary of the T-SET design and findings to read and consider. The research physiotherapist in T-SET then met with each stroke survivor at a mutually convenient time to discuss information provided and to seek their views on how it should influence a subsequent trial.

1.3.3 Results

1.3.3.1 Population

Both expressed that if ability allowed, a priority would be to offer the intervention early. However, they also highlighted the non-physical challenges associated with rehabilitation early after stroke (fatigue, cognitive and mood disturbance etc) and felt that some flexibility should be included in the recruitment timeline to give stroke survivors a reasonable chance to weigh up their competing challenges and take up the research opportunity.

1.3.3.2 Intervention

Both stroke survivors valued rehabilitation and expressed that therapy support should be extended if possible. They also felt that control stroke survivors should be given subsequent access to the device to minimise attrition.

1.3.3.3 Outcome

Both stroke survivors expressed that a successful outcome would mean that users could perform more everyday life tasks independently.

1.3.4 Discussion

The PPI work conducted suggests that future research should refine the EMPOWER Help for Hands Programme by extending its duration, if possible, to improve acceptability and providing the intervention early but with some flexibility included to allow others, not initially ready, to have a reasonable chance to take up the opportunity. Additionally, it suggests that a future evaluation trial should offer the intervention later to control stroke survivors to manage attrition and utilise an outcome measure that reflects a meaningful change in independence with life tasks.

1.4 Conclusions

The Help for Hands EMPOWER intervention in T-SET was found to be feasible in the setting it was evaluated in as intervention adherence, safety, acceptability to stroke survivors, cares, occupational and physiotherapists, and glove laundering turnaround time and durability appeared to be acceptable.

The trial design piloted was also found to be feasible in the setting it was evaluated in as a recruitment rate of 1.3 stroke survivors per month was found which is comparable to other stroke upper limb rehabilitation trials (Brkic *et al*. 2016; Held *et al*. 2019), retention was 100% and outcome measure completion exceeded 99%. Additionally, a promising improvement in all clinical measures, including the ARAT (a measure of independence in functional tasks that involve the upper limb) was observed suggesting that the measures studied are responsive to change. However, the small, predominantly male sample size, absence of a control group and long term follow up limit interpretation.

An adequately powered, multi-site blinded randomised controlled evaluation trial with long term follow up involving the intervention should now be considered. Ideally such research should be delivered within an NHS service to establish if feasibility remains acceptable within this real-life setting. Usual care therapy dose and content should also be recorded to permit group comparison and inform context. To optimise intervention feasibility, it should also provide improved clarity over the amount of active digital flexion that is likely to be required to establish grasp (likely ≥2 cm in thumb and ≥ one finger based on the research physiotherapists experience) in the inclusion criteria and exclude people with hand swelling that is considered to be severe enough to cause discomfort when a glove is worn, particularly when a larger glove is not available.

Feasibility involving other recruitment sites will rely on staff involved having the expertise and dedicated time to conduct all research activities in the study protocol and a coordinator is recommended to oversee the conduct of study activities. To optimise reliability and validity of findings across different recruiting sites central training and standardised training resources should be provided where possible. Although the intervention was found to be acceptable,

future research should provide an in-depth exploration of the self-management support needs (barriers and facilitators) of stroke survivors to aid successful implementation in different contexts in clinical settings if it is found to be effective.

The pilot study and PPI work both highlight that intervention feasibility (and acceptability) could further be improved in future work by increasing the intervention duration if possible and continuing to offer the intervention early and with sufficient flexibility to allow stroke survivors a reasonable chance to consider and take up the opportunity given other challenges encountered (e.g. managing fatigue, adapting to discharge home etc.). Similarly, utilising a responsive outcome measure that reflects a meaningful change in independence with life tasks (e.g. the ARAT, a measure of upper limb function), and offering the intervention later to stroke survivors randomised to the control group to reduce attrition are likely to improve the feasibility (and acceptability) of a future evaluation trial design.

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Appendix G – RCT recruitment documents

Patient information sheet – Main version

Stroke research study: hand and arm rehabilitation (SUSHI)
Patient Information Sheet

Invitation & introduction to study
You are being invited to take part in a clinical research study of a new rehabilitation device designed to improve hand and arm function in people with weakness. The device is called the SaeboGlove.

Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If you decide you are willing to participate or have any questions please contact the research team. The contact details are in this information sheet. The first part of information explains what will happen if you decide to participate and the second explains important information about what will happen to the data we generate in the study and your rights as a participant.

Thank you for your consideration and time.

Purpose of the study
One of the commonest problems after stroke is weakness in the hand and arm. This causes difficulties carrying out everyday tasks and is one of the biggest problems facing someone during recovery from stroke. We know that people who carry out lots of hand and arm movements involving grasping and releasing objects recover better, particularly if this is started early after stroke. However, many people can't open their hand enough to carry out these useful rehabilitation activities and this limits recovery.

The SaeboGlove assists people with stroke who have hand opening difficulty to open their hand in preparation for grasping and releasing. We want to see if it helps people engage more fully in useful rehabilitation activities and improves their recovery. The SaeboGlove is shown below.


Elastic bands assist hand opening

The SaeboGlove



The study will compare usual NHS rehabilitation treatment with usual NHS rehabilitation **plus** rehabilitation using a SaeboGlove. The research is being undertaken as part completion of one of the study researchers Doctorate qualification in Cardiovascular Sciences Research.

Why have I been chosen?
You have been chosen because you have suffered a recent stroke and this has caused problems with how you use your hand and arm. We are inviting around 110 patients with arm weakness in total.

Do I have to take part?
No, it is up to you. If you want to take part, you can sign a consent form. You can stop taking part whenever you want and you don't need to tell us why. If you stop taking part it will not change the care you receive.

If you are unable to sign the consent form yourself as you are unable to write we will ask you to give your consent verbally in the presence of an independent witness who will sign the consent form on your behalf.

Sometimes a stroke can affect a person's ability to understand, speak, read or write words and numbers. This is called aphasia. Our research team is very experienced in communicating with patients with aphasia but specialist advice will be sought from a stroke speech and language therapist if you require assistance to explain the study to you or during the consent process to ensure that you understand what your participation would involve.

What will happen to me if I take part?

If you want to take part in the study you will be asked to sign a consent form confirming that you wish to take part. We will then check your eligibility to take part in the study by looking at your medical records and by assessing how much your arm and hand have been affected. It is important to note that some people who wish to take part may not be eligible to continue in the study.

If you are eligible to take part you will have a more detailed assessment of your hand and arm and be asked some questions. This will be done at the hospital and will take about 2 hours. These assessments involve a researcher watching you complete various movements or tasks (usually sat at a table) and asking you questions about how the stroke has affected you and about the health care and social support you have recently received.

You will then be allocated to one of two treatments at **random**, like tossing a coin. One group will continue with usual NHS rehabilitation for 6-weeks and the other will receive additional therapy with the SaeboGlove for 6-weeks. More details on each of these treatments is given below. Participants in the study and the research staff carrying out the study cannot choose who will be given a particular rehabilitation treatment.

Around 6-weeks after starting the trial, when the treatment period has finished, you will have another assessment like you had at the start of the study where we assess your hand and arm movements and ask more questions about how the stroke has affected you. This will also be done in the hospital and will take about 2 hours. This will be repeated at 14-weeks.

Around 6-months after starting the trial you will have a final assessment which we plan to do by telephone. We will ask questions about your hand and arm, how the stroke has affected you and the health care and social support you received during the time you were in the SUSHI Trial. If this is not possible and you would prefer a face-to-face visit, this will be organised. This assessment will last approximately 45 minutes and is the end of the study.

After the 14-week visit, people who did not receive SaeboGlove therapy will be offered a 6-week course of therapy. This is not a formal part of the study but means all participants will be able to try the therapy at some point but allows us to make a better comparison of whether it is really working.

Throughout the study you will also be asked to record brief details about the hand and arm rehabilitation you receive in a booklet provided.

We will also write to your GP to advise him/her that you are taking part in the SUSHI trial and let your clinical physiotherapist and occupational therapist know so they have an overview of your care. We also have an information sheet for relatives that we can give to you if you wish.

What will happen if I am given usual NHS rehabilitation

You will continue to receive the usual stroke care available to all stroke patients in your area and have the assessments described above. You will also have a progress review with a therapist to check your progress on 4 occasions during the first 6 weeks. You will receive a weekly phone call to remind you to record brief details of the hand and arm rehabilitation you receive in a booklet we give you. Once your 14-week assessment is completed your participation in the trial will end. However, you will then be able to receive 6-weeks of SaeboGlove Therapy **if** you want it. It is possible some people may recover so well that we don't think the SaeboGlove will help. If this is the case a research therapist will offer you an individualised training program to help your recovery continue. If you opt for more therapy you will have a progress review with the research therapist on 4 of the 6-weeks. If you are discharged home you can attend reviews at your local hospital. If necessary, on occasion, for your convenience, advice can be provided by phone or video call (using a web-based platform called Attend Anywhere) instead. Once your 6 month visit is completed your participation in the trial will end.

What will happen if I am given SaeboGlove Therapy

If you are allocated to receive SaeboGlove Therapy you will have the assessments described above and be given a SaeboGlove to use daily for 6-weeks with or without the help of a carer. A research therapist will train you or your carer how to get the SaeboGlove on and off and give you an individualised training program involving grasping and releasing. You will have a progress review with the research therapist in 4 of the 6-weeks. If you are discharged home you will attend reviews at your local hospital. If necessary, on occasion, for your convenience, advice can be provided by phone or video call (using a web-based platform called Attend Anywhere) instead.

You will receive written information on the exercises you are given for your training program. However, if you think it is easier, you can ask the research therapist to film you doing the exercises on you or your carers mobile telephone or camera so that you can view it at home later.

You will receive a weekly phone call to remind you to record brief details of the hand and arm rehabilitation you receive in a booklet we give you. Once your 14-week assessment is completed your participation in the trial will end.

A few participants and carers allocated to SaeboGlove Therapy will be invited to share their views on SaeboGlove therapy by attending up to two interviews with a researcher. Participation in interviews is optional. If you are invited you will be given further details another time.

What are the possible benefits of taking part?

Everybody in the study will be offered additional SaeboGlove therapy. Research suggests that carrying out more therapy generally leads to better functional recovery. However, we do not know yet if SaeboGlove Therapy is actually beneficial after a stroke. This study aims to find this out.

What are the possible disadvantages and risks of taking part?

With all therapy programmes, people can experience tiredness, frustration and pain. We will monitor closely for signs of these as you and your safety and comfort remain our biggest priority. If present, we will alter the therapy you carry out and/or discuss with you whether to continue therapy. All people taking part in this study will take part in research assessments which will ask you about how your stroke affects your everyday life. This may be upsetting.

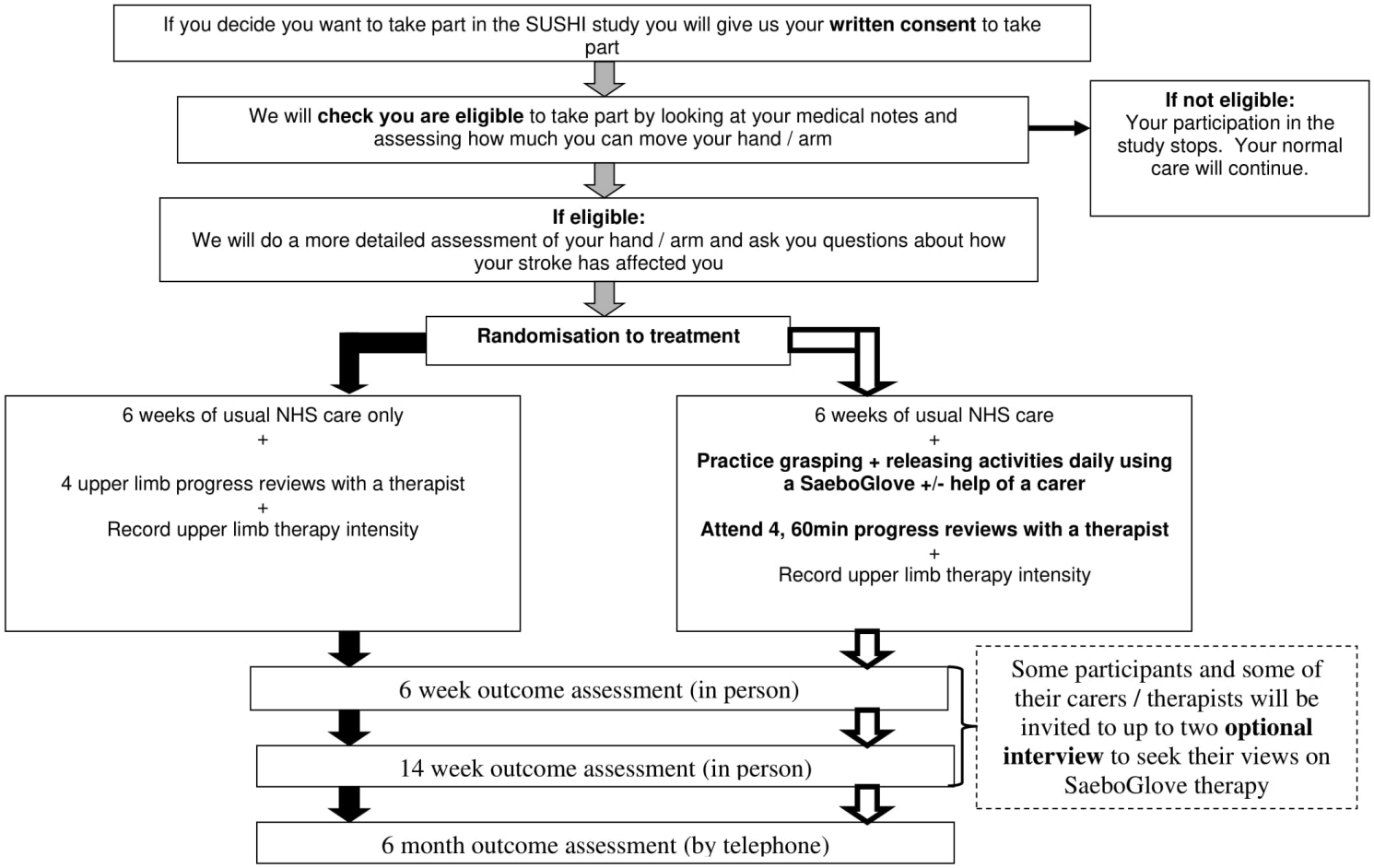
If you are discharged home during the trial you will need to travel to your local hospital to therapy and/or assessment visits. SaeboGlove Therapy and travelling may be tiring and will take time.

Expenses

If you make your own travel arrangements to any study therapy or assessments appointments your travel expenses can be reimbursed.

This completes part 1 of this information sheet. If this has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Figure 1: SUSHI FLOW CHART



PART 2

What will happen if I withdraw from the study?
You can withdraw from the study at any point and this will not affect the care you receive. If you decide to do so, we would ask if we could still use the data we have gathered so far. You can refuse this and data can be destroyed if you wish.

What if there is a problem?
If you have any questions, concerns, or issues you would like to raise please contact The Stroke Research Team at Glasgow University who are coordinating the SUSHI trial (Telephone - 0141 451 5870, Email – ggc.srunit@nhs.scot) or Professor Jesse Dawson who is overseeing it (Telephone switchboard - 0141 2011100 and ask for Prof Dawson).

If you wish to speak to an independent person who is not involved in the study then you can contact Dr Scott Muir (Tel - 0141 201 1110) via the switchboard at the Queen Elizabeth University Hospital.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Greater Glasgow and Clyde but you may have to pay your legal costs. There are no special compensation arrangements for non-negligent harm. The normal NHS complaints mechanisms will still be available to you (Tel - 0141 201 4500, Email - complaints@ggc.scot.nhs.uk).

Will my participation in the study be kept confidential?
Yes, all the information collected about you will be coded by a unique identifier meaning that all your personal details are made anonymous and kept strictly confidential. The researchers will analyse all information and store it securely at the University of Glasgow. Any published report of the research will not use your name or make your identity known.

Researchers from the University of Glasgow and NHS Greater Glasgow and Clyde collect, store and process all personal information in accordance with the General Data Protection Regulation (2018). To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information from [Insert title, name and telephone number of principal investigator].

We will collect and store identifiable information from you so that we can contact you if needed during the study. This will include your name, date of birth, address and contact details. We will keep identifiable information about you for 3 years after the study has finished. We will not pass this information to a third party without your express permission. After 3 years, your indentifiable information will be destroyed, but we will store your consent form for 10 years.

The anonymous research data will be stored on a research repository call Enlighten. It will be stored here for 10 years from the time of last data access. Your rights to access, change or move the information we store may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained but will destroy your identifiable data. Once we have anonymised the reseacrh data we will be unable to withdraw your data.

Your identifiable information might be shared with people who check that the study is done properly and, if you agree, in coded form with other organisations or universities to carry out research to improve scientific understanding. Your data will form part of the study results that will be published in expert journals, presentations.

What will happen to the results of the study?

We hope the whole study will be completed in 36 months and that the data will be used to help us decide if we should use these devices in clinical practice. The results will be presented at academic meetings and published in a medical journal and PhD thesis report. A report will also be submitted to Chest Heart and Stroke Scotland who is funding the research. You will not be identified in any report or publication. We will also send a summary of the results to all study participants. A copy of the detailed final report will also be available to participants upon request.

What if relevant new information becomes available?

If new information about the treatments being tested in this study become available during your participation in it we will tell you about it in case it affects your decision to take part.

Who is organising and funding the study?

The study is being run by the Queen Elizabeth University Hospital in Glasgow and the University of Glasgow. The cost of carrying out the study has been funded by a postgraduate fellowship grant from Chest Heart and Stroke Scotland and a grant from the Chief Scientific Office.

Who has reviewed the research?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the West of Scotland Research Ethics Committee.

Patient information sheet – Aphasia version

Stroke research study: hand and arm rehabilitation (SUSHI)

Patient Information Sheet – Part 1

Invitation & introduction to study

You are being invited to take part in a clinical research study of a new rehabilitation device. This device has been designed to improve hand and arm function in people with weakness. The device is called the SaeboGlove.

It is important that you understand why the research is being done and what it will involve. Please take time to read the information carefully.

If you decide to participate or have any questions please contact the research team. The contact details are in the information sheet.

This information sheet is in two parts:

Part 1 - Explains what will happen if you decide to participate

Part 2 - Explains important information about what will happen to the data we generate in the study and your rights as a participant.

Thank you for your consideration and time.

Purpose of the study

One of the commonest problems after stroke is weakness in the hand and arm. This causes difficulties carrying out everyday tasks and is one of the biggest problems facing someone during recovery from stroke. We know that people who carry out lots of hand and arm movements involving grasping and releasing objects recover better, particularly if this is started early after stroke. However, many people can't open their hand enough to carry out these useful rehabilitation activities and this limits recovery.

The SaeboGlove assists people with stroke who have hand opening difficulty to open their hand in preparation for grasping and releasing. We want to see if it helps people engage more fully in useful rehabilitation activities and improves their recovery. The SaeboGlove is shown below.

The SaeboGlove



Elastic bands assist hand opening



The study will compare usual NHS rehabilitation treatment with usual NHS rehabilitation **plus** rehabilitation using a SaeboGlove. The research is being undertaken as part completion of one of the study researchers Doctorate qualification in Cardiovascular Sciences Research.

Why have I been chosen?

You have been chosen because

- you have suffered a recent stroke
- you have problems with how you use your hand and arm.

We are inviting around 110 patients with arm weakness in total.

Do I have to take part?

- No, the decision is entirely up to you
- If you agree you will be asked to sign a consent form or give verbal consent in the presence of an independent witness who will sign the form on your behalf
- You can withdraw from the trial at any time without reason
- Withdrawing from the study will not change the care you receive
- To ensure you fully understand the consent process you can have communication support from a Speech & Language Therapist

What will happen if I take part?

If you decide to take part, you will be asked to sign a consent form confirming your participation. We will then check your eligibility to take part by checking your medical records and by assessing how much your arm and hand have been affected.

It is important to note that some people who wish to take part may not be eligible to continue in the study.

If you are eligible to take part you will have a more detailed assessment of your hand and arm and be asked some questions. This is called a baseline assessment. It will be done at the hospital and will take about 2 hours.

This assessment will involve:

- a researcher watching you complete various movements or tasks (usually sitting at a table)
- being asked questions about how the stroke has affected you
- being asked questions about the health care and social support you have recently received.

You will then be allocated to one of two treatment groups:

- one group will continue with usual NHS rehabilitation for 6 weeks
- the other group will receive additional therapy with the SaeboGlove for 6 weeks

Please note the groups will be decided at random. Participants in the study and the research staff carrying out the study cannot choose who will be given a particular rehabilitation treatment.

Around 6 weeks after starting the trial, when the treatment period has finished you will have another assessment similar to the one detailed above. This will involve:

- a researcher watching you complete various movements or tasks (usually sitting at a table)
- being asked questions about how the stroke has affected you

This will be done in the hospital and will take about 2 hours.

The baseline assessment described earlier will be repeated around 14 weeks after starting the trial. Around 6 months after starting the trial you will have a final assessment which we plan to do by telephone.

This assessment will involve:

- a researcher asking you questions about your hand and arm
- being asked questions about how the stroke has affected you
- being asked questions about the health care and social support you received during the time you were in the SUSHI Trial.

If this is not possible and you would prefer a face to face visit, this will be organised. This assessment will last approximately 45 minutes and is the end of the study.

After this 14-week visit, people who did not receive SaeboGlove therapy will then be offered a 6-week course of therapy. This is not a formal part of the study but means all participants will be able to try the therapy at some point but allows us to make a better comparison of whether it is really working.

Throughout the study you will also be asked to record brief details about the hand and arm rehabilitation you receive in a booklet provided.

We will also write to your GP to advise him/her that you are taking part in the SUSHI Trial and let your clinical physiotherapist and occupational therapist know so they have an overview of your care.

We also have an information sheet for relatives that we can give to you if you wish.

What will happen if I am given usual NHS rehabilitation?

You will continue to receive the usual stroke care available to all stroke patients in your area and have the assessments described above.

You also have a progress review by a therapist to check your progress on 4 occasions during the first 6 weeks.

You will receive a weekly phone call to remind you to record brief details of the hand and arm rehabilitation you receive in a booklet we give you.

Once your 14-week assessment is completed, you will then be able to receive 6 weeks of SaeboGlove Therapy **if** you want it.

It is possible some people may recover so well that we don't think the SaeboGlove will help.

If this is the case a research therapist will offer you an individualised training program to help your recovery continue. If you opt for more therapy you will have a progress review with the research therapist on 4 of the 6-weeks.

If you are discharged home you can attend reviews at your local hospital. If necessary, on occasion, for your convenience, advice can be provided by phone or video call (using a web-based platform called Attend Anywhere) instead. Your participation in the trial will end once your 6-month assessment is completed.

What will happen if I am given SaeboGlove Therapy

If you are allocated to receive SaeboGlove Therapy you will have the assessments described above and be given a SaeboGlove to use daily for 6-weeks with or without the help of a carer.

A research therapist will train you or your carer how to get the SaeboGlove on and off and give you an individualised training program involving grasping and releasing.

You will have a progress review with the research therapist on 4 of the 6 weeks.

If you are discharged home you will attend reviews at your local hospital. If necessary, on occasion, for your convenience, advice can be provided by phone or video call (using a web-based platform called Attend Anywhere) instead.

You will receive written information on the exercises you are given for your training program.

However, if you think it is easier, you can ask the research therapist to film you doing the exercises on you or your carers mobile telephone or camera so that you can view it at home later.

You will receive a weekly phone call to remind you to record brief details of the hand and arm rehabilitation you receive in a booklet we give you. Once your 6 month assessment is completed your participation in the trial will end.

A few participants and carers allocated to SaeboGlove Therapy will be invited to share their views on SaeboGlove therapy by attending up to two interviews with a researcher. Participation in interviews is optional. If you are invited you will be given further details another time.

What are the possible benefits of taking part?

Everybody in the study will be offered additional SaeboGlove therapy. Research suggests that carrying out more therapy generally leads to better functional recovery.

However, we do not know yet if SaeboGlove Therapy is actually beneficial after a stroke. This study aims to find this out.

What are the possible disadvantages and risks of taking part?

With all therapy programmes, people can experience tiredness, frustration and pain. We will monitor closely for signs of these as you and your safety and comfort remains our biggest priority.

If present, we will alter the therapy you carry out and/or discuss with you whether to continue therapy.

All people taking part in this study will take part in research assessments which will ask you about how your stroke affects your everyday life. This may be upsetting.

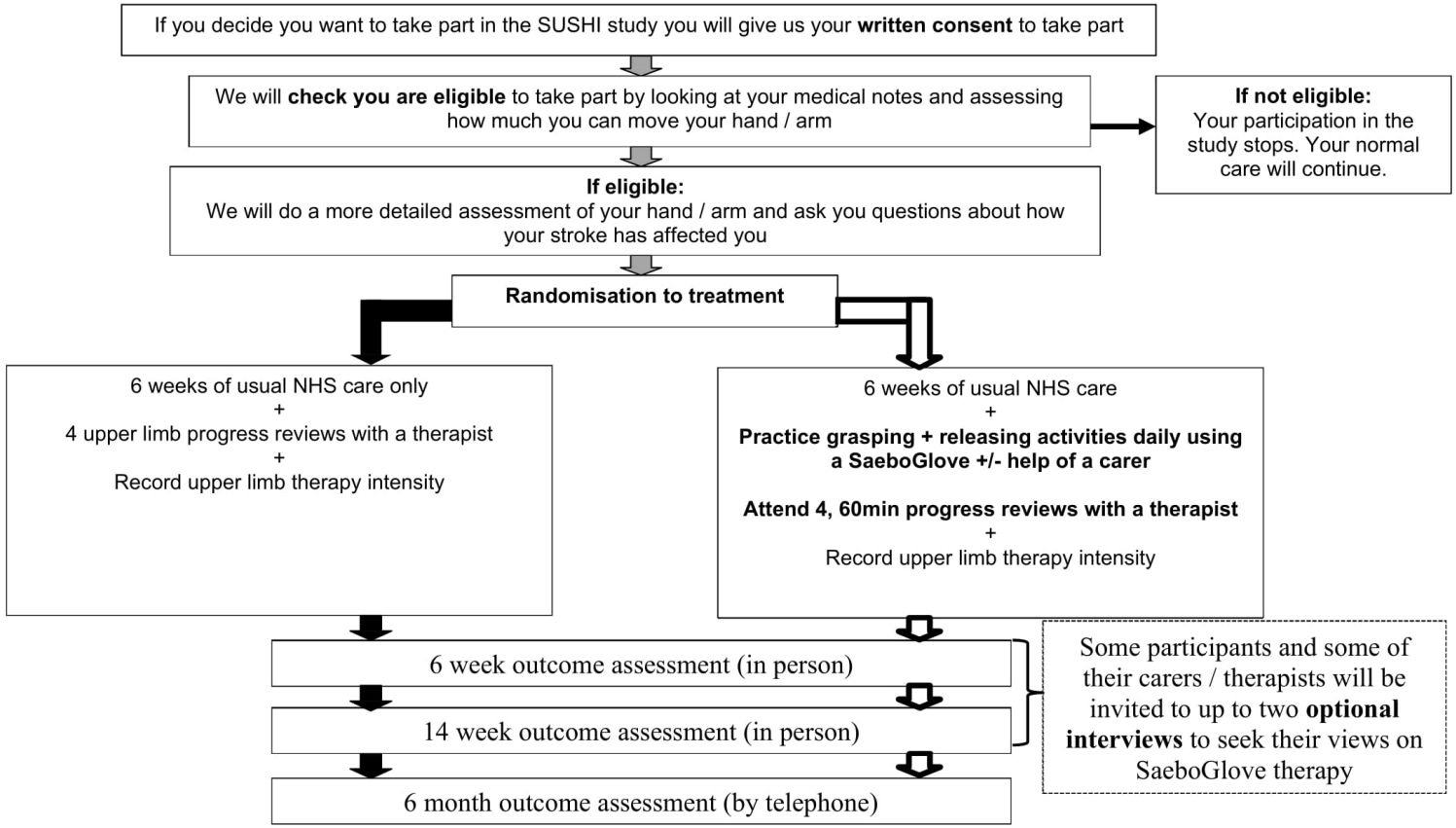
If you are discharged home during the trial you will need to travel to your local hospital to therapy and/or assessment visits. SaeboGlove Therapy and travelling may be tiring and will take time.

Expenses

If you make your own travel arrangements to any study therapy or assessment appointments your travel expenses can be reimbursed.

This completes Part 1 of this information sheet. If this has interested you and you are considering participation, please read the additional information in Part 2 before making a decision.

Figure 1: SUSHI FLOW CHART



What will happen if I withdraw from the study?

You can withdraw from the study at any point. This will not affect the care you receive.

If you do so, we would ask if we could still use the data we have gathered so far. You can refuse this and data can be destroyed if you wish.

What if there is a problem?

If you have any questions, concerns or issues you would like to raise please contact either:

1. The Stroke Research team at Glasgow University -T[Insert telephone number and email address]
2. Professor Jesse Dawson, who is overseeing the SUSHI trial via switchboard on Telephone No. 0141 201 1100

If you wish to speak to an independent person who is not involved in the study you can contact:

Dr. Scot Muir, Queen Elizabeth University Hospital via the switchboard on Telephone No. 0141 201 1100

In the event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you have grounds for legal action for compensation against NHS Greater Glasgow & Clyde but you may have to pay your own legal costs. There are no special compensation arrangements for non-negligent harm. The normal NHS complaints mechanism will still be available to you.
Telephone No. 0141 201 4500 or email complaints@ggc.scot.nhs.uk

Will my participation in the study be kept confidential?

Identifiable Information

- Researchers will collect, store and process all personal information in accordance with the General Data protection Regulation (2018)
- We will use the minimum personally-identifiable information possible to safeguard your rights.
- The identifiable information collected and stored will include your name, date of birth, address and contact details
- We will hold identifiable information for 3 years after the study has finished
- We will not pass this information on to a third party without your express permission.
- Identifiable information will be destroyed after 3 years
- Your consent form will be stored for 10 years

Anonymous Research Data

- Anonymous Research Data will be stored on a research repository called Enlighten
- The data will be stored for 10 years from the time of the last data access
- We need to manage the data in specific ways to keep the research reliable and accurate
- Your rights to access, change or move the information we store may be limited
- If you withdraw from the study we will be unable to withdraw your data as it will have been anonymised
- We will retain any Anonymous Research Data but destroy Identifiable Data

Please note your identifiable information may be shared with people who check the study is done properly.

With your permission it may be shared in coded form with other organisations or universities to carry out research to improve scientific understanding.

Your data will form part of the study results that will be published in expert journals, a PhD thesis report and presentations.

What will happen to the results of the study?

We hope the whole study will be completed in 42 months and that the data will be used to help us decide if we should use these devices in clinical practice. The results will be presented at:

- academic meetings
- published in medical journals and a PhD thesis report

A report will be submitted to Chest, Heart & Stroke Scotland and the Chief Scientist Office who are funding the research.

A summary of the results will be sent to all study participants. A copy of the full detailed final report will also be available to participants upon request.

Please note participants will not be identified in any report or publication.

What if relevant new information becomes available?

If new information about treatments being tested in this study becomes available during your participation in it we will tell you about it in case it affects your decision to take part.

Who is organising and funding the study?

The study is being run by the Queen Elizabeth University Hospital in Glasgow and the University of Glasgow. The cost of carrying out the study has been funded by a postgraduate fellowship grant from Chest, Heart & Stroke Scotland and a grant from the Chief Scientist Office.

Who has reviewed the research?

All research in the NHS is looked at by an independent group of people, called a Research Ethics committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the West of Scotland Research Ethics Committee.

Patient information sheet – Relative version

Stroke research study: hand and arm rehabilitation (SUSHI)

Relative Information Sheet

Invitation & introduction to study

Your relative is being invited to take part in a clinical research study of a new rehabilitation device designed to improve hand and arm function in people with weakness. The device is called the SaeboGlove.

Before your relative decides, it is important that he/she understands why the research is being done and what it will involve. Please take time to read the following information carefully so that you can assist them in their decision. If your relative decides he/she is willing to participate or if either of you have any questions please contact the research team. The contact details are in this information sheet. The first part of the information explains what will happen to your relative if he/she decides to participate and the second explains important information about what will happen to the data we generate in the study and his/her rights as a participant.

Thank you for your consideration and time.

Purpose of the study

One of the commonest problems after stroke is weakness in the hand and arm. This causes difficulties carrying out everyday tasks and is one of the biggest problems facing someone during recovery from stroke. We know that people who carry out lots of hand and arm movements involving grasping and releasing objects recover better, particularly if this is started early after stroke. However, many people can't open their hand enough to carry out these useful rehabilitation activities and this limits recovery.

The SaeboGlove assists people with stroke who have hand opening difficulty to open their hand in preparation for grasping and releasing. We want to see if it helps people engage more fully in useful rehabilitation activities and improves their recovery. The SaeboGlove is shown below.



Elastic bands assist hand opening

The SaeboGlove



The study will compare usual NHS rehabilitation treatment with usual NHS rehabilitation **plus** rehabilitation using a SaeboGlove. The research is being undertaken as part completion of one of the study researchers Doctorate qualification in Cardiovascular Sciences Research.

Why has my relative been chosen?

Your relative has been chosen because he/she has suffered a recent stroke and this has caused problems with how he/she uses his/her hand and arm. We are inviting around 110 patients with arm weakness in total.

Does my relative have to take part?

No, it is up to him/her. If he/she wants to take part, he/she can sign a consent form. He/she can stop taking part whenever he/she wants and he/she don't need to tell us why. If he/she stops taking part it will not change the care he/she receives.

If he/she is unable to sign the consent form him/herself as he/she is unable to write we will ask him/her to give his/her consent verbally in the presence of an independent witness who will sign the consent form on his/her behalf.

Sometimes a stroke can affect a person's ability to understand, speak, read or write words and numbers. This is called aphasia. Our research team is very experienced in communicating with patients with aphasia but specialist advice will be sought from a stroke speech and language therapist if they require assistance to explain the study to your relative or during the consent process to ensure that your relative understands what his/her participation would involve.

What will happen to my relative if he/she takes part?

If he/she wants to take part in the study he/she will be asked to sign a consent form confirming that he/she wishes to take part. We will then check that your relative is eligible to take part in the study by looking at his/her medical records and by assessing how much his/her arm and hand have been affected. It is important to note that some people who wish to take part may not be eligible to continue in the study.

If he/she is eligible to take part he/she will have a more detailed assessment of his/her hand and arm and be asked some questions. This will be done at the hospital and will take about 2 hours. These assessments involve a researcher watching him/her complete various movements or tasks (usually sat at a table) and asking him/her questions about how the stroke has affected him/her and about the health care and social support he/she has recently received.

Your relative will then be allocated to one of two treatments at **random**, like tossing a coin. One group will continue with usual NHS rehabilitation for 6-weeks and the other will receive additional therapy with the SaeboGlove for 6-weeks. More details on each of these treatments is given below. Participants in the study and the research staff carrying out the study cannot choose who will be given a particular rehabilitation treatment.

Around 6-weeks after starting the trial, when the treatment period has finished, your relative will have another assessment like he/she had at the start of the study where we assess his/her hand and arm movements and ask more questions about how the stroke has affected him/her. This will also be done in the hospital and will take about 2 hours. This will be repeated at 14-weeks.

Around 6-months after starting the trial your relative will have a final assessment which we plan to do by telephone. We will ask questions about his/her hand and arm, how the stroke has affected him/her and the health care and social support he/she received during the time he/she was in the SUSHI Trial. If this is not possible and he/she would prefer a face to face visit, this will be organised. This assessment will last approximately 45 minutes and is the end of the study.

After the 14-week visit, people who did not receive SaeboGlove therapy will be offered a 6-week course of therapy. This is not a formal part of the study but means all participants will be able to try the therapy at some point but allows us to make a better comparison of whether it is really working.

Throughout the study your relative will also be asked to record brief details about the hand and arm rehabilitation he/she receives in a booklet provided.

We will also write to your relatives GP to advise him/her that he/she is taking part in the SUSHI trial and let his/her clinical physiotherapist and occupational therapist know so they have an overview of your relative's care.

What will happen if my relative is given usual NHS rehabilitation

Your relative will continue to receive the usual stroke care available to all stroke patients in his/her area and have the assessments described above. He/she will also have a progress review with a therapist to check his/her progress on 4 occasions during the first 6 weeks. He/she will receive a weekly phone call to remind him/her to record brief details of the hand and arm rehabilitation he/she receives in a booklet we give him/her. Once his/her 14-week assessment is completed he/she will then be able to receive 6-weeks of SaeboGlove Therapy **if** he/she wants it. It is possible some people may recover so well that we don't think the SaeboGlove will help. If this is the case a research therapist will offer him/her an individualised training program to help his/her recovery continue. If he/she opt for more therapy he/she will have a progress review with the research therapist on 4 of the 6-weeks. If he/she is discharged home he/she can attend reviews at his/her local hospital. If necessary, on occasion, for his/her convenience, advice can be provided by phone or video call (using a web-based platform called Attend Anywhere instead. Once his/her 6 month visit is completed his/her participation in the trial will end.

What will happen if my relative is given SaeboGlove Therapy

If he/she is allocated to receive SaeboGlove Therapy he/she will have the assessments described above and be given a SaeboGlove to use daily for 6-weeks with or without the help of a carer. A research therapist will train him/her or his/her carer how to get the SaeboGlove on and off and give him/her an individualised training program involving grasping and releasing. He/she will have a progress review with the research therapist on 4 of the 6-weeks. If he/she is discharged home he/she will attend reviews at his/her local hospital. If necessary, on occasion, for his/her convenience, advice can be provided by phone or video call (using a web-based platform called Attend Anywhere instead.

He/she will receive written information on the exercises he/she is given for his/her training program. However, if he/she think it is easier, he/she can ask the research therapist to film him/her doing the exercises on his/her or his/her carers mobile telephone or camera so that he/she can view it at home later.

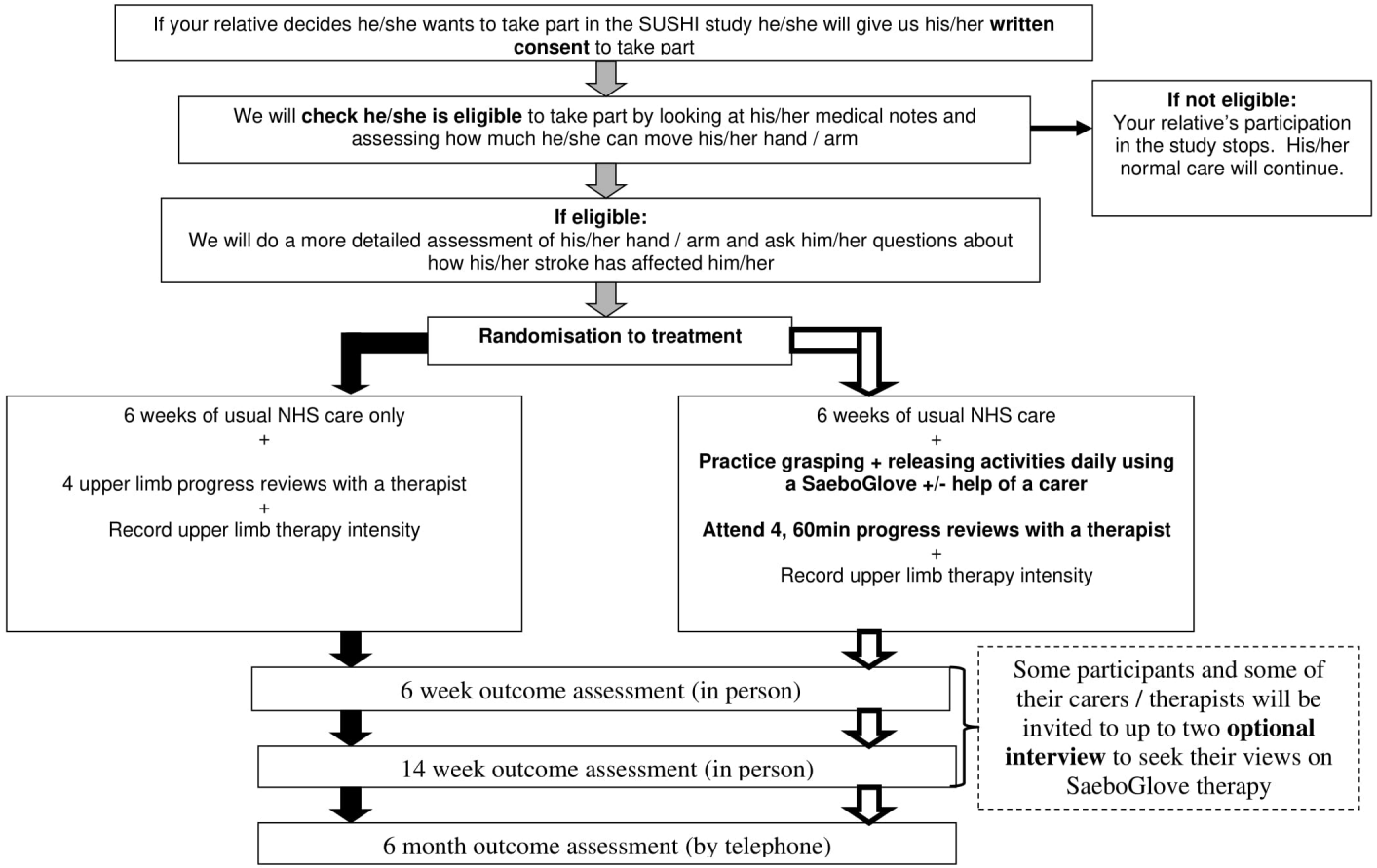
He/she will receive a weekly phone call to remind him/her to record brief details of the hand and arm rehabilitation he/she receives in a booklet we give him/her. Once his/her 6 month assessment is completed his/her participation in the trial will end.

A few participants and carers allocated to SaeboGlove Therapy will be invited to share their views on SaeboGlove therapy by attending up to two interviews with a researcher. Participation in interviews is optional. If your relative is invited he/she will be given further details another time.

What are the possible benefits of taking part?

Everybody in the study will be offered additional SaeboGlove therapy. Research suggests that carrying out more therapy generally leads to better functional recovery. However, we do not know yet if SaeboGlove Therapy is actually beneficial after a stroke. This study aims to find this out.

Figure 1: SUSHI FLOW CHART



What are the possible disadvantages and risks of taking part?
With all therapy programmes, people can experience tiredness, frustration and pain. We will monitor closely for signs of these as your relative and his/her safety and comfort remain our biggest priority. If present, we will alter the therapy he/she carries out and/or discuss with him/her whether to continue therapy. All people taking part in this study will take part in research assessments which will ask him/her about how his/her stroke affects his/her everyday life. This may be upsetting.

If he/she is discharged home during the trial he/she will need to travel to his/her local hospital to therapy and/or assessment visits. SaeboGlove Therapy and travelling may be tiring and will take time.

Expenses
If he/she makes his/her own travel arrangements to any study therapy or assessments appointments his/her travel expenses can be reimbursed.

This completes part 1 of this information sheet. If this has interested you, please read the additional information in Part 2 before helping your relative to make their decision.

PART 2

What will happen if my relative withdraws from the study?
He/she can withdraw from the study at any point and this will not affect the care he/she receives. If he/she decides to do so, we would ask if we could still use the data we have gathered so far. He/she can refuse this and data can be destroyed if he/she wishes.

What if there is a problem?
If you or your relative have any questions, concerns or issues you would like to raise please contact The Stroke Research Team at Glasgow University who are coordinating the SUSHI trial (Telephone - 0141 451 5870, Email - ggc.srunit@nhs.scot) or Professor Jesse Dawson who is overseeing it (Telephone switchboard - 0141 201 1100 and ask for Prof Dawson).

If you or your relative wishes to speak to an independent person who is not involved in the study then you can contact Dr Scott Muir (Tel - 0141 201 1100) via the switchboard at the Queen Elizabeth University Hospital.

In the event that something does go wrong and your relative is harmed during the research and this is due to someone's negligence then he/she may have grounds for a legal action for compensation against NHS Greater Glasgow and Clyde but he/she may have to pay his/her legal costs. There are no special compensation arrangements for non-negligent harm. The normal NHS complaints mechanisms will still be available to him/her (Tel - 0141 201 4500, Email - complaints@ggc.scot.nhs.uk).

Will my relatives participation in the study be kept confidential?
Yes, all the information collected about your relative will be coded by a unique identifier meaning that all his/her personal details are made anonymous and kept strictly confidential. The researchers will analyse all information and store it securely at the University of Glasgow. Any published report of the research will not use your relatives name or make his/her identity known.

Researchers from the University of Glasgow and NHS Greater Glasgow and Clyde collect, store and process all personal information in accordance with the General Data Protection Regulation (2018). To

safeguard your relatives rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your relatives information from [Insert title, name and telephone number of principal investigator].

We will collect and store identifiable information from your relative so that we can contact him/her if needed during the study. This will include his/her name, date of birth, address and contact details. We will keep identifiable information about him/her for 3 years after the study has finished. We will not pass this information to a third party without your express permission. After 3 years, his/her indentifiable information will be destroyed, but we will store his/her consent form for 10 years.

The anonymous research data will be stored on a research repository call Enlighten. It will be stored here for 10 years from the time of last data access. Your relatives rights to access, change or move the information we store may be limited, as we need to manage his/her information in specific ways in order for the research to be reliable and accurate. If your relative withdraws from the study, we will keep the information about him/her that we have already obtained but will destroy his/her identifiable data. Once we have anonymised the reseach data we will be unable to withdraw his/her data.

Your relatives identifiable information might be shared with people who check that the study is done properly and, if he/she agrees, in coded form with other organisations or universities to carry out research to improve scientific understanding. Your relative's data will form part of the study results that will be published in expert journals, presentations.

What will happen to the results of the study?

We hope the whole study will be completed in 42 months and that the data will be used to help us decide if we should use these devices in clinical practice. The results will be presented at academic meetings and published in a medical journal and PhD thesis report. A report will also be submitted to Chest Heart and Stroke Scotland and the Chief Scientist Office who are funding the research. Your relative will not be identified in any report or publication. We will also send a summary of the results to all study participants. A copy of the detailed final report will also be available to participants upon request.

What if relevant new information becomes available?

If new information about the treatments being tested in this study become available during your relative's participation in it we will tell him/her about it in case it affects his/her decision to take part.

Who is organising and funding the study?

The study is being run by the Queen Elizabeth University Hospital in Glasgow and the University of Glasgow. The cost of carrying out the study has been funded by a postgraduate fellowship grant from Chest Heart and Stroke Scotland and a grant from the Chief Scientist Office.

Who has reviewed the research?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the West of Scotland Research Ethics Committee.

Consent form

SUSHI Trial | Patient ID ☐☐☐☐☐ | **Consent Form**

Consent form: Participation in SUSHI rehabilitation study

Name of Researchers:
Prof J Dawson (Professor in Stroke Medicine), Ms J Alexander (Senior Research Physiotherapist).

Contact details: [Enter title, name and phone number of principal investigator]

Please initial

Please read information below and initial boxes

1. I confirm that I have read and understand the information sheet dated _____ (version _____) (control group SG/NSG*) _____) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the study team or from NHS Greater Glasgow & Clyde, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my G.P, Occupational Therapist(s) and Physiotherapist(s) being informed about my participation in the above study. ☐

5. I understand that a written copy of my training program will be provided to me but that if I think I will find it easier I can ask the research therapist to film me carrying out my program using my / my carers mobile phone / camera so I/we can refer to it later. ☐

6. I agree to take part in the above study. ☐

OPTIONAL
7. I agree to being contacted by the SUSHI research team to be invited to take part in an interview about my views and experiences about the rehabilitation received. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature
_____	_____	_____
Name of Witness (if applicable)	Date	Signature

*Please enter SG or NSG depending on whether information sheet provided offers control group participants optional additional therapy with a SaeboGlove (SG) or with no SaeboGlove (NSG).

When completed, 1 for research site file (original); 1 for participant (copy); 1 to be kept in medical notes (copy); 1 for GP (copy).

Assignment of unique five digit identification number

SUSHI - STUDY ID ASSIGNMENT LOG

All patients who have consented should be recorded in this log in addition to the screening log

Site No / Name: 01 / Queen Elizabeth University Hospital

Screening ID	Consented? (Yes/No)	Consent Date	Suitable for Study? (Yes/No)	Randomised? (Yes/No)	Randomised Date	Any notes
01001						
01002						
01003						

Example shown is for site 01 / Queen Elizabeth University Hospital

Personal identification log



Personal Identification Log	
5-digit subject number	
Name	
DOB	
CHI	
Home Address	
Reliable telephone number(s)	
Any other useful contact details	
GP name / address	
Race	
Ethnicity	

Screening log



SUSHI Screening Log **Site No / Name** .....

Initials	DOB	Approached (please tick)	Approach Date	Consented (please tick)	Consent Date	Screened (please tick)	Screened Date	Eligible (please tick)	Randomised (please tick)	Randomised Date	Notes

GP letter

[Enter site name and address of principal investigator]

Dear Dr. _____

[Enter site name] is taking part in the SUSHI Trial (**S**aeboGlove therapy for **U**pper limb disability and **S**evere **H**and **I**mpairment after stroke). This is a randomised control trial comparing usual NHS stroke care with Usual NHS stroke care plus 6 weeks of self-directed, repetitive, functional based, upper limb rehabilitation using a SaeboGlove rehabilitation device. This device assists the hand to open. The aim of the study is to determine if using a SaeboGlove increases upper limb functional recovery after stroke and whether it should be implemented routinely into NHS practice. In this study usual care participants will also be offered 6 weeks of self-directed, repetitive, functional based, upper limb rehabilitation using a SaeboGlove rehabilitation device but only after completing their 6 and 14 week outcome assessments. Trial participation will end following a final 6 month telephone follow up.

Your patient, _____ has agreed to participate in the trial and was randomised on _____to receive usual NHS stroke care / usual NHS stroke care plus 6 weeks of self-directed, repetitive, functional based, upper limb rehabilitation using a SaeboGlove rehabilitation device.

All participants are recruited during their stroke inpatient stay and have reduced active hand opening, upper limb disability and severe hand impairment after stroke.

Participants receiving 6 weeks of self-directed, repetitive, functional based, upper limb rehabilitation using a SaeboGlove rehabilitation device will be encouraged to use it independently daily, with or without the help of a carer. A physiotherapist / occupational therapist will provide them with an individualised functional based exercise program that will be reviewed at least four times over the 6 week treatment period.

It is expected that most trial therapy will be carried out during the in-patient stay, but if further treatment is needed we will organise this and arrange appropriate transport.

Like any upper limb rehabilitation, SaeboGlove therapy may cause shoulder discomfort and fatigue and we will closely monitor the occurrence of this.

If you need any further information, please feel free to contact me.

Thanks and yours sincerely,

[Insert signature, title, name, position, address, email and telephone number of principal investigator]

Poster



Suffered a **stroke**?

Got difficulty opening your **hand**?

Interested in more **rehabilitation**?

If yes, please ask a member of staff for information on our **SUSHI trial** or contact the stroke research team at Glasgow University who are running the trial.
We would love to hear from you.

Stroke Research Team
Tel: 0141 451 5870 / 5871
Email: ggc.srunit@nhs.scot

University of Glasgow · SUSHI Enabling hand function · Chief Scientist Office · Chest Heart & Stroke Scotland NO LIFE HALF LIVED · NHS Greater Glasgow and Clyde

Leaflets

What to do if you want to take part?

If you would like more information on this research study please ask a member of staff for information on our SUSHI trial or contact the SUSHI research team who are coordinating it:

Stroke Research Team

[Enter contact name, address, telephone number and email address]

Alternatively, tear off this section of this leaflet and return it to the above address. A member of the study team will contact you soon.

Your name (Please print):

Your telephone number (including area code):

Email (if prefer to be contacted initially by email):

SUSHI

Enabling hand function





Stroke arm rehabilitation research study

Suffered a stroke?

Got difficulty opening your hand?

Interested in more rehabilitation?

If the answer to all these questions is 'yes' then our arm rehabilitation research study could be for you

University of Glasgow · Chief Scientist Office · Chest Heart & Stroke Scotland · NHS Greater Glasgow and Clyde

NO LIFE HALF LIVED

Background

After a stroke around 85% of people lose the use of their hand and arm. They report that this is very upsetting and that rehabilitation often doesn't focus enough on arm or hand recovery. People who have had a stroke say that finding new treatments to improve hand and arm recovery is a high research priority for them.

At the moment we know that people who carry out lots of hand and arm movements involving grasping and releasing objects in everyday activities such as feeding and dressing recover better, especially when they are performed early after a stroke. However, many people can't open their hand enough to carry out these useful rehabilitation activities and this limits recovery.

A SaeboGlove is a new rehabilitation aid. It is worn on the affected hand when weakness makes hand opening difficult after stroke. It assists the hand to open, which is crucial for people to grasp, lift and release objects. Wearing a SaeboGlove may help people with limited hand opening carry out useful rehabilitation activities involving grasping and releasing objects in everyday activities and this may improve their recovery.

The SaeboGlove is shown in the picture opposite.

Arm rehabilitation research study

This study is comparing two arm rehabilitation options to see which one provides the most benefit to stroke patients:

1. Usual NHS rehabilitation
2. Usual NHS rehabilitation **plus** rehabilitation using a SaeboGlove which helps to open the hand to enable the practice of everyday functional tasks.

The SaeboGlove



What is involved?

In a clinical study, people are given a treatment at **random,** like tossing a coin. The people taking part in the study and the research staff carrying out the study cannot choose who will be given a particular rehabilitation treatment.

In this clinical study, some people will get usual NHS rehabilitation (called "usual therapy") and some people will get usual NHS rehabilitation **plus** rehabilitation using a SaeboGlove (called "SaeboGlove therapy)".

People who get SaeboGlove therapy will be given a SaeboGlove to use independently with or without the help of a carer. A research therapist will provide them with functional tasks to practice daily while wearing the SaeboGlove.

All people taking part will have their recovery assessed 6 and 14 weeks, and 6 months after joining the study so that the effects of each type of rehabilitation can be compared.

After the 14 week assessment those in the usual therapy group will be offered 6 weeks of SaeboGlove therapy.

Appendix H – RCT assessment documents

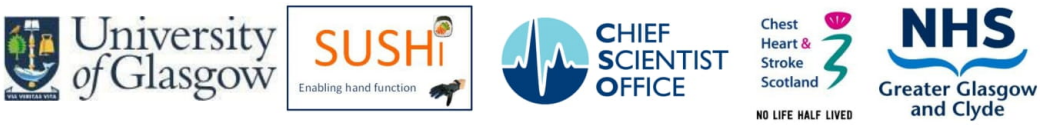
Screening assessment

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Screening Assessment

SUSHI
SCREENING ASSESSMENT



SUSHI Trial

Patient ID Number ☐☐☐☐☐

Screening Assessment

SCREENING ASSESSMENT

INFORMED CONSENT

Has the patient given written consent to take part in the study?

No ☐ The patient **MUST NOT** proceed further in the study until informed consent has Been obtained

Yes ☐ Date of consent: __ __ / __ __/ __ __ __ __
If Yes, continue with trial participation

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Screening Assessment

STROKE DETAILS / COMORBIDITY

Date of stroke: __ __ / __ __ / __ __ __ __

Arm affected by stroke: Left ☐ Right ☐

HANDEDNESS:

Right ☐

Left ☐

Ambidextrous ☐

Was stroke due to:

- Cerebral Infarction ☐
- Primary Intracerebral Haemorrhage ☐
- Subaracnoid Haemorrhage ☐
- Unknown ☐

Does the patient have any other significant upper limb impairment in their paretic upper limb?

	No	Yes
Fixed contracture		
Frozen shoulder		
Severe arthritis		
Recent fracture		
Other		

If other, please detail: _____

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Screening Assessment

FUGL-MEYER MOTOR AND SENSORY SCALE (HAND SUB-SECTION)

Please consult the SUSHI assessment manual for full instructions on how to complete the Fugl-Meyer. You must demonstrate the required movement then instruct the participant to complete that movement with the unaffected arm first to ensure that the participant understands the movement. Unlike all other sections of the Fugl-Meyer, in the hand sub-section if a participant is unable to perform a particular movement the assessor can give full assistance to the participants forearm with the elbow in 90º flexion. No assistance can be given to the wrist or fingers. If the participant cannot open the fingers to receive an object they will automatically score zero. Participant should be given the opportunity to demonstrate their best possible performance over 3 attempts. More than 3 attempts are ONLY permitted if it is clear that a participant has not understood the assessors instructions.

IMPORTANT - Tasks in:

Black – precision of hand start position does not affect score (for reproduction only)

Green – perfect hand start position must be achieved or automatically score zero

a) Flexion of the fingers from the position of full extension

Suggested instructions: *'Begin with your fingers straight* (assessor moves fingers into full extension passively if patient unable to do so actively) *and then close your fingers fully to make a fist'*

no flexion	some, but not full **active** flexion	full active flexion (active equals passive)	
0	1	2	

b) Extension of the fingers from the position of full flexion

Suggested instructions: *'Begin with your fingers closed* (assessor moves fingers into full flexion passively if patient unable to do so actively) and then *straighten all your finger joints fully'*

no extension	some, but not full ext. or release of an active mass flexion grasp	full active extension (active equals passive)	
0	1	2	

c) Grasp A: extension MCP, flexion PIP and DIP grasp is tested against resistance

Suggested instructions: *'Hook your fingers so that your knuckles are fully straight. Now try really hard to hold this position while I try to straighten your fingers'*

Cannot achieve required hand position	Can achieve and maintain required hand position but not against medium resistance	Can achieve and maintain required hand position and hold it well against medium resistance	
0	1	2	

Adapted from: Fugl-Meyer, A.R. et al. 1975. The post-stroke hemiplegic patient. 1. a method for evaluation of physical performance. *Scandinavian Journal of Rehabilitation Medicine.* **7**, pp. 13-31

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Screening Assessment

d) *Grasp B: extended **index** and **thumb*** - patient should perform a pure thumb adduction (holding a sheet of A4 paper folded in quarter against a horizontal tug)

Suggested instructions: *'I am going to offer you a piece of paper. Open your thumb and index finger to receive it. Now grasp the paper between your thumb and index finger keeping your thumb joints fully straight (1st CMC, MCP and IP extended to 0º). Now hold this position and try not to let me pull the paper back out'*

Cannot achieve required hand position or can but unable to hold paper	Can achieve and maintain required hand position and hold paper but not against medium resistance	Can achieve and maintain required hand position and paper well against medium resistance (no sliding)	
0	1	2	

e) *Grasp C: pulpa **thumb** against the pulpa of the **index*** (holding a pencil against a vertical tug)

Suggested instructions: *'I am going to offer you a pencil. Open your thumb and index finger to receive it. Now grasp the pencil with the pads, not side or nail, of your thumb and finger **tips**. Now hold this position and try not to let me pull the pencil back out'*

Cannot achieve required hand position or can but unable to hold pencil	Can achieve and maintain required hand position and hold pencil but not against medium resistance	Can achieve and maintain required hand position and hold pencil well against medium resistance (no sliding)	
0	1	2	

f) *Grasp D: cylindrical - volar surface of the **thumb** and **index** against each other* (holding a **drinks can** against a vertical tug)

Suggested instructions: *'I am going to offer you a can. Open your thumb and index finger to receive it. Now grasp the can with the palm side of your thumb and index finger, not the side of these fingers. Now hold this position and try not to let me pull the can back out' (score 0 if additional digits in contact or if palm side not in contact)*

Cannot achieve required hand position or can but unable to hold the can	Can achieve and maintain required hand position and hold can but not against medium resistance	Can achieve and maintain required hand position and hold can well against medium resistance (no sliding)	
0	1	2	

g) *Grasp E: spherical grasp* (grasping a tennis ball and holding it against a downwards tug)

Suggested instructions: *'I am going to hold a tennis ball and offer it to you. From above open your hand to receive it. Now grasp the tennis ball with the palm side of all of your finger tips (unless hand is wider than ball and it is not natural to use all fingers using unaffected hand). Now hold this position and try not to let me pull the ball back out"*

Cannot achieve required Hand position or can but unable to hold ball	Can achieve and maintain required hand position and hold ball but not against medium resistance	Can achieve and maintain required hand position and hold ball well against medium resistance (no sliding)	/14
0	1	2	

Fugl Meyer content reproduced with permission, Fugl-Meyer, A.R., Jääskö, L., Leyman, I., Olsson, S. and Steglind, S. (1975) 'The post-stroke hemiplegic patient. 1. a method for evaluation of physical performance', *Scand J Rehabil Med*, 7(1), 13-31, available: http://dx.doi.org/https://doi.org/10.2340/1650197771331. Published in Scandinavian Journal of Rehabilitation Medicine for the Foundation for Rehabilitation Information

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Screening Assessment

ACTION RESEARCH ARM TEST

Please consult the SUSHI assessment manual for full instructions on how to complete the ARAT. There are four subtests: grasp, grip, pinch and gross movement. If a patient scores 3 in item one of a subtest then they automatically score 3 in all other items in that subtest. If a patient scores zero in the first and the second items in a subtest, then they automatically score zero in all other items in that subtest. The patient must be able to sit unaided in order to attempt the test. If not, the patient scores 0. The body / front of the body cannot be used to help pick up an object.

Score 0 = can perform no part of the test; 1 = performs test partially; 2 = completes test, but takes abnormally long time or has great difficulty; 3 = performs test normally

Start with the least impaired arm first

	R	L
a) Grasp		
1. 10cm cube (if score = 3 then total = 18 & go to *Grip*)	☐	☐
2. 2.5cm cube (if Grasp score = 0 so far then Grasp total = 0 & go to *Grip*)	☐	☐
3. 5cm cube	☐	☐
4. 7.5cm cube	☐	☐
5. cricket ball	☐	☐
6. stone **(specific requested grasp essential or score zero)**	☐	☐
***Grasp* total /18:**	☐	☐
b) Grip		
1. Pour water glass to glass (if score = 3 then total = 12 & go to *Pinch*)	☐	☐
2. 2.25cm tube (if Grip score = 0 so far then Grip total = 0 & go to *Pinch*)	☐	☐
3. 1cm tube	☐	☐
4. washer over bolt	☐	☐
***Grip* total /12:**	☐	☐
***c) Pinch* (thumb and specific requested finger only (any part), if unable without an additional finger(s) supporting object after explanation, score zero)**		
1. 6mm bearing ring (3rd) finger & thumb (if score = 3 then total = 18 & go to *Gross*)	☐	☐
2. marble index & thumb (if Pinch score = 0 so far then Pinch total = 0 & go to *Gross*)	☐	☐
3. 6mm bearing middle (2nd) finger & thumb	☐	☐
4. 6mm bearing index (1st) finger & thumb	☐	☐
5. marble middle (2nd) finger & thumb	☐	☐
6. marble ring (3rd) finger & thumb	☐	☐
***Pinch* total/18:**	☐	☐
Gross (Head and body must be upright, if unable after explanation and assessor help to secure chin / shoulders, score ≤ 1 i.e. not complete)		
1. Place hand behind head (if score = 3 then total = 9 &finish)	☐	☐
2. Place hand on top of head	☐	☐
3. Hand to mouth	☐	☐
***Gross* total /9:**	☐	☐
Total: /57:	☐	☐

Taken from: Lyle, R.C. 1981. A performance test for assessment of upper limb function in physical rehabilitation treatment and research. *INT J REHABIL RES.* **4**, pp.483-92.

ARAT content/scoring reproduced from Lyle, R.C. (1981) 'A performance test for assessment of upper limb function in physical rehabilitation treatment and research', *Int J Rehabil Res*, 4(4), 483-92, available: http://dx.doi.org/10.1097/00004356-198112000-00001 under the Copyright Fee Paid service. Full details: http://www.bl.uk/reshelp/atyourdesk/docsupply/help/terms/index.html

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Screening Assessment

CONFIRMATION OF STUDY ELIGIBILITY

	No	Yes
1. Does the patient have capacity to consent?	☐	☐
2. Is the patient aged ≥18 years?	☐	☐
3. Has the patient been identified during their stroke inpatient stay?	☐	☐
4. Has the patient had a new clinical stroke diagnosis between 7-60 days (inclusive) ago?	☐	☐
5. Will consent, baseline assessment and randomisation occur during their stroke inpatient stay or within 2 weeks of discharge home?	☐	☐
6. Do they have severe hand impairment (FMUE hand Sub-section ≤7)	☐	☐
7. Do they have upper limb disability (ARAT ≤ 46) due to their stroke?	☐	☐
8. Is the patient suitable to use a SaeboGlove?		
a. Able to learn to don / doff a SaeboGlove +/- help of willing carer	☐	☐
b. The ability to engage in independent rehabilitation +/- help of willing carer	☐	☐
c. Reduced active range of finger extension with wrist held passively by assessor in full extension	☐	☐
d. At least 5° passive wrist extension possible when assessor holds the fingers in full extension	☐	☐
e. Nil to minimal digital contractures (5-10° may be accommodated)	☐	☐
f. Some ability to actively squeeze their hand into a fist (≥ 2 cm in thumb plus ≥ 1 other digit)	☐	☐
g. Modified Ashworth wrist and fingers ≤ 2 and considered to have consistent hand opening / closing with SaeboGlove on to enable grasp/release despite tone present	☐	☐

Name of Assessor _____ Signature _____ Date _____

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Screening Assessment

	No	Yes
9. Is the patient able to comply with the requirements of the protocol (e.g. participate in outcome assessments, questionnaires +/- help from proxy, independent SaeboGlove therapy +/- help of willing carer, medically stable, cognitively and psychologically capable)	☐	☐

Qu 10 below only needs to be answered for patient needing help to carryout SaeboGlove therapy:

10. For patients requiring help to put a SaeboGlove on and / or carryout SaeboGlove therapy, are they able to arrange a willing helper?	☐	☐

If the answer is NO to any of questions 1-10, the patient is NOT eligible to participate in the trial.

11. Does patient have other significant impairment of the upper limb affected by stroke e.g. fixed contracture, frozen shoulder, severe arthritis, fracture within 6 months?	☐	☐
12. Does the patient have any diagnosis likely to make rehabilitation or study outcome assessments/questionnaires too difficult? e.g. registered blind or terminally ill	☐	☐
13. Does patient have swelling in their paretic upper limb considered severe enough to cause discomfort when glove is worn?	☐	☐
14. Is the patient currently participating in another intervention trial?	☐	☐

The answer must be NO to all of questions 11-14. If the answer is YES to any of questions 11-14, the patient is NOT eligible to participate in the trial.

If the patient remains eligible for the trial continue with the baseline assessment below.

_____	_____	_____
Name of Assessor	Signature	Date

Baseline assessment



SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

SUSHI BASELINE ASSESSMENT

N.B. The 6 week and 14 week Assessment share the same content as the baseline assessment here with the following exceptions. They have:
- no screening checklist (page 6-7)
- no baseline treatment (page 9) and
- different tasks to tick off on the last page (page 36)



SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

Study Centre Number: ☐☐

Assessment date: ☐☐/☐☐/☐☐☐☐

Assessor 1 All pages except (insert) _ _ to _ _

(print name): _____ (sign name): _____

Assessor 2 Pages (insert) _ _ to _ _

(print name): _____ (sign name): _____

Has a SUSHI screening assessment been completed confirming that the patient is eligible for the SUSHI study?

Yes ☐

No ☐

If no, please complete the SUSHI screening assessment – the SUSHI screening assessment must be completed prior to the SUSHI baseline assessment.

If yes, has the SUSHI screening assessment been completed ≤ 48 hours ago?

Yes ☐ If yes, go to VAS on page 8.

No ☐ If no, go to page 3 below.

(If no, as the SUSHI screening assessment has been completed > 48 hours ago, study eligibility must be re-confirmed)

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

FUGL-MEYER MOTOR AND SENSORY SCALE (HAND SUB-SECTION)

Please consult the SUSHI assessment manual for full instructions on how to complete the Fugl-Meyer. You must demonstrate the required movement then instruct the participant to complete that movement with the unaffected arm first to ensure that the participant understands the movement. Unlike all other sections of the Fugl-Meyer, in the hand sub-section if a participant is unable to perform a particular movement the assessor can give full assistance to the participants forearm with the elbow in 90º flexion. No assistance can be given to the wrist or fingers. If the participant cannot open the fingers to receive an object they will automatically score zero. Participant should be given the opportunity to demonstrate their best possible performance over 3 attempts. More than 3 attempts are ONLY permitted if it is clear that a participant has not understood the assessors instructions.

IMPORTANT - Tasks in:

Black – precision of hand start position does not affect score (for reproduction only)

Red – perfect of hand start position must be achieved + maintained throughout desired action or automatically score zero

a) *Flexion of the fingers* from the position of full extension

Suggested instructions: *'Begin with your fingers straight* (assessor moves fingers into full extension passively if patient unable to do so actively) *and then close your fingers fully to make a fist'*

no flexion	some, but not full **active** flexion	full active flexion (active equals passive)	
0	1	2	

b) *Extension of the fingers* from the position of full flexion

Suggested instructions: *'Begin with your fingers closed* (assessor moves fingers into full flexion passively if patient unable to do so actively) and then *straighten all your finger joints fully'*

no extension	some, but not full ext. or release of an active mass flexion grasp	full active extension (active equals passive)	
0	1	2	

c) *Grasp A: extension MCP, flexion PIP and DIP* grasp is tested against resistance

Suggested instructions: *'Hook your fingers so that your knuckles are fully straight. Now try really hard to hold this position while I try to straighten your fingers'*

Cannot achieve required hand position	Can achieve and maintain required hand position but not against medium resistance	Can achieve and maintain required hand position and hold it well against medium resistance	
0	1	2	

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

d) Grasp B: extended **index** and **thumb** - patient should perform a pure thumb adduction (holding a sheet of A4 paper folded in quarter against a horizontal tug)

Suggested instructions: *'I am going to offer you a piece of paper. Open your thumb and index finger to receive it. Now grasp the paper between your thumb and index finger keeping your thumb joints fully straight (1st CMC, MCP and IP extended to 0º). Now hold this position and try not to let me pull the paper back out'*

Cannot achieve required hand position or can but unable to hold paper	Can achieve and maintain required hand position and hold paper but not against medium resistance	Can achieve and maintain required hand position and paper well against medium resistance (no sliding)	
0	1	2	

e) Grasp C: pulpa **thumb** against the pulpa of the **index** (holding a pencil against a vertical tug)

Suggested instructions: *'I am going to offer you a pencil. Open your thumb and index finger to receive it. Now grasp the pencil with the pads, not side or nail, of your thumb and finger **tips**. Now hold this position and try not to let me pull the pencil back out'*

Cannot achieve required hand position or can but unable to hold pencil	Can achieve and maintain required hand position and hold pencil but not against medium resistance	Can achieve and maintain required hand position and hold pencil well against medium resistance (no sliding)	
0	1	2	

f) Grasp D: cylindrical - volar surface of the **thumb** and **index** against each other (holding a **drinks can** against a vertical tug)

Suggested instructions: *'I am going to offer you a can. Open your thumb and index finger to receive it. Now grasp the can with the palm side of your thumb and index finger, not the side of these fingers. Now hold this position and try not to let me pull the can back out' (score 0 if additional digits in contact or if palm side not in contact)*

Cannot achieve required hand position or can but unable to hold the can	Can achieve and maintain required hand position and hold can but not against medium resistance	Can achieve and maintain required hand position and hold can well against medium resistance (no sliding)	
0	1	2	

g) Grasp E: spherical grasp (grasping a tennis ball and holding it against a downwards tug)

Suggested instructions: *'I am going to hold a tennis ball and offer it to you. From above open your hand to receive it. Now grasp the tennis ball with the palm side of all of your finger tips (unless hand is wider than ball and it is not natural to use all fingers using unaffected hand). Now hold this position and try not to let me pull the ball back out"*

Cannot achieve required Hand position or can but unable to hold ball	Can achieve and maintain required hand position and hold ball but not against medium resistance	Can achieve and maintain required hand position and hold ball well against medium resistance (no sliding)	**/14**
0	1	2	

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SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

CONFIRMATION OF STUDY ELIGIBILITY

	No	Yes
1. Does the patient have capacity to consent?	☐	☐
2. Is the patient aged ≥18 years?	☐	☐
3. Has the patient been identified during their stroke inpatient stay?	☐	☐
4. Has the patient had a new clinical stroke diagnosis between 7-60 days (inclusive) ago?	☐	☐
5. Will consent, baseline assessment and randomisation occur during their stroke inpatient stay or within 2 weeks of discharge home?	☐	☐
6. Do they have severe hand impairment (FMUE hand Sub-section ≤7)	☐	☐
7. Do they have upper limb disability (ARAT ≤ 46) due to their stroke?	☐	☐
8. Is the patient suitable to use a SaeboGlove?		
a. Able to learn to don / doff a SaeboGlove +/- help of willing carer	☐	☐
b. The ability to engage in independent rehabilitation +/- help of willing carer	☐	☐
c. Reduced active range of finger extension with wrist held passively by assessor in full extension	☐	☐
d. At least 5° passive wrist extension possible when assessor holds the fingers in full extension	☐	☐
e. Nil to minimal digital contractures (5-10° may be accommodated)	☐	☐
f. Some ability to actively squeeze their hand into a fist (≥ 2cm in thumb plus ≥ 1 other digit)	☐	☐
g. Modified Ashworth wrist and fingers ≤ 2 and considered to have consistent hand opening/closing with SaeboGlove on to enable grasp/release despite tone present	☐	☐

Name of Assessor _____ Signature _____ Date _____

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

CONFIRMATION OF STUDY ELIGIBILITY

	No	Yes
9. Is the patient able to comply with the requirements of the protocol (e.g. participate in outcome assessments, questionnaires +/- help from proxy, independent SaeboGlove therapy +/- help of willing carer, medically stable, cognitively and psychologically capable)	☐	☐

Qu 10 below only needs to be answered for patient needing help to carryout SaeboGlove therapy:

10. For patients requiring help to put a SaeboGlove on and / or carryout SaeboGlove therapy, are they able to arrange a willing helper?	☐	☐

If the answer is NO to any of questions 1-10, the patient is NOT eligible to participate in the trial.

11. Does patient have other significant impairment of the upper limb affected by stroke e.g. fixed contracture, frozen shoulder, severe arthritis, fracture within 6 months?	☐	☐
12. Does the patient have any diagnosis likely to make rehabilitation or study outcome assessments/questionnaires too difficult? e.g. registered blind or terminally ill	☐	☐
13. Does patient have swelling in their paretic upper limb considered severe enough to cause discomfort when glove is worn?	☐	☐
14. Is the patient currently participating in another intervention trial?	☐	☐

The answer must be NO to all of questions 11-14. If the answer is YES to any of questions 11-14, the patient is NOT eligible to participate in the trial.

If the patient remains eligible for the trial continue to page 8 to complete the baseline assessment below.

Name of Assessor _____ Signature _____ Date _____

SUSHI Trial

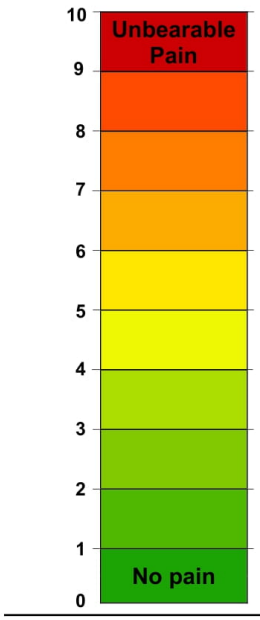
Patient ID Number ☐☐☐☐☐

Baseline Assessment

TO BE COMPLETED BY THE PATIENT PRIOR TO STARTING THERAPY:

Upper Arm Pain (shoulder to just proximal to olecranon of elbow)

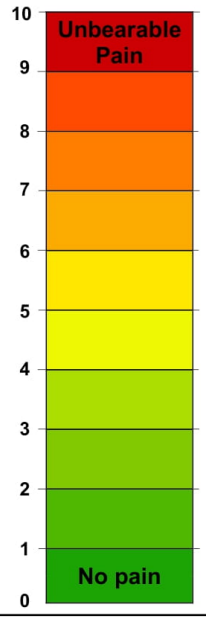
Please draw a line on the following scale, to indicate where the intensity of your upper arm pain is represented best **on average** over the last 1 week.



☐

Lower Arm Pain (elbow to finger tips)

Please draw a line on the following scale, to indicate where the intensity of your lower arm pain is represented best **on average** over the last 1 week.



☐

Please enter VAS Score in boxes provided

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SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

Please ask for details of any current upper limb rehabilitation treatments being received by the patient.

Treatment	**Yes**	**No**	**Unknown**
Physiotherapy/ occupational therapy	☐	☐	☐
Splints	☐	☐	☐
Shoulder sling	☐	☐	☐
TENS	☐	☐	☐
Antispasticity medication (e.g. Dantrolene, Baclofen, Tizanidine)	☐	☐	☐
Botulinum toxin If yes, date of last injection: ☐☐/☐☐/☐☐☐☐	☐	☐	☐
Other upper limb rehabilitation If other please give details: …… ……	☐	☐	☐

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

FUGL-MEYER - MOTOR

Please consult the SUSHI assessment manual for full instructions on how to complete the Fugl- Meyer Motor and Sensory Scale.

Passively move the patient's arm through the range of motion specified + CIRCLE the score that applies

a) Passive joint motion - Score passive range of joint motion

		only few degrees of range-of-motion	decreased passive range-of-motion	normal passive range-of-motion	
Shoulder	Flexion	0	1	2	
	abduction to 90 °	0	1	2	
	outward rotation	0	1	2	
	inward rotation	0	1	2	
Elbow	Flexion	0	1	2	
	Extension	0	1	2	
Forearm	Pronation	0	1	2	
	Supination	0	1	2	
Wrist	Flexion	0	1	2	
	extension	0	1	2	
Fingers	flexion	0	1	2	
	extension	0	1	2	**/24**

SUSHI Trial

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Baseline Assessment

b) Joint pain

Suggested instructions: *'Please tell me whether you feel any pain'*
Notes: Score occurrence of joint pain

		pronounced pain during all the movement or very marked pain at the end of the actual range of motion	some pain	no pain	
Shoulder	flexion	0	1	2	
	abduction to 90 °	0	1	2	
	outward rotation	0	1	2	
	inward rotation	0	1	2	
Elbow	flexion	0	1	2	
	extension	0	1	2	
Forearm	pronation	0	1	2	
	supination	0	1	2	
Wrist	flexion	0	1	2	
	extension	0	1	2	
Fingers	flexion	0	1	2	
	extension	0	1	2	**/24**
		TOTAL RANGE OF MOTION AND JOINT PAIN, UPPER LIMB			___/48

I REFLEX-ACTIVITY (patient sitting, verbalise the findings)

Use a tendon hammer to assess reflex-activity in the biceps, triceps and finger flexors

	no reflex-activity	reflex-activity in biceps or finger flexors	
Biceps or finger flexors	0	2	
	no reflex-activity	reflex-activity in triceps	
Triceps	0	2	**/4**

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

You must demonstrate each movement then instruct the participant to complete that movement with the unaffected arm first to ensure that the participant understands the movement. During demonstrations you should sit opposite the participant. Patients can be assisted into the starting position for each movement but must be able to maintain that position independently after being placed/released in tasks where the starting position is essential to score > 0 (Green + Red). Patients should be given the opportunity to demonstrate the best possible performance over 3 attempts. More that 3 attempts are ONLY permitted if it is clear that a participant has not understood the assessors instructions. Complete each task separately with a clear interval (approx. 3 seconds) between tasks (except the "finger flexion" and "finger extension" task, which may be linked).

IMPORTANT - Tasks in:

Black – precision of start position does not affect score (for reproduction only)

Green – perfect start position must be achieved or automatically score zero

Red – perfect start position must be achieved + maintained throughout desired action or automatically score zero

II ACTIVE MOVEMENTS IN SYNERGIES (patient sitting with the back against the backrest)

a) Flexor synergy: (hand to ipsilateral ear with shoulder retraction)

Suggested instructions: 'Rest your hand on your knee on that side. Now l*ift your hand to your ear as if you are answering the telephone…turn your palm fully to face behind you, lift your elbow as high as your shoulder and move your elbow back so that it is in line with (not in front of your) body.'*
Notes: Assessor may need to hold the shoulder down to ensure true abduction is seen, not compensatory shoulder blade (girdle) elevation.

		none	partial	perfect	
Forearm	supination	0	1	2	
Elbow	flexion:	0	1	2	
Shoulder	outward rotation	0	1	2	
	abduction (90˚)	0	1	2	
	elevation	0	1	2	
	retraction	0	1	2	

b) Extensor synergy: (knuckles to opposite knee from flexor synergy.)

Suggested instructions: *'Please can you move your hand back to your ear as you did a minute ago. From your ear reach to touch your opposite knee with your knuckles…make sure your elbow is fully straight and that your palm is facing forwards'*
Notes: Assessor may need to secure shoulders to ensure true adduction is seen, not compensatory trunk rotation.

		none	partial	perfect	
Forearm	pronation	0	1	2	
Elbow	extension	0	1	2	
Shoulder	adduction and internal rotation	0	1	2	/18

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

III DYN. FLEXOR+EXTENSOR SYNERGY (patient sitting)			
a) Hand to lumbar spine (place hand against low back in the midline) Suggested instructions *'Slide your bottom to the front of your chair. Now keep your body upright while you take your hand from your lap to touch the bottom of your back with the back of your hand.'* Notes: Assessor holds body vertical at shoulders as needed to prevent compensatory hip flexion/trunk rotation.			
hand not behind ant. sup. iliac spine with body upright 0	hand behind ant. sup. iliac spine with body upright 1	perfect 2	
b) Shoulder flexion 0° to 90° elbow extended, (forearm in mid-position) . Suggested instructions: *'Make your elbow poker straight and keep it poker straight [This is the required starting position]. Now lift your arm up in front, not in front and to the side, with your thumb pointing towards the ceiling'*			
Starting position impossible +/or arm immediately abducts to side or elbow flexes immediately (forearm not scored) 0	Starting position possible but arm abducts +/ or elbow flexes but not immediately or shoulder flexion is only partial (forearm not scored) 1	Perfect (forearm not scored) 2	
c) Pro-Supination of the forearm elbow flexed 90°, shoulder 0° in all planes Suggested instructions: *'Tuck your elbow into your ribs, keep your forearm level and keep your forearm pointing straight forward, not pointing diagonally inwards [This is the required starting position]. Now keep this position while you rotate your palm fully to the floor and then fully towards the ceiling'*			
starting position impossible +/or not maintained during the movement or no pro-supination 0	starting position possible and maintained during the movement but limited pro- supination 1	perfect 2	/6

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

IV ACTIVE MOVEMENT, WITH LITTLE OR NO SYNERGY (patient sitting)

a) *Shoulder abduction 0° to 90°* elbow fully extended and forearm pronated

Suggested instructions: *'Make your elbow poker straight and keep it poker straight. Turn your palm side on, not facing backwards or forward [This is the required starting position]. Now keep this elbow and palm position while you lift your arm out to the side (not to the side and in front) so that your hand is level with your shoulder.'*

starting position impossible +/or arm immediately supinates +/or elbow flexes immediately	starting position possible but arm supinates +/or elbow flexes but not immediately or shoulder abduction is only partial	perfect	
0	1	2	

b) *Shoulder flexion 90° to 180°* arm in 0° abduction, elbow extended (and forearm in mid-position)

Suggested instructions: "Lift your hand so it is as high as your shoulder. In this position make your elbow poker straight. Now keep your hand as high as your shoulder and keep your elbow straight [This is the starting position]. Now turn your palm side on / thumb up and keep your elbow poker straight, lifting your arm fully forwards towards the ceiling, not forwards and to the side"

starting position impossible +/or arm immediately abducts to side or elbow flexes immediately (forearm not score)	starting position possible but arm abducts +/or elbow flexes but not immediately or shoulder flexion is only partial (forearm not scored)	perfect (forearm not scored	
0	1	2	

c) *Pro-Supination of the forearm* shoulder 30° - 90° flexion, elbow in extension

Suggested instructions: "Lift your arm up in front of you, below shoulder height. Now make your *elbow poker straight and keep it poker straight* [This is the starting position]. *Keeping this height and your elbow poker straight move your palm fully to the floor and then fully towards the ceiling'*

Notes: Score against the passive ROM, don´t mistake the rotation of the glenohumeral joint.

starting position impossible +/or not maintained during the movement or no pro-sup	starting position possible and maintained during the movement but limited pro-sup	perfect	
0	1	2	/6

V NORMAL REFLEX-ACTIVITIES - Only assessed if in the previous section total score = 6

not assessed (because score of B. IV < 6)	assessed: ≥ 2 of 3 reflex-activities are markedly hyperactive	assessed: 1 reflex markedly hyperactive or ≥ 2 lively	assessed: no hyperactive reflexes	
0	0	1	2	/2

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Baseline Assessment

For this wrist section of the Fugl-Meyer participants must be able to achieve and maintain the starting position throughout each action requested with or without the support of a flat hand under the proximal forearm.

a) Wrist stability in 15° wrist extension shoulder 0°, elbow 90°, forearm pronated

Suggested instructions: *'Tuck your elbow into your waist, keep your forearm level and point your forearm forward, not diagonally. Turn your palm towards the floor. Now lift your knuckles up slightly to bend your wrist [This is the starting position]. Now keep this elbow, forearm and wrist position while I push your hand down lightly (between the crease of your hand and the knuckles).*
Notes: Resistance applied only if patient can reach starting position.

Starting position impossible +/or not maintained during resistance or wrist extension to required position not possible	Starting position possible + maintained during resistance but wrist extension not maintained against some (slight) resistance	Starting position possible + maintained during resistance and wrist extension maintained against some (slight) resistance	
0	1	2	

b) Repeated maximum wrist flexion – extension shoulder in 0°, elbow 90°, forearm pronated

Suggested instructions: *'Tuck your elbow into your waist, keep your forearm level and point your forearm forward, not diagonally. Turn your palm towards the floor* [This is the starting position]. *Now keep this elbow, forearm and wrist position while you lift your knuckles fully above your forearm and lower your knuckles fully below your forearm repeatedly."*

Starting position impossible +/or not maintained during the movement or no active repeated movements	Starting position possible + maintained during movement but active movements smaller than passive movements	Starting position possible + maintained during movement and active movements equal passive movements	
0	1	2	

c) Wrist stability in 15° wrist extension shoulder slightly flexed and/or abducted, elbow extended, forearm pronated

Suggested instructions: *'Keep your elbow straight with your arm in front and turn your palm towards the floor. Now lift your knuckles up slightly to bend your wrist [This is the starting position]. Now keep this elbow, forearm and wrist position while I push your hand down lightly (between the crease of your hand and the knuckles).*
Notes: Resistance applied only if patient can reach starting position.

Starting position impossible +/or not maintained during resistance or wrist extension to required position not possible	Starting position possible + maintained during resistance but wrist extension not maintained against some (slight) resistance	Starting position possible + maintained during resistance and wrist extension maintained against some (slight) resistance	
0	1	2	

d) Repeated max. wrist flexion – extension shoulder slightly flexed and/or abducted, elbow extended, forearm pronated

Suggested instructions: *'Put your arm out in front of you, make your elbow fully straight and turn your palm towards the floor* [This is the starting position]. Now keep this elbow, forearm and palm position *while you lift your knuckles fully above your forearm and lower your knuckles fully below your forearm repeatedly."*

Starting position impossible +/or not maintained during the movement or no active repeated movements	Starting position possible + maintained during movement but active movements smaller than passive movements	Starting position possible + maintained during movement and active movements equal passive movements	
0	1	2	

e) Circumduction of the wrist shoulder 0°, elbow 90°.

Suggested instructions: : *'Tuck your elbow into your waist, keep your forearm level and point your forearm forward, not diagonally* [This is the starting position]. *Now keep this elbow and forearm position and try to keep your palm facing the floor while you make a small circle with your wrist as if you are drawing an orange'*

Starting position impossible +/or not maintained during the movement or no active circumduction in any direction	Starting position possible + maintained during movement but active movements smaller than passive movements	Starting position possible + maintained during movement and active movements equal passive movements	
0	1	2	**/10**

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

FUGL-MEYER - COORDINATION

E. COORDINATION/ SPEED **(no compensation of trunk - head allowed)**

Finger-to-nose test: eyes closed, starting position is index tip (or if unable index knuckle ie MCP) on affected knee

Suggested instructions: *'Close your eyes and put your index finger tip/knuckle on your knee (same side). When I say "go" move your index finger from your knee to the tip of your nose as fast as you can 5 times like this (demonstrate)".*
We will start with your unaffected arm and then do the same with your affected arm. Keep your eyes closed'
Notes: Time both the unaffected and affected arms. Use the difference in time for c)
If the patient cannot assume the starting position the score will be 0 for all subtests.

TIME: Right_____secs Left_____secs

	marked	slight	no	
a) Tremor	0	1	2	
	pronounced or unsystematic	slight and systematic	no	
b) Dysmetria	0	1	2	
	> 6 sec	2-5 sec	< 2 sec	
c) Time	0	1	2	/6
	TOTAL MOTOR FUNCTION, UPPER LIMB (SECTIONS B, C, D AND E)			___/66

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

FUGL-MEYER - SENSORY

a) Light touch

Suggested instructions: *'Please keep your eyes closed. I am going to lightly run my fingers over your arms and hand, please tell me what you feel.'*
Notes: Ask the patient whether she/he feels that light touch on both arms and whether the palmar surface of the hands gave the same qualitative and quantitative impression.

	anaesthesia	hypaesthesia, dysaesthesia	normaesthesia	
volar side of the forearm	0	1	2	/4
palmar surface of the hand	0	1	2	

b) Position sense of the joints

Suggested instructions: *'Please keep your eyes closed. I am going to move your affected arm gently. Please can you tell me which direction each part of your body has been moved. If you are finding this difficult please put your unaffected arm into the same position as I have put your affected arm.'*
Notes: Score position sense of the joints as follows:

	absence of sensation	considerable difference compared with the joint on the unaffected side, but at least ¾ of the answers correct	all answers correct, little or no difference comparing unaffected with affected limb	
thumb (interphalangeal joint)	0	1	2	
wrist	0	1	2	
elbow	0	1	2	/8
glenohumeral joint	0	1	2	
	TOTAL SENSATION, UPPER LIMB			**___/12**

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SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

Modified Rankin Scale

Remember:

- Score according to how patient is functioning and not what you think they are capable of
- If in any doubt score upper possibility i.e. score with greater disability

Please tick correct score using discriminators of scale below as needed:

☐ 0 = No symptoms at all

☐ 1 = No significant disability despite symptoms; able to carry out all usual duties and activities

☐ 2 = Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance

☐ 3 = Moderate disability; requiring some help, but able to walk without assistance

☐ 4 = Moderately severe disability; unable to walk without assistance, and unable to attend to own bodily needs without assistance

☐ 5 = Severe disability: bedridden, incontinent, and requiring constant nursing care and attention

Discriminators of scale:

Remaining symptoms	≥ 1, not 0
Inability to do all previous activities	≥ 2, not 1
Dependence on others in ADL for ANY help (can be left on own for wk)	≥ 3, not 2
Inability to walk without assistance (can be left on own for few hrs)	≥ 4, not 3
Bedridden requiring constant nursing care (24hr care)	≥ 5, not 4

Modified Rankin Scale 0-5 reproduced with copyright permission from van Swieten, J.C., Koudstaal, P.J., Visser, M.C., Schouten, H.J. and van Gijn, J. (1988) 'Interobserver agreement for the assessment of handicap in stroke patients', Stroke, 19(5), 604-7, available: http://dx.doi.org/10.1161/01.str.19.5.604.

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

Motor Activity Log (MAL)

How well scale

0 – The weaker arm was not used at all for that activity (never)

1 – The weaker arm was moved during that activity, but was not very helpful (very poor)

2 – The weaker arm was of some use during that activity, but needed some help from the stronger arm, moved very slowly, or with difficulty (poor)

3 – The weaker arm was used for the purpose indicated, but movements were slow or were made only with some effort (fair)

4 – The movements made by the weaker arm were almost normal, but not quite as fast or accurate as normal (almost normal)

5 – The ability to use the weaker arm for that activity was as well as before the stroke

Amount scale

0 – Did not use my weak arm (not used)

1 – Occasionally tried to use my weaker arm (very rarely)

2 – Sometimes used my affected arm, but did most of the activity with my stronger arm (rarely)

3 – Used my weaker arm about half as much as before the stroke (half prestroke)

4 – Used my weaker arm almost as much as before the stroke (3/4 prestroke)

5 – Used my weaker arm as much as before the stroke (same as prestroke)

When zero if scored in these scales please record why it is zero using the following codes:

- "I used the unaffected arm entirely." (assign "**0**").
- "Someone else did it for me." (assign "**0**").
- "I never do that activity, with or without help from someone else because it is impossible." For example, combing hair for people who are bald. (assign "**N/A**" and drop from list of items).
- "I sometimes do that activity, but did not have the opportunity since the last time I answered these questions." (**carry-over last assigned number for that activity**).
- Unilateral task only requiring dominant hand only, non-dominant hand hemiparesis. (only applicable to number 7; assign "**N/A**" and drop from list of items).

MAL how well/amount scales reproduced with copyright permission from swatte, G., Taub, E., Morris, D., Vignolo, M. and McCulloch, K. (2005) 'Reliability and Validity of the Upper-Extremity Motor Activity Log-14 for Measuring Real-World Arm Use', *Stroke*, 36(11), 2493-2496, available: http://dx.doi.org/10.1161/01.STR.0000185928.90848.2e.

Codes for recording "zero" responses reproduced with copyright permission from Taub, E., McCulloch, K., Uswatte, G. and Morris, D. (2011) *Motor Activity Log [Manual].* available: https://www.uab.edu/citherapy/images/pdf_files/CIT_Training_MAL_manual.pdf.



SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

"Considering your activities during the past week, did you use your weaker arm to…

1 Hold a book for reading

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

2 Use a towel to dry your face or other part of your body

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

3 Pick up a glass

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

4 Pick up a toothbrush and brush teeth

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

5 Put on makeup/shave

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____



6 Use a key to open door

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

---

7 Write on paper

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

---

8 Steady yourself when standing

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

---

9 Put arm through sleeve of clothing

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

---

10 Carry an object from place to place

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____



SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

11 Pick up fork and spoon and use for eating

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

12 Comb hair

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

13 Pick up cup by handle

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

14 Tie and untie buttons

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

15 Open a bottle or jar

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

16 Tie laces

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

17 Handcraft/card playing/hobbies

☐ Yes
____ Amount.
____ How Well

☐ No, If score "0" above use codes to record why _____

Copyright information: Adapted from Taub, E., Miller, N. E., Novack, T. A., Cook, E. W., Fleming, W. C., Nepomuceno, C. S., et al. (1993). Technique to improve chronic motor deficit after stroke. *Archives of Physical Medicine Rehabilitation, 74*, 347–354.

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

BARTHEL ACTIVITIES OF DAILY LIVING INDEX

Please consult the SUSHI assessment manual for instructions on how to complete the Barthel ADL Index.

Function	Description	Score	
Bowels	Incontinent (or needs to be given enema) Occasional accidence (once a week) Continent	0 1 2	☐
Bladder	Incontinent, or catheterised and unable to manage Occasional accident (max. once per 24 hours) Continent (for over 7 days)	0 1 2	☐
Grooming	Needs help with personal care Independent face/hair/teeth/shaving (implements provided)	0 1	☐
Toilet Use	Dependent Needs some help but can do some things alone Independent (on and off, dressing, wiping)	0 1 2	☐
Feeding	Unable Needs help in cutting, spreading butter etc. Independent (food provided in reach)	0 1 2	☐
Transfer	Unable - no sitting balance Major help (1 or 2 people, physical), can sit Minor help (verbal or physical) Independent	0 1 2 3	☐
Mobility	Immobile Wheelchair independent, including corners etc. Walks with help of one person (verbal or physical) Independent (but may use aid e.g. stick)	0 1 2 3	☐
Dressing	Dependent Needs help but can do about half unaided Independent (including buttons, zips, laces etc.)	0 1 2	☐
Stairs	Unable Needs help (verbal, physical, carrying aid) Independent up and down	0 1 2	☐
Bathing	Dependent Independent (Bath: must get in and out unsupervised and wash self. Shower: unsupervised/unaided)	0 1	☐
Total (0-20)			☐

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SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

EQ-5D-5L

EQ-5D-5L

Health Questionnaire

English version for the UK

Sample

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SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

Sample

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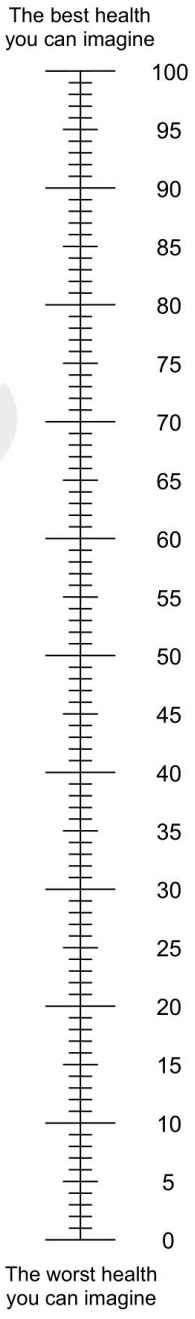
SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Please mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Sample

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SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

ABOUT YOUR STROKE

Stroke Impact Scale

(UK English version of SIS)

Access to the SIS 3.0 can be requested via ePROVIDE™ - Online Support for Clinical Outcome Assessments (mapi-trust.org)

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Baseline Assessment

The baseline assessment is complete. Please now complete the following tasks:

Task	**Tick when complete**
Randomise the patient ≤ 1 working day	
Enter participant's study ID number here: ☐☐☐☐☐	
Advise the participant about which study group they have been allocated to and explain therapy log book	
Give participant a therapy box + a Hand and Arm Therapy Booklet (ensure you complete the participant study ID on the front cover)	
Make necessary study treatment appointments and transport arrangements	
Give usual care record CRF to clinical OT	
Give usual care record CRF to clinical PT	
Give upper limb therapy reviews CRF to OT/PT	
Add the participant to the SUSHI enrolment log	
Send the GP letter	
Enter this participant's screening and baseline data on to the study electronic database	
File this participant's screening and baseline paper records in your investigator site file	
File this participant's consent form in your investigator site file. Ensure copies are:	
- Given to the patient	
- Filed/scanned in their casenotes	
- Sent to the patient's GP	

Assessment manual

SaeboGlove therapy for severe Upper limb disability and Severe Hand Impairment after Stroke



ASSESSMENT MANUAL

Stroke Research Dept,
QEUH, Glasgow

Principal Investigator:	**Professor Jesse Dawson**
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1. PURPOSE OF THIS DOCUMENT

This document describes how to conduct some of the SUSHI research assessments. Included are those where assistance and/or reminders may be useful for administration and scoring. It is intended to serve as a reference and resource guide for clinicians doing assessments for SUSHI. It should be used in conjunction with the SUSHI assessment forms. All clinicians performing SUSHI assessments should also have received appropriate training.

2. GENERAL INSTRUCTIONS FOR COMPLETING SUSHI ASSESSMENT PAPERWORK

Please write clearly using a black ballpoint pen.
Always make sure that the "YES/NO" square box answers are completed with a tick.

Errors
If an error needs to be rectified after the forms have been completed:
1. Draw a single line through the error, do not obscure the original entry
2. Enter the correct data beside
3. Initial and date the change and add a comment if necessary
4. Never use correction fluids.

Missing Data
Please do not leave blank boxes where a response is expected.

If data is missing the following should apply:
1. **ND** (for not done) should be entered into the field for all tests and examinations which should have been carried out but were omitted.
2. **NA** (for not applicable) should be entered into the field for missing data if a question does not apply to a participant status.
3. **NK** (for not known) should be entered when historical information, such as dates of onset of medical conditions is not known/not available.

Dates
Please record dates as follows: DD/MM/YYYY.
If part of a date is unknown, please complete the corresponding boxes with NK.
N.B: The **date is very important** and may help to ID the participant if an incorrect participant ID is entered by mistake.

Participant Identification
Please complete the header of all pages with the participants ID. The first two boxes represent the specific ID for the recruiting site and the last three boxes represent the number given to a participant on randomisation.

3. ACTION RESEARCH ARM TEST (ARAT)

The Action Research Arm Test is the primary outcome measure for the SUSHI study. It measures upper limb function. The test is performed immediately before study entry (screening) and at 6 and 14 weeks after study entry.

The following instructions describe how to perform the ARAT. They have been adapted from Platz, T., Pinkowski, C., van Wijck, F. & Johnson, G. 2005. *ARM Arm Rehabilitation Measurement: Manual for performance and scoring* and documentation provided by Professor F van Wijck.

4. BARTHEL ACTIVITIES OF DAILY LIVING INDEX

The Barthel Activities of Daily Living Index is a secondary outcome measure for SUSHI.

These administration and scoring instructions have been reproduced from Collin, C., Wade, D. T., Davies, S., Horne, V., *The Barthel ADL Index: a reliability study.* International disability studies, 1988. **10**(2): p. 61-3.

General Instructions:

- The Barthel Index should be used as a record of **what the participant does NOT as a record of what a participant could do**.
- The main aim is to establish degree of independence from **any help, physical or verbal**, however minor and for whatever reason.
- The need for **supervision** renders the participant **NOT independent**
- A participant's performance should be established using the best available evidence.
- The performance over the preceding **24-48 hours** is important.
- **Middle categories** imply that the participant **supplies over 50% of the effort**.
- **Use of aids to be independent is allowed** and should not in itself negatively affect scoring.

Bowels (preceding week)

If needs enema then 'incontinent'
Occasional accident = once a week

Bladder (preceding week)

Occasional accident = less than once a day
A catheterised participant who can completely manage the catheter alone is registered as 'continent'

Grooming (preceding 24-48 hours)

Refers to personal hygiene: doing teeth, fitting false teeth, doing hair, shaving, washing face. Implements can be provided by helper.

Toilet Use

Should be able to reach toilet/ commode, undress sufficiently, clean self, dress and leave.
With help = can wipe self, and do some other of above.

Feeding

Able to eat and normal food (not only soft food). Food cooked and served by others but not cut up.
Help = food cut up, participant feeds self.

Transfer

From bed to chair and back
Dependent = NO sitting balance (unable to sit); to people to lift
Major help = one strong/skilled, or two normal people. Can sit up.
Minor help = one person easily, OR needs any supervision for safety

Mobility

Refers to mobility about house or ward, indoors. May use aid. If in wheelchair, must negotiate corners/doors unaided.
Help = by one, untrained person including supervision/moral support

Dressing

Should be able to select and pull on clothes which may be adapted.
Half = help with buttons, zips etc (check), but can put on garments alone.

Stairs

Must carry any walking aid used to be independent

Bathing

Usually the most difficult activity.
Must get in and out unsupervised and wash self.
Independent in shower = 'independent' if unsupervised/unaided.

Reprinted with permission of Taylor and Francis from Collin, C., Wade, D.T., Davies, S. and Horne, V. (1988) 'The Barthel ADL Index: A reliability study', International Disability Studies, 10(2), 61-63, available: http://dx.doi.org/10.3109/09638288809164103.

5. FUGL-MEYER MOTOR AND SENSORY SCALE (ARM SECTION)

The Fugl-Meyer motor and sensory scale (arm section) is a secondary outcome measure for SUSHI.

The following instructions describe how to perform the Fugl-Meyer. They have been adapted from Platz, T., Pinkowski, C., van Wijck, F. & Johnson, G. 2005. *ARM Arm Rehabilitation Measurement: Manual for performance and scoring* and documentation provided by Professor F van Wijck.

6. MOTOR ACTIVITY LOG (MAL)

Instructions

1. **Read this to participants**

"The **purpose** of this test is to examine how much and how well you use your more-affected arm when you are not in our laboratory. You will use **two <u>different</u> rating scales** to describe **how much** and **how well** you use your weaker arm while you are doing specific activities. **If for some reason, you do not perform these tasks, we will try to determine why.** We will **first discuss how much** you do each of the activities with your weaker arm and **then we will discuss how well** you do them when using your weaker arm. It is important that you realize that **these questions are about what you <u>actually</u> do** in everyday life outwith your therapy – not what you think you may be able to do with your weaker arm. There are **no right or wrong answers**; simply select the ratings you believe best describes what you do. Please understand that I must follow a script with this procedure. Do you have any questions?"

Assessors please remember to keep participants orientated by reminding them for each task:

1. How affected arm would be used in task prestroke
2. Time frame we are interested in
3. Interested in affected arm only
4. Specific Task interested in

2. **Read this to participants**

"Considering your activities during the **<u>past week (pre-treatment)</u>** / **<u>since the last time I asked you these questions (post-treatment)</u>**, did you use your weaker arm to… (state the activity)?"

If no, then ask why and direct the participant to the list of possible reasons why the arm was not used. For scoring on the recording form, use the codes at the bottom of the score sheet (A-E) to categorize the participant's response. It is desirable to have these codes printed on a separate sheet so that it is easy for the participant to make a selection.

If Yes, proceed to Amount rating / How well rating:

Amount Rating: Ask the participant:

HIGHLIGHT TRADITIONAL ROLE OF AFFECTED UL IN TASK AND ENCOURAGE PARTICIPANT TO CONSIDER HOW MUCH OF TASK THEIR AFFECTED UL IS NOW INVOLVED IN IT AND HOW FREQUENTLY THEY ATTEMPT TO CARRY OUT THE TASK USING THEIR AFFECTED UL. "Using the Amount Rating Scale, tell me how you would **rate the amount you used your weaker arm** to… (state the activity)."

Verify participants response by repeating the selected rating in the following manner; " **So, you believe that you (read the description of the selected Amount Scale rating) – Is that correct?"** When verifying the descriptor, at a minimum, repeat the abbreviated descriptor in the parentheses **(e.g., half prestroke).**

Probe the participants response (not applicable on first scoring / pre-treatment). Refer back to the scores of the immediately previous test administered to confirm that there has been a change. That score sheet should be out of view of the subject. If a rating change occurs (increase or decrease), the tester should probe the response using the following questions:

1. "Today, you rated this activity… (state either "higher" or "lower" - whichever is accurate) than during the last test when you gave it a (repeat the previous score)." "Why is that?" or "Does this represent a real change?"
2. "So, now that you have thought about it more, how would you rate it?" "So, you believe that the rating should be… (read the specified rating). Is that accurate?" If Yes, record the answer and go to the next question. If No, ask "Why?" and clarify.
3. "So, you believe that the rating should be… (read the specified rating). Is that accurate?" If Yes, record the answer and go to the next question. If No, ask "Why?" and go back to question 2 – just above.

How Well Rating:

Emphasize the difference between the AS and HW scales: “Remember that I am asking you to rate something different on this scale, the How Well Scale, than you did before on the Amount Scale. Before you were supposed to rate how much you used your more-affected arm. Now I would like you to rate how well you used your more-affected arm, if you did use it. For example, you might have used your more-affected hand to pick up a glass and drink only rarely. The Amount rating might therefore be a 1.5 or 2. However, when you did use it, your use of the hand was really quite good: let us say between fair and almost normal, or a 3.5. Is the difference between the two types of ratings I am asking you to make clear?" Go over this several times if necessary and have the person verbalize the difference between the two types of ratings to make sure they understand it.

Ask the subject: HIGHLIGHT TRADITIONAL ROLE OF AFFECTED UL IN TASK AND ENCOURAGE TO CONSIDER HOW WELL AFFECTED UL PERFORMED CONSIDERING ITS USUAL PURPOSE. “Using the How Well Rating Scale, tell me how you would **rate how well you used your weaker arm to**… (state the activity)”

Verify – as above but for how well scale

N.B. For How well scale at pre-treatment assessment only – ask participants to demonstrate a number of activities (at least the first six activities) to allow the tester to get an idea of the subject's general frame of reference. During the pre-treatment administration, demonstration of the performance of an activity should also be requested whenever the tester is unsure of what the participant means by a rating. The demonstration should be carried out after the participant attempts to rate the activity and only when using the HW rating scale.

Observation of the pantomime of an activity allows the tester an opportunity to discuss the participant 's HW rating in order to set an agreed-upon rating frame of reference. Since this process should increase the likelihood that the participant understands the intended motor referent or meaning of the HW rating scale, it should increase the comparability of results across participants.

The tester need not have the participant demonstrate every item on the MAL if in their opinion the HW rating is consistent with the performance previously demonstrated on a similar task (e.g., opening a refrigerator and opening a door by turning a door knob/ handle).

If obvious discrepancies exist between what is observed and the rating provided, the tester should discuss the rating with the participant to develop a common frame of reference (i.e., “You rated that activity a "5". However, you moved your arm very slowly to do the activity. So, for this project that would be more like a "2". Do you agree?"). The final rating is determined by the participant.

Probe – as above but for how well scale

Amount scale

0 – Did not use my weak arm (not used)

1 – **Occasionally** tried to use my weaker arm (very rarely) **i.e. Unaffected dominates in task execution**

2 – **Sometimes** used my affected arm, but **did most of the activity with my stronger arm** (rarely)

3 – Used my weaker arm about half as much as before the stroke (half prestroke)

4 – Used my weaker arm almost as much as before the stroke (3/4 prestroke)

5 – Used my weaker arm as much as before the stroke (same as prestroke)

How well scale

0 – The weaker arm was not used at all for that activity (never)

1 – The **weaker arm** was moved during that activity, but was **not very helpful** (very poor) **i.e. Unaffected dominates in task execution**

2 – The **weaker arm was of some use** during that activity, but **needed some help from the stronger arm**, moved very slowly, or with difficulty (poor)

3 – The weaker arm was used for the **purpose indicated**, but movements were slow or were made only with some effort (fair)

4 – The movements made by the weaker arm were almost normal, but not quite as fast or accurate as normal (almost normal)

5 – The ability to use the weaker arm for that activity was as well as before the stroke

When zero if scored in these scales please record why it is zero using the following codes:

A - "I used the unaffected arm entirely." (data entry: assign "**0**").

B - "Someone else did it for me." (data entry: assign "**0**").

C - "I never do that activity, with or without help from someone else because it is impossible (pre-stroke)." For example, combing hair for people who are bald. (data entry: assign "**N/A**" and drop from list ofitems).

D - "I sometimes do that activity, but did not have the opportunity since the last time I answered these questions." (data entry: **carry-over last assigned number for that activity, or if 1st time** assign **"0"**).

E - Unilateral task only requiring dominant hand only, non-dominant hand hemiparesis. (**only applicable to number 7) (**data entry: assign "**N/A**" and drop from list of items).

N.B. If A and B apply, record A only please

MAL how well/amount scales reproduced with copyright permission from the Copyright Clearance Center, available: Uswatte, G., Taub, E., Morris, D., Vignolo, M. and McCulloch, K. (2005) 'Reliability and Validity of the Upper-Extremity Motor Activity Log-14 for Measuring Real-World Arm Use', *Stroke*, 36(11), 2493-2496, http://dx.doi.org/10.1161/01.STR.0000185928.90848.2e.

Instructions, and codes (A-E) for recording "zero" responses reproduced with copyright permission from cas-cilab@uab.edu, available: Taub, E., McCulloch, K., Uswatte, G. and Morris, D. (2011) *Motor Activity Log [Manual].* https://www.uab.edu/citherapy/images/pdf_files/CIT_Training_MAL_manual.pdf.

MAL Summary

1. **Read Instructions to participant**

2. **Ask to consider activity of weak arm**
   - **over <u>past week (pre-treatment)</u>**
   - **<u>since the last time I asked you these questions (post-treatment)</u>**

3. **How MUCH Scale**

Did you use your weak arm over the past week / since the last time I asked you these questions?

No – Offer reason codes A-E

Yes, then:
Verify how much: "So you believe that you…..(read choice)?"
Probe (If not 1st time scored) ie if there has been a change since last time scored compare **highlight change** and say **"So you believe that you….(read choice), is that accurate?"**

4. **How WELL Scale**

Emphasize difference between 2 scales

"How would you rate how well you used your weak arm to …..?"

No – Offer reason codes A-E
Yes, then:
Verify how much: "So you believe that you…..(read choice)?" (1st time, can challenge discrepancies)

Probe (If not 1st time scored) ie if there has been a change since last time scored compare **highlight change** and say **"So you believe that you….(read choice), is that accurate?"**

7. MODIFIED RANKIN SCALE (mRS)

0 = No symptoms at all

1 = No significant disability despite symptoms; able to carry out all usual duties and activities

2 = Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance

3 = Moderate disability; requiring some help, but able to walk without assistance

4 = Moderately severe disability; unable to walk without assistance, and unable to attend to own bodily needs without assistance

5 = Severe disability: bedridden, incontinent, and requiring constant nursing care and attention

Modified Rankin Scale 0-5 reproduced with copyright permission from van Swieten, J.C., Koudstaal, P.J., Visser, M.C., Schouten, H.J. and van Gijn, J. (1988) 'Interobserver agreement for the assessment of handicap in stroke patients', Stroke, 19(5), 604-7, available: http://dx.doi.org/10.1161/01.str.19.5.604.

- scored according to how pt is functioning and not what you think they are capable of
- any doubt score upper possibility i.e. score with greater disability

Discriminators used:

Remaining symptoms	≥ 1, not 0
Inability to do all previous activities	≥ 2, not 1
Dependence on others in ADL for ANY help (can be left on **own for wk**)	≥ 3, not 2
Inability to walk without assistance (can be left on **own for few hrs**)	≥ 4, not 3
Bedridden requiring constant nursing care (24hr care)	≥ 5, not 4

N.B. If someone has new stroke symptoms (cognitive, visual, psychological (incl new fear), physical) which prevent them driving they must score ≥2. However, if they are not driving **purely** as they are legally not allowed to e.g. are < 4wks post stroke and are therefore routinely not legally allowed to drive this should not be considered an activity limitation. If they have been deemed to require a post stroke driving assessment by a HCP it should be considered an activity limitation.

8. VISUAL ANALOGUE SCALE (VAS)

In the SUSHI trial we are required to measure participants perceived pain intensity in their upper / lower arm **on average over the past week,** not just at that moment. To do this, please follow the instructions below.

Instructions:

Introduce scale:
"This is a scale we use to measure arm pain. It's measured on a scale from 0-10 where 0 is no pain and 10 is unbearable pain or the worst pain you can imagine."

Ask if had any pain over last week:
"If you think about your upper arm over the last 1 week (not before that) have you had any pain in your upper (lower) arm over the past week?"

If no, say "so on this scale where 0 is no pain and 10 is unbearable pain or the worst pain you can imagine, you would say your pain in your upper arm over the last 1 wk was 0, is that correct?" Assuming they agree, mark 0.

If yes, say "Has your pain been there constantly (very unlikely)? Assuming they say "No", say "so, what is the highest your pain has been over the last week? Pt answers. "..and has it been this high often?" Patient answers. "ok, so what has been the lowest your pain has been this week, has it been zero?" Patient answers. "And how often has it been this low / zero?"

Summarise and ask for answer:
Great, so considering that your pain has been between x and y (e.g. 0-4) this week and its mainly been z (e.g. 0 and only 4 briefly during occasional movements), if we look at the scale together, how would you rate the intensity of pain in your upper arm on average over the past week?

9. CONTACT DETAILS

Thank you for your contribution to the SUSHI trial.

Contact for further information:

If you have any queries or require further information about the SUSHI trial please contact:

Stroke Research Dept
ICAMS
QEUH
Glasgow
Tel: 0141 451 5870

Appendix I – RCT randomisation documents

Appointment sheet – Active group

Study Team: [Insert contact name, phone number, email and address]

STUDY APPOINTMENTS

Name: **Study ID:**
Address:

Tel:

Appointment	Day	Date	Time	Taxi Pick Up Time (if used)	Reminder
Screening					
Baseline					
Therapy 01					
Therapy 02					
Therapy 03					
Therapy 04					
6-week assessment					Return therapy box, glove + 1-6 wk booklet
14-week assessment					Return 7-14 wk therapy booklet
6-month assessment (by telephone)					

Appointment sheet – Control group

Study Team: [Insert contact name, phone number, email and address]

APPOINTMENTS

Name: **Study ID:**
Address:

Tel:

Appointment	Day	Date	Time	Taxi Pick Up Time (if used)	Reminder
Study Appointments					
Screening					
Baseline					
6-week assessment					Return therapy box + 1-6 wk booklet
14-week assessment					Return 7-14 wk therapy booklet
6-month assessment (by telephone)					
Optional Therapy Appointments					
Therapy 01					
Therapy 02					
Therapy 03					
Therapy 04					
Final appointment					Return SaeboGlove

Randomisation record instruction and record

SUSHI Trial Randomisation Record Instructions

****RANDOMISATION MUST BE PERFORMED WITHIN ONE WORKING DAY OF THE BASELINE ASSESSMENT****

Randomisation instructions:

1. Go to Randomisation website: **https://www.rcbweb.com/SUSHI_rand/**
2. Once at the site, enter your username and password then click "login"
3. Click "Randomisation" at top right of screen
4. Select "Site ID" for the site participant using drop down options offered
5. Enter 5 digit "Subject Number". The first two numbers are an identification number unique to the site the participant was recruited from e.g. 01 for the QEUH, the last 3 digits are the number allocated to the participant e.g. 001, 002 etc
6. Select "Event severity" – either **ARAT 0-10** or **ARAT 11-28** or **ARAT 29-46**
7. Select "Time since stroke" - either **≤ 1 month** or **> 1 month**
8. Confirm that patient meets randomization criteria by ticking the box offered
9. Click "Randomise Patient"
10. Complete a SUSHI Randomisation Record Form



SUSHI Trial

Site Number ☐☐

Randomisation Record

Randomisation Record

Please Complete the following details at randomization:

Subject Number: ☐☐☐☐☐

Treatment Group: Saebo Glove group ☐

Usual Care group ☐

Date Randomised: __ __ / __ __ / __ __ __ __

_____ _____ __ __ / __ __ / __ __ __ __

Name of person completing form (PRINT) Signature Date

Please Complete the following after randomization:

Participant advised of group allocation within 1 working day of randomisation:

Yes ☐ No ☐ If no, date advised: __ __ / __ __ / __ __ __ __

Advised by: Telephone ☐ Visit ☐

_____ _____ __ __ / __ __ / __ __ __ __

Name of person completing form (PRINT) Signature Date

Box letter

Thank you for your participation in the SUSHI trial.

You will soon be given a Hand and Arm Therapy Booklet to fill in during your participation in the trial. A staff member will phone you weekly to help you fill it in.

Please bring this therapy box and your Hand and Arm Therapy Booklet in the polly pocket provided to all your study visits.

Please do not discuss the contents of your box or the group you are placed in with SUSHI staff who are Outcome Assessors as this may influence the scores they give you during your assessments which will affect the study findings.

Thank you

Appendix J – RCT intervention documents

Usual care occupational therapy – Initial version

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Usual occupational therapy during trial

(1 per patient per day)

A. ALL OCCUPATIONAL THERAPY

1. Did participant get 45 mins of occupational therapy today (cognitive, perceptual, etc + upper limb)?
   Please tick as appropriate Yes ☐ No ☐

B. UPPER LIMB OCCUPATIONAL THERAPY

1. Usual **upper limb** occupational therapy interventions:

	Duration	No. of repetitions
Passive movements, positions and stretching	__ __ hrs __ __ mins	__ __ __
Active assisted movements with facilitation	__ __ hrs __ __ mins	__ __ __
"Hands-on" therapy (manual therapy techniques)	__ __ hrs __ __ mins	__ __ __
Strength training	__ __ hrs __ __ mins	__ __ __
Task-specific training (e.g. reach to grasp)	__ __ hrs __ __ mins	__ __ __
Repetitive task training	__ __ hrs __ __ mins	__ __ __
Bilateral arm training	__ __ hrs __ __ mins	__ __ __
Weight bearing on affected limb	__ __ hrs __ __ mins	__ __ __
Sensory interventions	__ __ hrs __ __ mins	__ __ __
Mirror Therapy	__ __ hrs __ __ mins	__ __ __
Electrical stimulation to improve motor control	__ __ hrs __ __ mins	__ __ __
Mental practice	__ __ hrs __ __ mins	__ __ __
Virtual reality (i.e. commercial video gaming)	__ __ hrs __ __ mins	__ __ __
Constraint-Induced Movement Therapy (CIMT)	__ __ hrs __ __ mins	__ __ __
Other **upper limb** intervention Please specify: _____	__ __ hrs __ __ mins	__ __ __

2. Was **upper limb** treatment session missed? Yes ☐ Please specify: _____
   No ☐

3. Usual **upper limb** occupational therapy ongoing?
   Yes ☐ No ☐ Date of discharge __ / __ / __ __ __ __

_____ _____ __ / __ / __ __ __ __
Name of person completing form (PRINT) Signature Date

Reproduced and adapted with permission of creator Robertson Centre for Biostatistics, University of Glasgow (Alex McConnachie)

Usual care physiotherapy – Initial version

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Usual physiotherapy during trial

(1 per patient per day)

A. ALL PHYSIOTHERAPY

1. Did participant get 45 mins of physiotherapy today (gait, balance etc + upper limb)?
   Please tick as appropriate Yes ☐ No ☐

B. UPPER LIMB PHYSIOTHERAPY

1. Usual **upper limb** physiotherapy interventions:

	Duration	No. of repetitions
Passive movements, positions and stretching	__ __ hrs __ __ mins	__ __ __
Active assisted movements with facilitation	__ __ hrs __ __ mins	__ __ __
"Hands-on" therapy (manual therapy techniques)	__ __ hrs __ __ mins	__ __ __
Strength training	__ __ hrs __ __ mins	__ __ __
Task-specific training (e.g. reach to grasp)	__ __ hrs __ __ mins	__ __ __
Repetitive task training	__ __ hrs __ __ mins	__ __ __
Bilateral arm training	__ __ hrs __ __ mins	__ __ __
Weight bearing on affected limb	__ __ hrs __ __ mins	__ __ __
Sensory interventions	__ __ hrs __ __ mins	__ __ __
Mirror Therapy	__ __ hrs __ __ mins	__ __ __
Electrical stimulation to improve motor control	__ __ hrs __ __ mins	__ __ __
Mental practice	__ __ hrs __ __ mins	__ __ __
Virtual reality (i.e. commercial video gaming)	__ __ hrs __ __ mins	__ __ __
Constraint-Induced Movement Therapy (CIMT)	__ __ hrs __ __ mins	__ __ __
Other **upper limb** intervention Please specify: _____	__ __ hrs __ __ mins	__ __ __

2. Was **upper limb** treatment session missed? Yes ☐ Please specify: _____
   No ☐

3. Usual upper limb physiotherapy ongoing?
   Yes ☐ No ☐ Date of discharge __ / __ / __ __ __ __

_____ _____ __ __ / __ __ / __ __ __ __
Name of person completing form (PRINT) Signature Date

Reproduced and adapted with permission of creator Robertson Centre for Biostatistics, University of Glasgow (Alex McConnachie)

SaeboGlove therapy review form

Therapy Reviews for SUSHI Trial



THERAPY REVIEW

1

Did review take place? Yes ☐ No ☐

If No, please specify _____

Review date: ☐☐/☐☐/☐☐☐☐

Reviewed by OT ☐ PT ☐

Did review take place during inpatient stay? Yes ☐ No ☐

Did review take place face-to-face? Yes ☐ No ☐

If not, please specify reason _____

Please indicate (tick one) who has been supporting participant with daily SaeboGlove therapy

☐ No one, participant independent with glove & exercises

☐ Informal carer e.g. friend, family

☐ Formal carer e.g. usual care clinical team

☐ Combination of informal and formal carer

Therapist (print name): _____

Therapist (sign name): _____

SUSHI Trial

Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

SaeboGlove Measuring Form

1. Affected Arm: L ☐ R ☐

2. Measure for splint + glove

To maximize comfort and fit, there are (4) measurements required (2 for the Wrist Splint and 2 for the Glove Liner). The four measurements will indicate the best possible size recommendation. Once you have determined the below measurements, use the chart overleaf to determine the appropriate recommended size.

STEP 1: WRIST SPLINT MEASUREMENTS:





Refer to the "Wrist Splint Sizing" chart on page 2 for final measurement.

A.) **Wrist Circumference:** measure wrist circumference just proximal to head of ulna: _____

B.) **Dorsal Hand Width:** measure dorsal hand width just proximal to MCPs (do not wrap tape down lateral or medial side of hand): _____

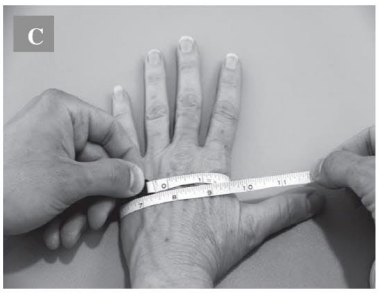
SUSHI Trial

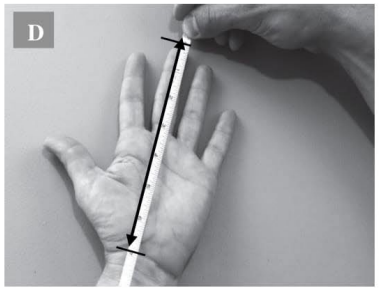
Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

STEP 2: GLOVE LINER MEASUREMENTS:

Refer to the "Glove Liner Sizing" chart below for final measurement.





C.) **Hand Circumference:** measure hand circumference by wrapping tape circumferentially around hand: _____

D.) **3rd Finger Length:** measure from tip of 3rd digit to the most distal wrist crease: _____

3. Selecting correct splint + glove size from sizing charts

Wrist Splint Sizing

(A) WRIST CIRCUMFERENCE							
(B) DORSAL HAND WIDTH		10.2-11.4	11.4-14	14-16.5	16.5-19	19-21.6	>21.6
	<6.3	S	S	S			
	6.3-7.6	S	S	M	M		
	7.6-8.9	S	M	M	M	M	L
	8.9-10.2			M	M	L	L
	>10.2				L	L	L

Glove Liner Sizing

(A) HAND CIRCUMFERENCE							
(B) 3RD FINGER LENGTH		11.4-14	14-16.5	16.5-19	19-21.6	21.6-24.1	24.1-26.7
	15.2-16.5	XS	XS	XS			
	16.5-17.8	XS	XS	XS	S		
	17.8-19		S	S	S	M	
	19-20.3			M	M	L	XL
	>20.3				L	XL	XL

SaeboGlove Bands Guideline



Glove Size	DIP Joint	PIP Joint	MCP Joint	IP Thumb	MCP Thumb
XS	A	A	B/C	A/B	D/E
SM	A	A	B/C	A/B	D/E
MD	A	A	C	A/B	D/E
LG	A/B	A/B	C	B/C	D/E
XL	A/B	A/B	C	B/C	D/E

Code on glove given: ☐

Measuring Form adapted from Saebo UK Ltd with permission

SaeboGlove measuring form reproduced with copyright permission from Saebo UK

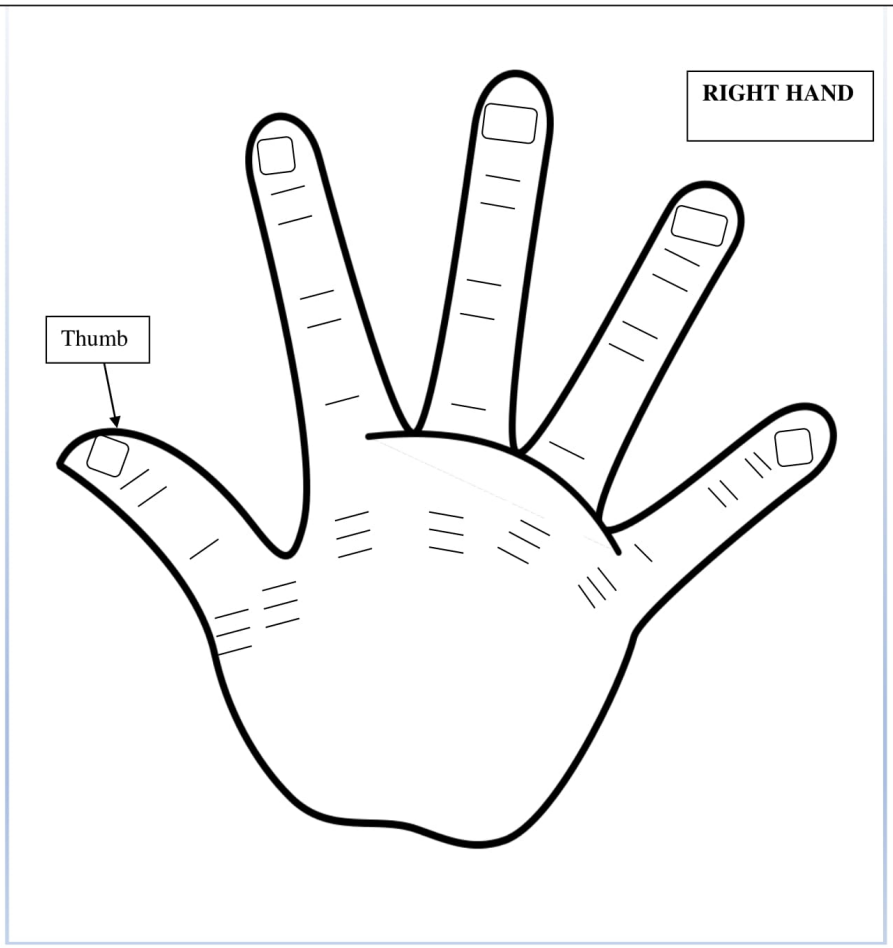
SUSHI Trial

Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

Record size of extensor assist bands - RIGHT

This lines on the hand diagram ___ represents a hook where bands can be attached. Please enter the size of the band selected on each joint e.g. A, B, C, D, E



SUSHI Trial

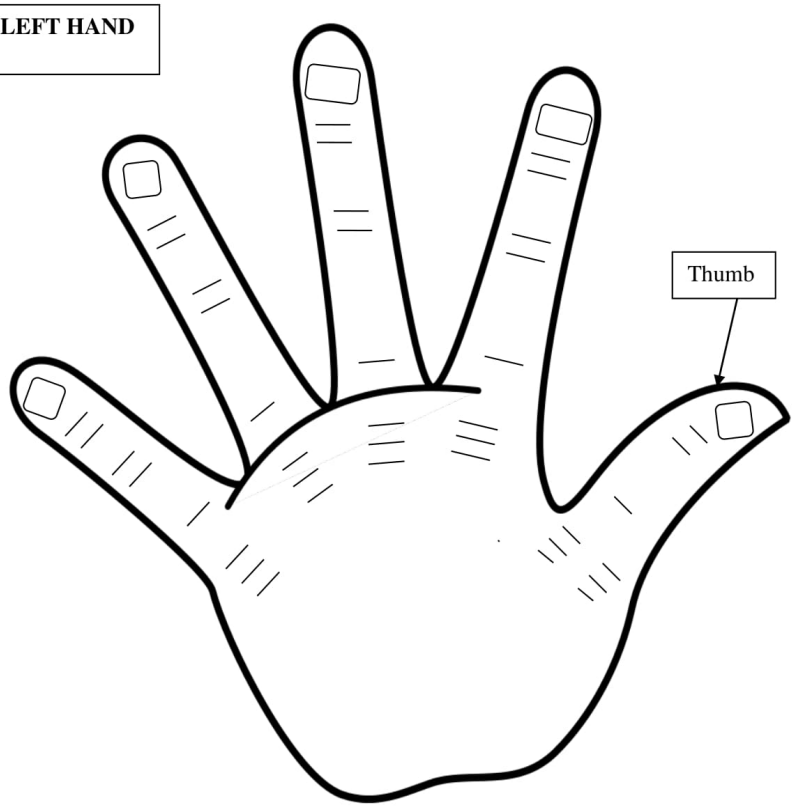
Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

Record size of extensor assist bands - LEFT

This line on the hand diagram —— represents a hook where bands can be attached. Please enter the size of the band selected on each joint e.g. A, B, C, D, E

LEFT HAND



SUSHI Trial

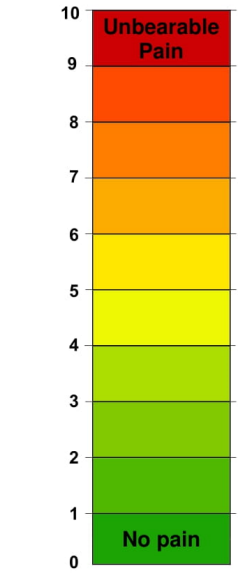
Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

TO BE COMPLETED BY THE PATIENT:

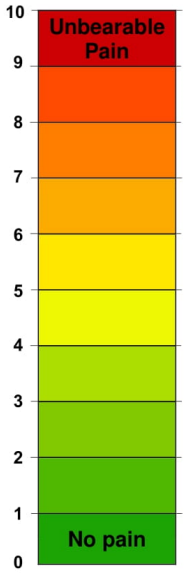
Upper Arm Pain (shoulder to just proximal to olecranon of elbow)

Please draw a line on the following scale, to indicate where the intensity of your upper arm pain is represented best **on average** over the last 1 week.



Lower Arm Pain (elbow to finger tips)

Please draw a line on the following scale, to indicate where the intensity of your lower arm pain is represented best **on average** over the last 1 week.



☐ Please enter VAS Score in boxes provided ☐

Reproduction: freely available

Hand Opening Exercises. **Aim**: ☐ **hand opening movements daily**

	Exercise 1	Exercise 2
Level 1	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____
Level 2	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____
Level 3	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____

Task	**Tick when complete**
Give week 1-6 Hand + Arm Therapy Booklet	
Inform clinical OT /PT of group allocation	

THERAPY REVIEW

2

Did review take place? Yes ☐ No ☐

If No, please specify _____

Review date: ☐☐/☐☐/☐☐☐☐

Reviewed by OT ☐ PT ☐

Did review take place during inpatient stay? Yes ☐ No ☐

Did review take place face-to-face? Yes ☐ No ☐

If not, please specify reason _____

Please indicate (tick one) who has been supporting participant with daily SaeboGlove therapy

☐ No one, participant independent with glove & exercises

☐ Informal carer e.g. friend, family

☐ Formal carer e.g. usual care clinical team

☐ Combination of informal and formal carer

Therapist (print name): _____

Therapist (sign name): _____

SUSHI Trial

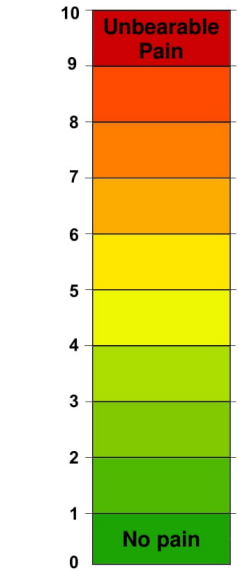
Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

TO BE COMPLETED BY THE PATIENT:

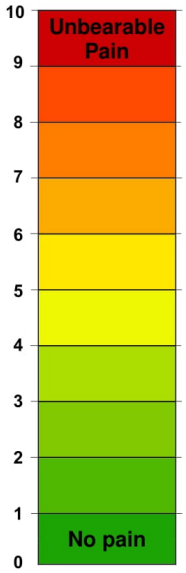
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Please draw a line on the following scale, to indicate where the intensity of your upper arm pain is represented best **on average** over the last 1 week.



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Please draw a line on the following scale, to indicate where the intensity of your lower arm pain is represented best **on average** over the last 1 week.



☐ Please enter VAS Score in boxes provided ☐

Reproduction: freely available

SUSHI Trial

Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

Hand Opening Exercises. **Aim**: ☐ **hand opening movements daily**

	Exercise 1	Exercise 2
Level 1	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____
Level 2	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____
Level 3	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____

THERAPY REVIEW

3

Did review take place? Yes ☐ No ☐

If No, please specify _____

Review date: ☐☐/☐☐/☐☐☐☐

Reviewed by OT ☐ PT ☐

Did review take place during inpatient stay? Yes ☐ No ☐

Did review take place face-to-face? Yes ☐ No ☐

If not, please specify reason _____

Please indicate (tick one) who has been supporting participant with daily SaeboGlove therapy

☐ No one, participant independent with glove & exercises

☐ Informal carer e.g. friend, family

☐ Formal carer e.g. usual care clinical team

☐ Combination of informal and formal carer

Therapist (print name): _____

Therapist (sign name): _____

SUSHI Trial

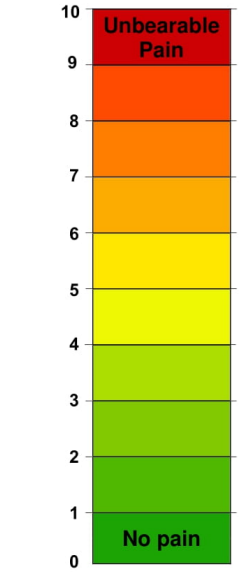
Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

TO BE COMPLETED BY THE PATIENT:

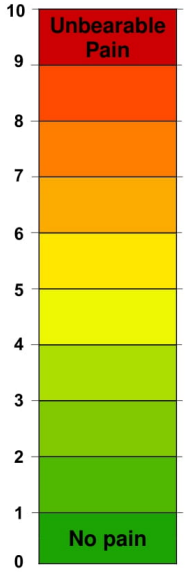
Upper Arm Pain (shoulder to just proximal to olecranon of elbow)

Please draw a line on the following scale, to indicate where the intensity of your upper arm pain is represented best **on average** over the last 1 week.



Lower Arm Pain (elbow to finger tips)

Please draw a line on the following scale, to indicate where the intensity of your lower arm pain is represented best **on average** over the last 1 week.



☐ Please enter VAS Score in boxes provided ☐

Reproduction: freely available

SUSHI Trial

Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

Hand Opening Exercises. **Aim**: ☐ **hand opening movements daily**

	Exercise 1	Exercise 2
Level 1	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____
Level 2	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____
Level 3	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____

THERAPY REVIEW

4

Did review take place? Yes ☐ No ☐

If No, please specify _____

Review date: ☐☐/☐☐/☐☐☐☐

Reviewed by OT ☐ PT ☐

Did review take place during inpatient stay? Yes ☐ No ☐

Did review take place face-to-face? Yes ☐ No ☐

If not, please specify reason _____

Please indicate (tick one) who has been supporting participant with daily SaeboGlove therapy

☐ No one, participant independent with glove & exercises

☐ Informal carer e.g. friend, family

☐ Formal carer e.g. usual care clinical team

☐ Combination of informal and formal carer

Therapist (print name): _____

Therapist (sign name): _____

SUSHI Trial

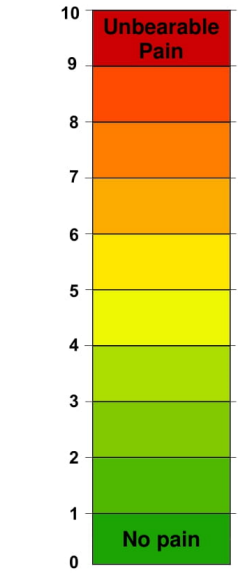
Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

TO BE COMPLETED BY THE PATIENT:

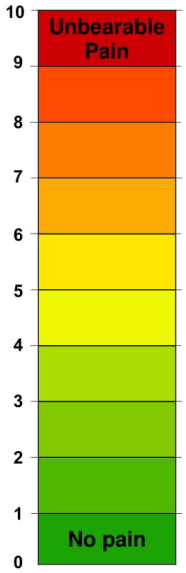
Upper Arm Pain (shoulder to just proximal to olecranon of elbow)

Please draw a line on the following scale, to indicate where the intensity of your upper arm pain is represented best **on average** over the last 1 week.



Lower Arm Pain (elbow to finger tips)

Please draw a line on the following scale, to indicate where the intensity of your lower arm pain is represented best **on average** over the last 1 week.



☐ Please enter VAS Score in boxes provided ☐

Reproduction: freely available

SUSHI Trial

Patient ID Number ☐☐☐☐☐

SaeboGlove Therapy Review

Hand Opening Exercises. **Aim**: ☐ **hand opening movements daily**

	Exercise 1	Exercise 2
Level 1	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____
Level 2	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____
Level 3	SaeboGlove used? Y ☐ N ☐ reason_____	SaeboGlove used? Y ☐ N ☐ reason_____

Usual care therapy review form

Therapy Reviews for SUSHI Trial



SUSHI Trial

Patient ID Number ☐☐☐☐☐

Usual carer physiotherapy + occupational Therapy upper limb review sessions

THIS FORM SHOULD ONLY BE COMPLETED OVER THE NEXT 6 WEEKS FOR SUSHI PARTICIPANTS WHO HAVE BEEN RANDOMISED TO THE USUAL CARE ONLY GROUP. IT SHOULD NOT BE USED FOR PARTICIPANTS RANDOMISED TO THE SAEBOGLOVE GROUP.

Has the participant been randomised to receive Usual Care?

Yes ☐ Please complete 4 Upper Limb Therapy Reviews over the next 6 weeks and complete the review paperwork overleaf.

No ☐ Please DO NOT carry out any reviews for the SUSHI Trial and DO NOT complete the review paperwork overleaf.

IMPORTANT: A member of the SUSHI Research Team will collect this paperwork from you in 6 weeks time. This team member may be an outcome assessor and MAY BE DELIBERATELY BLINDED to group allocation to prevent scoring bias and to maintain the quality of our research work and conclusions. Please do not discuss the trial with them. If you have any questions about this paperwork, please contact Jen Alexander or Ozzy Dincarslan on 0141 451 5870. They are aware of participants group allocation and will be happy to help you in any way they can.

THANK YOU VERY MUCH FOR ALL YOUR HELP

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Usual carer physiotherapy + occupational Therapy upper limb review sessions

UPPER LIMB THERAPY REVIEW TO ASSESS + REDEFINE TREATMENT PLANS / GOALS

1. DID REVIEW 1 TAKE PLACE?

Yes ☐ Date of review __ / __ / __ __ __ __ Reviewed by OT ☐ PT ☐

Review comments:

No ☐ Please specify _____

_____ _____ _ _ / _ _ / _ _ _ _

Name of person completing form (PRINT) Signature Date

---

2. DID REVIEW 2 TAKE PLACE?

Yes ☐ Date of review __ / __ / __ __ __ __ Reviewed by OT ☐ PT ☐

Review comments:

No ☐ Please specify _____

_____ _____ _ _ / _ _ / _ _ _ _

Name of person completing form (PRINT) Signature Date

SUSHI Trial

Patient ID Number ☐☐☐☐☐

Usual carer physiotherapy + occupational Therapy upper limb review sessions

UPPER LIMB THERAPY REVIEW TO ASSESS + REDEFINE TREATMENT PLANS / GOALS

3. DID REVIEW 3 TAKE PLACE?

Yes ☐ Date of review __ / __ / __ __ __ __ Reviewed by OT ☐ PT ☐

Review comments:

No ☐ Please specify _____

_____ _____ _ _ / _ _ / _ _ _ _

Name of person completing form (PRINT) Signature Date

4. DID REVIEW 4 TAKE PLACE?

Yes ☐ Date of review __ / __ / __ __ __ __ Reviewed by OT ☐ PT ☐

Review comments:

No ☐ Please specify _____

_____ _____ _ _ / _ _ / _ _ _ _

Name of person completing form (PRINT) Signature Date

pages 5-17 are blank for blinding purposes

SaeboGlove treatment interruptions form

SUSHI Trial	Patient ID ☐☐☐☐☐	Treatment interruption / termination Form

SaeboGlove Therapy for **U**pper Limb Disability and **S**evere **H**and **I**mpairment after stroke (SUSHI)

Instructions: Please complete this form for participants in the active group if SaeboGlove therapy is interrupted or terminated for any reason during the 6-week intervention period.

Missed SaeboGlove Therapy Days

1. Date treatment was interrupted i.e. stopped: __/__/_____

2. Was treatment re-started?

   No ☐ If No, enter date of first and last day of intervention period:

   First day: __/__/_____ Last day: __/__/_____

   Yes ☐ If Yes, date re-started: __/__/_____

3. Enter number of missed days? ☐

4. Reason for missed treatment day(s) (if known):

.....
.....
.....
.....
.....
.....
.....
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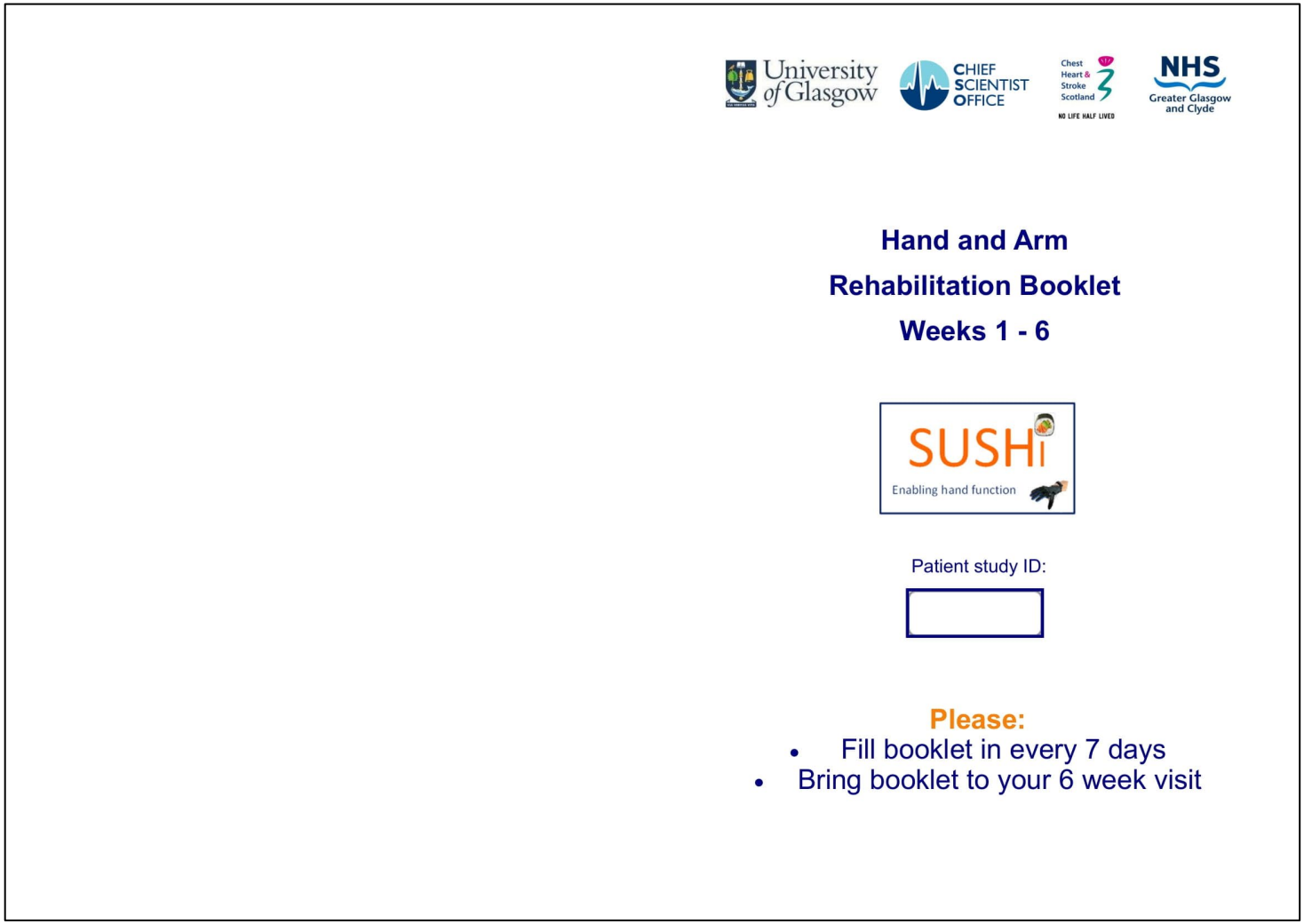
Signature of person recording: _____

Name of person recording (print): _____

Role of person recording (eg PI, therapist): _____

Date of recording: __/__/_____

Hand and arm rehabilitation booklet – Active group, weeks 1-6



Introduction

This booklet is to record information about any hand and arm rehabilitation you carry out with and without the help of a therapist.

Research shows that people recover better when they carryout high numbers of upper limb movements (> 100 movements daily) that are based on everyday tasks early after stroke. To try to improve your recovery you and your research therapist will decide how many hand opening movements you will aim to carry out daily using the SaeboGlove. You should record this number in this booklet for each of your 6 weeks of therapy and you should record how many movements you manage to carry out daily. This number may change at each therapy review visit.

Please fill the booklet in every 7 days. The SUSHI research team will try to phone you each week to help to remind you to fill it in.

Please bring the completed booklet to your 6 week visit. At this visit we will give you a second booklet to complete over weeks 7-14 of the study.

Thank you for your participation in the SUSHI study.





Thank you for taking part in the SUSHI study.

Stroke Research Team

[Enter contact name, address, telephone number and email address]

Please use this space if it is useful to help you keep track of your weekly therapy

Time spent moving hand and upper limb with therapists (minutes)

Week	Minutes by day of week						
1							
2							
3							
4							
5							
6							

Time spent moving hand and upper limb without therapists (minutes)

Week	Minutes by day of week						
1							
2							
3							
4							
5							
6							

Week 1 (Day, date) __ __ __, __ __/__ __ to __ __ __, __ __/__ __

Week 2 (Day, date) __ __ __, __ __/__ __ to __ __ __, __ __/__ __

Week 3 (Day, date) __ __ __, __ __/__ __ to __ __ __, __ __/__ __

Week 4 (Day, date) __ __ __, __ __/__ __ to __ __ __, __ __/__ __

Week 5 (Day, date) __ __ __, __ __/__ __ to __ __ __, __ __/__ __

Week 6 (Day, date) __ __ __, __ __/__ __ to __ __ __, __ __/__ __

EXAMPLE **Start Date:** 01/08/19

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☑

   or

   Yes ☐

   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   ____hours____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☑

   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   0 hours 25 minutes

3. This week your shared weekly goal is to **open your hand** 50 **times daily** while carrying out your grasp/release training program in the SUSHI trial. Please record the number of hand opening movements you carry out daily in the table below:

	Day of the week	Day of the week	Day of the week	Day of the week	Day of the week	Day of the week	Day of the week
	Mon	Tue	Wed	Thu	Fri	Sat	Sun
How many hand opening movements did you do?	45	50	50	0	50	50	70

Week 1 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

3. This week your shared weekly goal is to **open your hand _____ times daily** while carrying out your grasp/release training program in the SUSHI trial. Please record the number of hand opening movements you carry out daily in the table below:

	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week
How many hand opening movements did you do?							

Week 6 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

3. This week your shared weekly goal is to **open your hand _____ times daily** while carrying out your grasp/release training program in the SUSHI trial. Please record the number of hand opening movements you carry out daily in the table below:

	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week
How many hand opening movements did you do?							

Week 5 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

3. This week your shared weekly goal is to **open your hand _____ times daily** while carrying out your grasp/release training program in the SUSHI trial. Please record the number of hand opening movements you carry out daily in the table below:

	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week
How many hand opening movements did you do?							

Week 2 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

3. This week your shared weekly goal is to **open your hand _____ times daily** while carrying out your grasp/release training program in the SUSHI trial. Please record the number of hand opening movements you carry out daily in the table below:

	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week
How many hand opening movements did you do?							

Week 3 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

3. This week your shared weekly goal is to **open your hand _____ times daily** while carrying out your grasp/release training program in the SUSHI trial. Please record the number of hand opening movements you carry out daily in the table below:

	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week
How many hand opening movements did you do?							

Week 4 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

3. This week your shared weekly goal is to **open your hand _____ times daily** while carrying out your grasp/release training program in the SUSHI trial. Please record the number of hand opening movements you carry out daily in the table below:

	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week	Day of week
How many hand opening movements did you do?							

Hand and arm rehabilitation booklet – Control group, weeks 1-6

University of Glasgow · CHIEF SCIENTIST OFFICE · Chest Heart & Stroke Scotland – NO LIFE HALF LIVED · NHS Greater Glasgow and Clyde

Hand and Arm

Rehabilitation Booklet

Weeks 1 - 6

SUSHI
Enabling hand function

Patient study ID:

Please:

- Fill booklet in every 7 days
- Bring booklet to your 6 week visit

Introduction

This booklet is to record information about any hand and arm rehabilitation you carry out with and without the help of a therapist.

Please fill the booklet in every 7 days. The SUSHI research team will try to phone you each week to help to remind you to fill it in.

Please bring the completed booklet to your 6 week visit. At this visit we will give you a second booklet to complete over weeks 7-14 of the study.

Thank you for your participation in the SUSHI study.





Thank you for taking part in the SUSHI study.

Stroke Research Team

[Enter contact name, address, telephone number and email address]

Please use this space if it is useful to help you keep track of your weekly therapy

Time spent moving hand and upper limb with therapists (minutes)

Week	Minutes by day of week						
1							
2							
3							
4							
5							
6							

Time spent moving hand and upper limb without therapists (minutes)

Week	Minutes by day of week						
1							
2							
3							
4							
5							
6							

Week 1 (Day, date) _ _ _ , _ _ / _ _ to _ _ _ , _ _ / _ _

Week 2 (Day, date) _ _ _ , _ _ / _ _ to _ _ _ , _ _ / _ _

Week 3 (Day, date) _ _ _ , _ _ / _ _ to _ _ _ , _ _ / _ _

Week 4 (Day, date) _ _ _ , _ _ / _ _ to _ _ _ , _ _ / _ _

Week 5 (Day, date) _ _ _ , _ _ / _ _ to _ _ _ , _ _ / _ _

Week 6 (Day, date) _ _ _ , _ _ / _ _ to _ _ _ , _ _ / _ _

EXAMPLE **Start Date:** 01/08/19

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☑

   or

   Yes ☐

   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   ____hours____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☑

   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   0 hours 25 minutes

Week 1 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Week 6 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Week 5 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Week 2 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Week 3 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Week 4 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

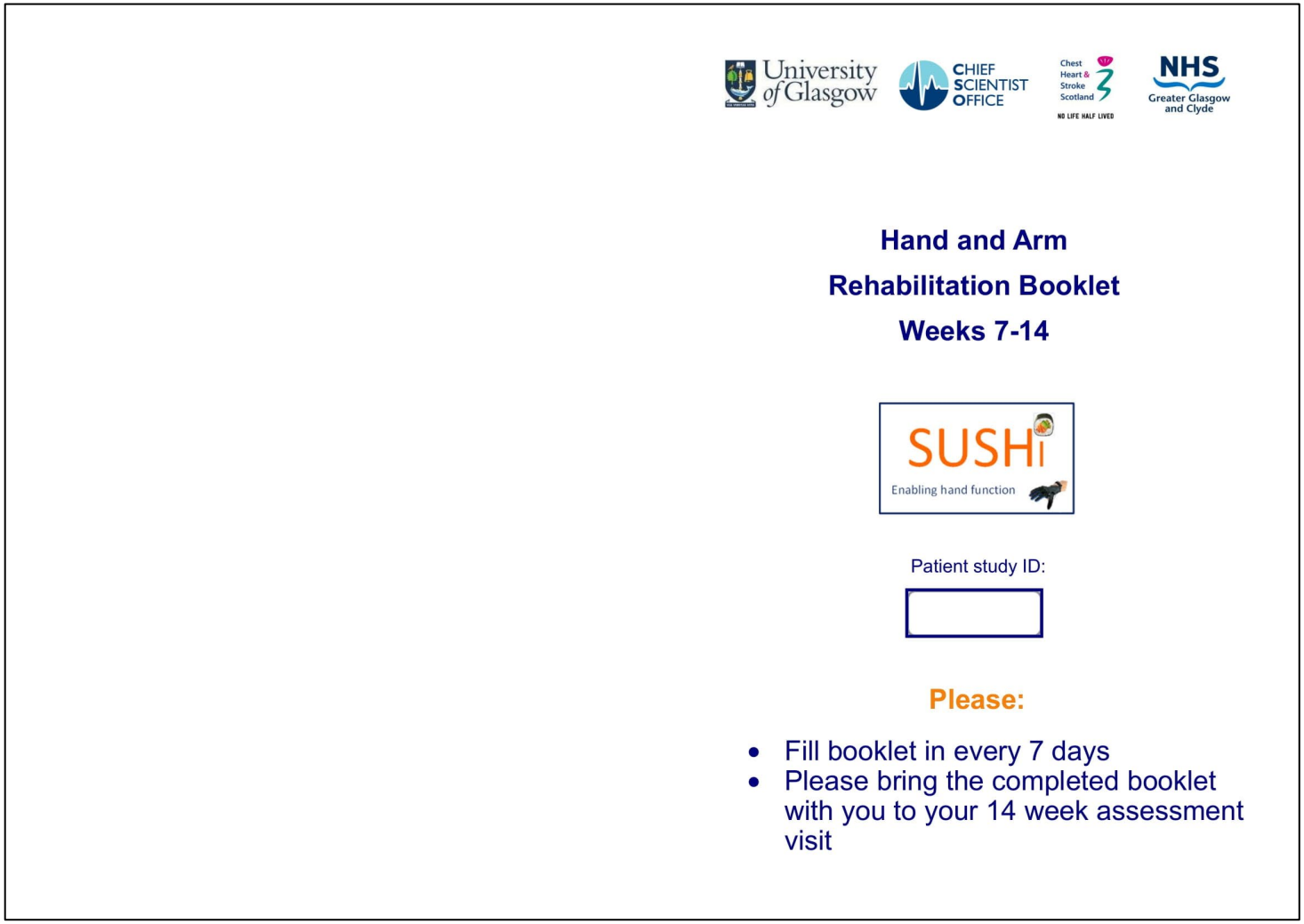
   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Hand and arm rehabilitation booklet – Both groups weeks 7-14



Introduction

This booklet is to record information about any hand and arm rehabilitation you carry out with and without the help of a therapist.

Please fill the booklet in every 7 days. The SUSHI research team will try to phone you each week to help to remind you to fill it in.

Please bring the completed booklet with you to your 14 week assessment visit.

Thank you for your participation in the SUSHI study.





Thank you for taking part in the SUSHI study.

Stroke Research Team

[Enter contact name, address, telephone number and email address]t

Please use this space if it is useful to help you keep track of your weekly therapy

Time spent moving hand and upper limb with therapists (minutes)

Week	Minutes by day of week						
1							
2							
3							
4							
5							
6							
7							
8							

Time spent moving hand and upper limb without therapists (minutes)

Week	Minutes by day of week						
1							
2							
3							
4							
5							
6							
7							
8							

Week 1 (Day, date) __ __ __ , __ __ / __ __ to __ __ __ , __ __ / __ __

Week 2 (Day, date) __ __ __ , __ __ / __ __ to __ __ __ , __ __ / __ __

Week 3 (Day, date) __ __ __ , __ __ / __ __ to __ __ __ , __ __ / __ __

Week 4 (Day, date) __ __ __ , __ __ / __ __ to __ __ __ , __ __ / __ __

Week 5 (Day, date) __ __ __ , __ __ / __ __ to __ __ __ , __ __ / __ __

Week 6 (Day, date) __ __ __ , __ __ / __ __ to __ __ __ , __ __ / __ __

Week 7 (Day, date) __ __ __ , __ __ / __ __ to __ __ __ , __ __ / __ __

Week 8 (Day, date) __ __ __ , __ __ / __ __ to __ __ __ , __ __ / __ __

EXAMPLE **Start Date:** 01/08/19

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☑

   or

   Yes ☐

   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   ____hours____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☑

   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   0 hours 25 minutes

Week 1 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Please use this space if it is useful to help you keep track of your weekly therapy

Please use this space if it is useful to help you keep track of your weekly therapy

Week 2 Start Date: / /

1. Did you do any hand or arm therapy <u>with</u> a therapist in the last 7 days?

   No ☐

   <u>or</u>

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy <u>with</u> a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy <u>without</u> the help of a therapist in the last 7 days?

   No ☐

   <u>or</u>

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy <u>without</u> a therapist in the last 7 days?

   _____hours_____minutes

Week 3 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Week 8 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Week 7 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   ____hours____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   ____hours____minutes

Week 4 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   ____hours____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   ____hours____minutes

Week 5 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Week 6 Start Date: / /

1. Did you do any hand or arm therapy with a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy with a therapist in the last 7 days?

   _____hours_____minutes

2. Did you do any hand or arm therapy without the help of a therapist in the last 7 days?

   No ☐

   or

   Yes ☐
   Approximately how much time did you spend doing hand and arm therapy without a therapist in the last 7 days?

   _____hours_____minutes

Adverse event reporting form for a CE-marked medical device

Please return completed reports to Pharmacovigilance Office
Fax: +44 (0) 141 357 5588
Email: pharmacovig@glasgowctu.org

Study Information	
Protocol Number:	**Subject ID:** ☐☐
Site Name:	**Investigator Name:**

Adverse Event			
NOTE: clinically significant abnormal lab results should be considered AEs			
Date of Report:	____/____/_____ DD MM YYYY	**Type of Report:**	☐ Initial ☐ Follow Up #_____
Adverse Event Term:	_____		
Date and time of Onset of Symptoms:	____/____/_____ DD MM YYYY	____:____ HH : MM	
Resolution date and time:	____/____/_____ DD MM YYYY	____:____ HH : MM	
Initial Date Reported to Sponsor:	____/____/_____ DD MM YYYY	**Date PI Aware of AE:**	____/____/_____ DD MM YYYY
Subject Outcome:	Resolved ☐		Death ☐
	Resolved with sequelae ☐		Unknown ☐
	Ongoing ☐		
Action Taken – Subject:	Continued Study ☐		Discontinued Study ☐
	If discontinued, was it due to **this** AE?	Yes ☐	No ☐

Seriousness Classification			
Seriousness Criteria: (please tick at least one box and provide additional information if required for that criterion)			
☐ Death	Date: ____/____/_____ DD MM YYYY	Cause: _____	
☐ Life threatening illness or injury			
☐ Permanent impairment of a body structure or a body function			
☐ Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function			
☐ In-patient / Prolonged Hospitalisation:	Admit Date: ____/____/_____ DD MM YYYY	Disch. Date: ____/____/_____ DD MM YYYY	
☐ Led to foetal distress, foetal death or a congenital abnormality or birth defect			
☐ Other (Please Specify):	_____		

Causality, Severity, and Expectedness					
Relationship to Study Device:	Not Related ☐		Possibly Related ☐		Related ☐
If related to the Study Device is the event due to a device malfunction?	Yes ☐	No ☐	If Y, please ensure that this is detailed within the narrative below.		

If related to study device; please specify the suspect device:			
Relationship to Study Procedure:	Not Related ☐	Possibly Related ☐	Related ☐
If related to study procedure please specify the procedure			
Severity Grade:	Mild ☐	Moderate ☐	Severe ☐
Expectedness:	Anticipated ☐	Unanticipated ☐	

Event Narrative:
(e.g. onset of symptoms, treatment, medications, outcome, reason for causality assessment)
Relevant Medical History: (please state any relevant pre-existing conditions)

Investigator Signature:			
Name	Position	Signature	Date

Does the serious adverse event meet the criteria for reporting to Sponsor/Manufacturer as per the protocol?	Yes ☐	No ☐	If No is ticked the event is not reportable to sponsor / manufacturer

Appendix K – RCT Consolidated Standards of Reporting Trials (CONSORT)

Table: CONSORT 2010 checklist of information to include when reporting a RCT

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	172
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-6
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	173-175
	2b	Specific objectives or hypotheses	175
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	176
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	179-181
Participants	4a	Eligibility criteria for participants	181-185
	4b	Settings and locations where the data were collected	179
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	193-204
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	204-207
	6b	Any changes to trial outcomes after the trial commenced, with reasons	179-180
Sample size	7a	How sample size was determined	193
	7b	When applicable, explanation of any interim analyses and stopping guidelines	193
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	192
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	192

Section/Topic	Item No	Checklist item	Reported on page No
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	192
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	192
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	205-207
	11b	If relevant, description of the similarity of interventions	193 - 204
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	210-211, 213-214
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	211-214
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	219-220
	13b	For each group, losses and exclusions after randomisation, together with reasons	219-220
Recruitment	14a	Dates defining the periods of recruitment and follow-up	216-217
	14b	Why the trial ended or was stopped	193
Baseline data	15	A Table showing baseline demographic and clinical characteristics for each group	222-228
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	219
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	235-263

Section/Topic	Item No	Checklist item	Reported on page No
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	264-269
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	264-266
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	277-281
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	281-286
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	270-286
Other information			
Registration	23	Registration number and name of trial registry	179
Protocol	24	Where the full trial protocol can be accessed, if available	407-427
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14-17

CONSORT 2010 checklist of information to include when reporting a RCT, adapted from Moher et al. 2012, available at: CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials - ScienceDirect under a Creative Commons CC BY 2.0. Full Terms at: Creative Commons — Attribution-NonCommercial 2.0 Generic — CC BY-NC 2.0

Appendix L – RCT statistical analysis plan

SaeboGlove therapy for Upper limb disability and Severe Hand Impairment after stroke (SUSHI): A pragmatic, multicentre, parallel-group, randomised controlled trial with blinded outcome assessment and process evaluation

SUSHI

STATISTICAL ANALYSIS PLAN (SAP)

Study Title:	SaeboGlove therapy for Upper limb disability and Severe Hand Impairment after stroke (SUSHI): A pragmatic, multicentre, parallel-group, randomised controlled trial with blinded outcome assessment and process evaluation		
Short Title:	SUSHI		
REC ID:	19/WS/0097		
Sponsor ID:	GN19ST318		
ClinicalTrials.gov ID:	NCT04007315		
Sponsor:	NHS Greater Glasgow and Clyde		
Funded by:	Chest Heart Stroke Scotland Chief Scientist Office		
Protocol Version:	4.0	Date:	02/12/2020
SAP Version Number:	1.0	Date:	02/06/2023
Date:			

		Signature	Date
Prepared by:	Patrycja Duklas Junior Biostatistician, Robertson Centre for Biostatistics, University of Glasgow		05/06/2023
Approved by:	Prof Alex McConnachie Assistant Director of Biostatistics, Robertson Centre for Biostatistics, University of Glasgow		02/06/2023
	Prof Jesse Dawson Professor of Stroke Medicine, School of Cardiovascular and Metabolic Health, University of Glasgow		06/06/2023

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1.1. Study Background 3
1.2. Study Objectives 3
1.3. Study Design 4
1.4. Randomisation 4
1.5. Sample Size and Power 4
1.6. Inter Analysis and Stopping Rules 5
1.7. Statistical Analysis Plan (SAP) 5
2. Analysis 6
2.1. Study Populations ..... **Error! Bookmark not defined.**
2.2. Study Status 6
2.3. Protocol Deviations ..... **Error! Bookmark not defined.**
2.4. Baseline Characteristics 7
2.5. Efficacy Outcomes 8
2.6. Safety Outcomes 9
3. Data Conventions 10
4. Tables and Figures 10
5. References ..... **Error! Bookmark not defined.**
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1. INTRODUCTION

1.1. STUDY BACKGROUND

Recovery of upper limb function following stroke is typically poor and is associated with poor quality of life. Despite rehabilitation efforts 50% of those who experience reduced upper limb function have no upper limb function 6 months post stroke, experiencing severe chronic upper limb disability.

Weakness in the finger extensors is the most common motor impairment experienced after stroke. National guidelines recommend that therapy involves intensive, repetitive practice of patient specific functional tasks and research suggests that optimal brain recovery occurs when stroke patients carry out >100 daily movement repetitions. However, this is consistently not achieved in the UK.

No clear evidence-based intervention exists for producing lasting gains in everyday upper limb function in people with severe upper limb weakness after stroke. The SaeboGlove is a rehabilitation aid released in October 2014 that could enable participation in functional upper limb activities during 1:1 therapy sessions, and independent practice throughout all stages of recovery regardless of weakness severity. It is a mechanical, functional hand orthosis. It provides finger extensor assistance using tensioners over weak joints and offers prolonged periods of stretch to the wrist and finger flexors thereby negating secondary complications such as stiffness and contractures that occur due to stroke impairments (weakness, spasticity, inattention). It also provides varying degrees of finger extensor assistance to enable patients to open their hand in order to engage the hand and arm actively in functional rehabilitation, creating an opportunity to improve functional recovery and reduce the inevitable effects of learned non-use.

A single group, open feasibility trial of SaeboGlove in people with recent stroke and reduced hand opening, concluded that the device was a safe and feasible intervention, and a significant improvement was observed in all five performance measures, including upper limb function. A definitive clinical trial utilising an improved methodological design is needed to assess efficacy and the role of the SaeboGlove in NHS stroke care.

1.2. STUDY OBJECTIVES

The primary objective is to determine whether 6-weeks of SaeboGlove self-directed repetitive functional-based practice (SDRFP) plus usual care improves the ARAT score in comparison to usual care alone in people with reduced active finger extension, upper limb disability and severe hand impairment after recent stroke.

The secondary objectives are:

1. To determine whether SaeboGlove SDRFP improves:

    a. upper limb impairment
    b. hand impairment
    c. perceived habitual functional upper limb use
    d. performance in activities of daily living
    e. quality of life
    f. upper limb pain intensity
    g. therapy participation
    h. degree of disability / dependence

2. To explore and understand the experiences of people receiving SaeboGlove SDRFP, and their carers, clinical physiotherapists and occupational therapists, particularly in relation to perceived self-management support needs, barriers and facilitators to its implementation in practice.

3. To develop a self-management SaeboGlove SDRFP training resource to enable independent progression following a period of supported use.

4. To estimate costs and benefit in terms of quality adjusted life years associated with SaeboGlove SDRFP compared to usual NHS care alone.

1.3. Study Design

Pragmatic, two-arm, multicentre, randomised controlled intervention trial with blinded outcome assessment, with a concurrent embedded process evaluation.

1.4. Randomisation

Participants have been randomised, on a 1:1 basis, to receive 6-weeks of SaeboGlove SDRFP plus usual NHS care or 6-weeks of usual NHS care. Individuals have been allocated using a minimisation algorithm designed to maintain balance with respect to study site, time since stroke (≤1 month, > 1 month) and severity of upper limb function (ARAT 0-10, 11-28, 29-46).

1.5. Sample Size and Power

Section 6.1 of the study protocol states:

> *"A mean change in ARAT score of 10 points is assumed in the control group. A mean difference between groups of 9 points has been used for our sample size calculation, based on our pilot data where participants improved by 19 points (standard deviation 13.5 points). A sample size of 49 per group will detect this difference with 90% power at a 5% significance level. We will*

randomise up to 110 participants to achieve this number with 6-week outcome measures. Analysis will be performed on an intention to treat basis."

1.6. Interim Analysis and Stopping Rules

There were no planned interim analyses or stopping rules in this trial. On the 21st September 2022 it was agreed with the Trial Steering Committee and the funder that we would aim to achieve 35 participants per group who have primary outcome data, which would give 80% power. It was therefore decided to enrol until November 2022 to ensure at least this revised sample size was met.

1.7. Study Population

The study population is adults with a new a new diagnosis of stroke (within 7-60 days), and severe hand impairment and upper limb disability. See section 3.3 of the study protocol for more details.

1.8. Statistical Analysis Plan (SAP)

1.8.1. SAP Objectives

The objective of this SAP is to describe the statistical analyses to be carried out for the SUSHI study. The SAP will cover analyses which address the primary objective and the quantitative secondary objectives described above. It does not cover the cost effectiveness or qualitative analyses.

The current study protocol at the time of writing is version 4.0, dated 02/12/2020. Future amendments to the protocol will be reviewed for their impact on this SAP, which will be updated only if necessary. If no changes are required to this SAP following future amendments to the study protocol, this will be documented as part of the Robertson Centre Impact Assessment process.

1.8.2. General Principles

Primary and secondary outcome measures will be summarised at baseline and at each follow up. All summaries will include the number of observed values and the number of missing values. Continuous variables will be summarised by the mean, standard deviation, median, interquartile range, minimum and maximum. Categorical variables will be summarised as the number and percentage of participants in each group.

The primary and continuous secondary efficacy outcomes will be compared between intervention groups using linear regression analyses, adjusting for baseline value of the outcome, study site, time since stroke (≤1 month, > 1 month) and severity of upper limb function (ARAT 0-10, 11-28, 29-46). The distribution of the residuals of each linear regression analysis will be reviewed

and transformations will be applied to the outcome variable as appropriate. If no suitable regression model can be identified, then groups will be compared using a stratified Wilcoxon test (van Elteren test).

mRS will be analysed using ordinal logistic regression methods. Binary logistic regression, for suitable mRS cut-offs, may also be applied.

Regression results will be reported as adjusted mean differences, or odds ratios, between intervention groups with 95% confidence intervals and p-value.

Safety outcomes will be reported in a descriptive fashion.

Missing values will not be imputed in main analyses. Multiple imputation for missing baseline and/or outcome data will be considered as sensitivity analyses, following the completion of the analyses described in this SAP.

1.8.3. Deviations To Those Specified In Study Protocol

This SAP contains no deviations from analyses planned in the study protocol.

1.8.4. Additional Analyses To Those Specified In Study Protocol

This SAP contains no additional analyses to those planned in the study protocol. Sensitivity analyses using multiple imputation for missing data will be explored following the completion of the analyses in this SAP.

1.8.5. Software

Data will be analysed using R version 3.6.2 or higher.

2. Analysis Populations

2.1. Analysis Population

The Analysis Population will consist of all randomised participants.

2.2. Efficacy

Efficacy analyses will be carried out according to randomised group, regardless of compliance with the intervention.

2.3. Safety

Safety analyses will be carried out according to whether or not the intervention was received.

3. ANALYSIS

3.1. SUBJECT DISPOSITION

The number of participants in the analysis population will be tabulated as a whole and by randomised group. The number and percentage who complete each study assessment will be reported. Reasons for not completing each assessment will be reported (death, withdrawal, loss to follow-up).

3.2. BASELINE CHARACTERISTICS

The following baseline characteristics will be summarised in the analysis population:

- Age
- Gender
- Ethnic group
- Study site
- FMA UE total motor score
- FMA hand motor score
- FMA UE sensory score
- ARAT subscores (grasp, grip, pinch, gross)
- ARAT score (total continuous, and categorised 0-10, 11-28, 29-46)
- Modified Rankin scale score
- Motor activity log scores (quantity, quality, % of tasks)
- Barthel index
- EQ-5D-5L Health Utility Score
- EQ-5D-5L VAS
- Pain above elbow VAS
- Pain below elbow VAS
- SIS hand subscore
- SIS total score
- SIS recovery
- Current upper limb rehab therapy
    - Physiotherapy/occupational therapy
    - Splints
    - Shoulder sling
    - TENS
    - Antispasticity medication (e.g. Dantrolene,Baclofen, Tizanidine)
    - Botulinum toxin
- Ischaemic stroke
- Haemorrhagic stroke
- Time from stroke (≤1 months, >1 month)
- Handedness
- Affected arm

Scores relating to left and right arms will be summarised for the affected arm only.

3.3. Efficacy Outcomes

3.3.1. Primary Outcome

The primary outcome of the SUSHI study is upper limb function measured by the Action Research Arm Test (ARAT) at six weeks post randomisation.

The primary outcome will be analysed in a linear regression analysis with predictor variables for randomised intervention group, baseline ARAT as a continuous measure, study site, and time since stroke (≤1 month, > 1 month). Only data concerning the affected upper limb will be reported for upper limb outcome scales.

3.3.2. Secondary Outcomes

The secondary outcomes are:

- ARAT total score at 14-weeks post randomisation
- Upper limb impairment
    - Fugl Meyer Upper Extremity (FMUE) Motor Function Total Score at 6 and 14-weeks
    - Fugl Meyer Upper Extremity (FMUE) Hand Score at 6 and 14-weeks
- Upper and lower arm pain intensity (Visual Analogue Scale (VAS)) at 6 and 14-weeks
- Self-reported SaeboGlove therapy participation
- Perceived habitual functional upper limb use (Motor Activity Log (MAL)) at 6 and 14-weeks
- Degree of disability / dependence (modified Rankin scale (mRS)) at 6 and 14-weeks
- Activities of daily living (Barthel Index (BI)) at 6 and 14-weeks
- Quality of life (Stroke Impact Scale (SIS) total score and hand score) at 6 and 14-weeks
- Euroquol (EQ-5D-5L) Health Utility Score and VAS, at 6 and 14-weeks

Each continuous secondary outcome measure will be analysed in a linear regression analysis with predictor variables for randomised intervention group, the baseline value of the outcome measure, baseline upper limb function (ARAT 0-10, 11-28, 29-46), study site, and time since stroke (≤1 month, > 1 month).

3.3.3. Exploratory Outcomes

Other outcomes not listed above may also be analysed in a similar way to the primary and secondary outcomes, but will be considered exploratory.

3.3.4. ADDITIONAL ANALYSES

Following completion of the analyses outlined in this SAP, additional analyses will explore the use of multiple imputation of missing baseline and/or outcome data.

3.3.5. SUB-GROUP ANALYSES

Subgroup analyses will be conducted for the primary outcome in relation to the following factors:

- age
- sex
- baseline ARAT
- baseline FM hand subscore
- study site
- time since stroke

The primary analysis regression model will first be extended to adjust for age and sex, then interaction terms will be added to assess whether the intervention effect varies according to each of the above factors.

3.4. TREATMENT

The following measures will be summarised for both randomised groups:

- attendance at therapy reviews – % in each group who had review 1,2,3,4 and all reviews.
- self-reported total number minutes of upper limb therapy with a therapist (reported for weeks 1-6, 7-14, weeks 1-14)
- self-reported total minutes of upper limb therapy without a therapist (reported for weeks 1-6, 7-14, weeks 1-14)

The following measures were only collected during the early part of the study, and will be summarised for both randomised groups:

- physiotherapist-reported receipt of upper limb daily therapy (total number of days and % of weekdays for weeks 1-6)
- occupational therapist-reported receipt of upper limb daily therapy (total number of days and % of weekdays for weeks 1-6)

The following measures will be reported descriptively in the intervention arm only.

- total number of SaeboGlove repetitions per week and in total
- total number of days where SaeboGlove was used per week and in total
- number of repetitions per SaeboGlove session per week and in total
- minimum number of target repetitions (for each SaeboGlove session) set by therapist per week and in total

- % of sessions performed where target repetitions were met per week and in total
- Level of support received for self practice (no one, informal carer, formal carer, combination of informal & formal carer) at reviews 1-4
- Mean therapy level at reviews 1-4
- Proportion of exercises without glove at reviews 1-4
- Number of exercises performed of each type (hand / lower arm / upper arm) at reviews 1-4
- Timing of reviews 1-4 (range 1-42 days from first session)
- Format of reviews (face to face or virtual/telephone, inpatient or outpatient)

3.5. Safety Outcomes

3.5.1. Premature Withdrawal

Withdrawals and withdrawal reasons will be summarised overall and by intervention group.

3.5.2. Adverse Events

The number of participants experiencing at least one ADEs, SADEs, and USADEs will be summarised overall and by intervention group up to 14-weeks. ADEs, SADEs, and USADEs characteristics (seriousness criteria, severity, expectedness, relation to intervention, outcome, and duration) will be summarised overall and by study group. All ADEs, SADEs, and USADEs will be listed.

4. Data Conventions

Any assumptions required to carry out the analyses in this SAP will be documented separately, and will be agreed prior to database lock.

5. Tables and Figures

The content of the final report will be based on a separate document of table templates, and dummy versions of the report will be reviewed and approved prior to unblinding.

6. Document History

This is version 1.0 of the SAP for the SUSHI study, its initial creation, dated 02/06/2023.

Appendix M - Qualitative study recruitment documents

Letter of invitation to interview

Name: Date:

Address:

Dear

Re: Stroke research study: hand and arm rehabilitation (SUSHI)

[insert "Thank you for your participation in the SUSHI research study. We would like to invite you to take part in an interview about the study." Or "Thank you for your participation in the SUSHI research study. We would like to invite you and your carer to take part in an interview about the study." for letters to participants]
[insert "One of your patients has participated in the SUSHI research study and we would like to invite you to take part in an interview about the study." for letters to therapists]

In SUSHI we are comparing usual NHS rehabilitation with usual NHS rehabilitation plus rehabilitation using a SaeboGlove. As part of our comparison, it is important for us to understand patients', carers' and therapists' views and experiences about the rehabilitation patients receive. The interviews are to ask you about what you think about the rehabilitation **[insert you have / you and your carer has / your patient has]** received.

The enclosed information sheet gives you more details about the interview.

If you would like to take part in the interview, please contact the Stroke Research Team at Glasgow University who are running the SUSHI trial (Enter telephone number and email address]) to let them know. They will answer any questions you may have and will arrange a convenient time to carry out the interview. Taking part is completely up to you. You can say no or change your mind at any time and withdraw, without giving a reason.

If you have any questions about the interview you can contact:

1. The Stroke Research Team at Glasgow University who are running the SUSHI trial:
   Telephone - 0141 451 5870
   Email - ggc.srunit@nhs.scot

Thank you once again for your participation in our research study.

Yours sincerely,

Enter signature, name, position, address, telephone number and email address of pricipal investigator]

Participant information sheet – Participant / carer (Main version)

Stroke research study: hand and arm rehabilitation (SUSHI)

Information about the interview(s)

Thank you for participating in the SUSHI research study. We would like to invite you to take part in up to two interviews with a researcher from the University of Glasgow. This information sheet tells you what this would involve for you. Please take time to read this before deciding if you would like to take part in the interviews.

What is the purpose of the interviews?

In SUSHI we are comparing usual NHS Rehabilitation with usual NHS Rehabilitation plus rehabilitation using a SaeboGlove. As part of our comparison, it is important for us to understand patients and carers views and experiences about the type of rehabilitation patients receive. In addition, we'd like to understand what it is like to take part in this research study. The interview(s) are to ask you about what you think about the rehabilitation received and your experience of the research. This research is being undertaken as part completion of one of the study researchers Doctorate qualification in Cardiovascular Sciences Research.

Why have I been invited to take part?

You have been invited to take part because either you or someone you care for is taking part in the SUSHI study. We are inviting a small number of people who are participating in SUSHI to take part in these interviews. We are selecting people who have a range of different circumstances, such as those living in different areas in Scotland and people with different levels of arm weakness.

Do I have to take part?

No, the decision is entirely up to you. If you agree to take part, we will ask you to sign a consent form before any interview you participate in. If you change your mind, you are free to withdraw at any time without giving a reason.

What will I be asked to do if I take part?

A researcher from the University of Glasgow will arrange an appointment that is convenient for you. The first interview will typically take place at your local hospital. This interview will last no more than 1 hour. However, if you have been invited for an interview along with **[delete as appropriate your**

carer / the participant] and choose to be interviewed together it will last no more than 1.5 hours.

If we invite you to a second interview it could be done by telephone and it will last no more than 30 minutes.

The interview will be audio-tape recorded to make sure we have an accurate record of what you say.

Expenses and payments

There are no payments for participation in the interview(s). If you need to travel to a venue for the interview(s), your travel expenses can be reimbursed.

Will there be any disadvantages to taking part?

There should be no disadvantages to taking part. Some people may find it difficult to talk about rehabilitation and adjusting to life after a stroke but these are important areas for us to learn about to improve current stroke services. If there are things that come up that do upset you the interviewer will be able to give you information on who you can speak to further to gain further help / support if this is something you would like. You can stop the interview at any time if you wish.

What are the possible benefits of taking part?

There may be no benefit to you as an individual, and the care you receive will not be affected at all, but the information you provide will help us to improve services for stroke survivors in the future. Some individuals, however, do feel some personal benefit from talking about their experiences of the care received.

What else might I need to know?

All the information collected about you will be made anonymous and kept strictly confidential. The researcher will analyse all information and store it securely at the University of Glasgow. The unique identifier number you were given at the start of the trial will be used in the interviews. Any published report of the research may include anonymous quotes from your interview(s) but will not use your name or make your identity known.

What will happen to my data?

Researchers from the University of Glasgow and NHS Greater Glasgow and Clyde collect, store

and process all personal information in accordance with the General Data Protection Regulation (2018). To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information from [Enter title, name and telephone number of principal investigator].

We will collect and store identifiable information from you so that we can contact you if needed during the study. This will include your name, date of birth, address and contact details. We will keep identifiable information about you for 3 years after the study has finished. We will not pass this information to a third party without your express permission. After 3 years, your identifiable information will be destroyed, but we will store your consent form for 10 years.

The anonymous research data will be stored on a research repository call Enlighten. It will be stored here for 10 years from the time of last data access. Your rights to access, change or move the information we store may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained but will destroy your identifiable data. Once we have anonymised the research data we will be unable to withdraw your data.

Your identifiable information might be shared with people who check that the study is done properly and, if you agree, in coded form with other organisations or universities to carry out research to improve scientific understanding. Your data will form part of the study results that will be published in expert journals, a PhD thesis report and presentations.

The audio recording of your interview(s) will be destroyed within 3 months of the study finishing.

What if I have questions or concerns?

If you have any questions, concerns or issues you would like to raise you can contact either:

1. The Stroke Research Team at Glasgow University who are running the SUSHI trial: Telephone - 0141 451 5870
   Email - ggc.srunit@nhs.scot
2. Professor Jesse Dawson who is overseeing the SUSHI trial via switchboard on 0141 201 1100.

If you remain unhappy and wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you through your local hospital.

What will happen to the results of the study?

Along with the other results of the SUSHI trial, the results of the interviews will be presented at academic meetings and published in medical journals. A report will also be submitted to Chest Heart and Stroke Scotland and the Chief Scientist Office who are funding the research. You will not be identified in any report or publication. We will also send a summary of the results to all study participants. A copy of the detailed final report will also be available to participants upon request.

What happens now?

If you would like to take part in the interview(s), please contact the Stroke Research Team at Glasgow University ([Enter telephone number and email address]) to let them know. They will answer any questions you may have and will arrange a convenient time to carry out the interview(s). Taking part is completely up to you. You can say no or change your mind at any time and withdraw, without giving a reason.

Who is organising and funding the research?

The SUSHI trial is being organised and run by Glasgow University and NHS Greater Glasgow and Clyde. It is funded by Chest Heart and Stroke Scotland and the Chief Scientist Office.

Who has reviewed the SUSHI study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. The study has been reviewed by the West of Scotland Research Ethics Committee.

Thank you for taking the time to read this information sheet.

Participant information sheet – Participant / carer (Aphasia version)

Stroke research study: hand and arm rehabilitation (SUSHI)

Information about the interview(s)

Thank you for taking part in the SUSHI research study.

We would like to invite you to take part in up to two interviews .The interviews will be carried out by a researcher from the University of Glasgow.

Please read this information sheet before deciding if you would like to take part, as it explains everything that this will involve for you.

Purpose of the interviews is:

- to compare usual NHS Rehabilitation with usual NHS Rehabilitation **plus** rehabilitation using a SaeboGlove.
- to understand patients and carers views and experiences about the type of rehabilitation patients receive.
- to understand what it is like to take part in this research study.

This research is being undertaken as part completion of one of the study researchers Doctorate qualification in Cardiovascular Sciences Research.

Why have I been invited to take part?

You have been invited to take part because either you or someone you care for is taking part in the SUSHI study.

Do I have to take part?

- no, the decision is entirely up to you.
- if you agree, you will be asked to sign a consent form
- you can withdraw from the trial at any time without reason

What will I be asked to do if I take part?

- a researcher will arrange an appointment for you.
- the first interview will typically take place at your local hospital
- the interview will last no longer than 1 hour
- if both patient and carer are being interviewed together the interview will last no more than 1.5 hours.
- if you are invited to attend a second interview this could be done by telephone and will last no more than 30 minutes
- the interview will be audio-taped to make sure we have an accurate record of what you say

Expenses and payments

There is no payment for participation in the interview (s).
If you need to travel to a venue for the interview(s), your travel expenses can be reimbursed.

Will there be disadvantages to taking part?

There should be no disadvantages to taking part. We understand it can be difficult to talk about rehabilitation and adjusting to life after stroke. If any matters raised do upset you we can give you information to access further support/help. You can stop the interview at anytime.

What are the possible benefits of taking part?

There may be no benefit to you but the information you provide will help us to improve services for stroke patients in the future.

What else do I need to know?

- all information will be anonymous and kept strictly confidential
- the researcher will analyse and store information securely at the University of Glasgow
- you will be given a unique identifier number at the start of the trial and it will be used throughout the proceedings
- any quotes included in the published report will be anonymous
- your participation will not affect the usual NHS care you receive

What will happen to my data?

Identifiable Information

- researchers will collect, store and process all personal information in accordance with the General Data Protection Regulation (2018)
- we will use the minimum personally identifiable information possible to safeguard your rights
- the identifiable information collected and stored will include your name, date of birth, address and contact details
- we will hold identifiable information for 3 years after the study has finished
- we will not pass this information on to a third party without your express permission.
- identifiable information will be destroyed after 3 years
- your consent form will be stored for 10 years
- the audio recording of your interview(s) will be destroyed within 3 month of the study finishing

Anonymous Research Data

- Anonymous Research Data will be stored on a research repository called Enlighten
- the data will be stored for 10 years from the time of the last data access
- we need to manage the data in specific ways to keep the research reliable and accurate
- your rights to access, change or move the information we store may be limited
- if you withdraw from the study we will be unable to withdraw your data as it will have been anonymised
- we will retain any Anonymous Research Data but destroy Identifiable Data

Please note your identifiable information may be shared with people who check the study is done properly.

With your permission it may be shared in coded form with other organisations or universities to carry out research to improved scientific understanding.

Your data will form part of the study results that will be published in expert journals, a PhD thesis report and presentations.

What if I have any questions?

To find out how we use your information contact the Principal investigator [Insert title, name and phone number].

If you have any questions, concerns or issues you would like to raise please contact either:

1. The Stroke Research team at Glasgow University - Telephone No. 0141 451 5870 Email - ggc.srunit@nhs.scot
2. Professor Jesse Dawson, who is overseeing the SUSHI trial via switchboard on Telephone No. 0141 201 1100

If you remain unhappy and wish to complain, or have concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you through your local hospital.

What will happen to the results of the study?

Together with the other results of the SUSHI trial, the results of the interviews will be presented at:

- academic meetings
- published in medical journals and a PhD thesis report

A report will be submitted to Chest, Heart & Stroke Scotland and the Chief Scientist Office who are funding the research.

A summary of the results will be sent to all study participants, with a copy of the full detailed final report available upon request.

Please note participants will not be identified in any report or publication.

What happens now?

If you wish to take part in the interview (s) please contact:

The Stroke Research team at Glasgow University -
Telephone No. 0141 451 5870, Email – ggc.srunit@nhs.scot

Who is organising and funding the research?

The SUSHI trial is being organised and run by Glasgow University and NHS Greater Glasgow & Clyde.

It is funded by Chest, Heart & Stroke Scotland and the Chief Scientist Office.

Who has reviewed the SUSHI study?

All research in the NHS is looked at by an independent group of people called the Research Ethics Committee. This study has been reviewed by the West of Scotland Research Ethics Committee.

Thank you for taking the time to read this information sheet

Participant information sheet – Therapy staff

Stroke research study: hand and arm rehabilitation (SUSHI)

Information about staff Interviews

As part of the SUSHI research study we'd like to invite you to take part in up to two interviews with a researcher from the University of Glasgow. This information sheet tells you what the interviews would involve for you. Please take time to read this before deciding if you would like to take part. Thank you for taking the time to consider the interviews.

What is the SUSHI research study?

The SUSHI research study is a randomised controlled trial funded by Chest Heart and Stroke Scotland and the Chief Scientist Office. The trial will compare usual NHS rehabilitation with usual NHS rehabilitation plus rehabilitation using a SaeboGlove. Patients who agree to take part in the trial are randomised to one of the two groups and followed up for 6 months. SUSHI aims to recruit 110 patients from Greater Glasgow and Clyde, Lanarkshire and Lothian.

What is the purpose of the interviews?

You have been invited to take part because one of your patients is taking part in the SUSHI study. In SUSHI we are comparing usual NHS rehabilitation with usual NHS rehabilitation plus rehabilitation using a SaeboGlove. As part of our comparison, it is important for us to understand the views of professionals about these two types of rehabilitation. This will help us to understand the feasibility and acceptability of the research treatments in routine stroke care.

The interviews are designed to ask you about what you think about SaeboGlove Therapy, usual NHS rehabilitation and/or the SUSHI study procedures. Your views about usual rehabilitation and the likely benefits of SaeboGlove Therapy are important.

Why have I been invited to take part?

We are inviting a small number of professionals who are involved in delivery of care to patients participating in SUSHI. As SUSHI is being conducted at sites within Greater Glasgow and Clyde and Lanarkshire, we are inviting staff from both of these areas. Within each of these areas, we are inviting several members of staff to be interviewed, to gain information about any differences in the experiences and views of individual staff members, if these exist.

Do I have to take part?

No, the decision is entirely up to you. If you agree to take part, we will ask you to sign a consent form before any interview you take part in. If you change your mind, you are free to withdraw at any time without giving a reason.

What will I be asked to do if I take part?

A researcher from the University of Glasgow will arrange to conduct an interview at a time and location that is convenient to you, typically at your place of work. The first interview will take around 30-45 minutes (no longer than an hour). If we invite you to a second interview, it will last no longer than 30 minutes and could be done by telephone. If you agree, they will be audio recorded to make sure we have an accurate record of what you say.

Will there be any disadvantages to taking part?

There should be no disadvantages to taking part, other than the time that it takes to be interviewed. You can stop the interviews at any time if you wish.

What are the possible benefits of taking part?

There may be no benefit to you as an individual, but the information you provide will help us to improve services for stroke patients. Some individuals, however, do feel some personal benefit from providing feedback about the way services are delivered, and the impact this may have on patients who are recovering from stroke. The information you provide may help to identify any challenges that are experienced in providing rehabilitation to study participants which can be fed back (anonymously) to the project team and be used to improve the conduct of the study.

What else might I need to know?

All the information collected about you and from your interview(s), will be kept strictly confidential by the research team and not shared with any of your colleagues. We are all bound by a written code of confidentiality. This means that we must take great care to prevent anyone from outside the research team seeing any personal information about you. We understand that, as a professional working in your particular role, it may be easy for other research team members to identify you from the comments made in your interview(s), however, every care will be taken to ensure that you cannot be identified personally from this information. The researcher will anonymise research transcripts by removing any identifying information such as named locations or persons to protect anonymity and

confidentiality. Transcribed data will be analysed and stored securely at Glasgow University. Any published report of the research will not use your name or make your identity known.

What will happen to my data?

Researchers from the University of Glasgow and NHS Greater Glasgow and Clyde collect, store and process all personal information in accordance with the General Data Protection Regulation (2018). To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information from [Insert title, name and telephone number of principal investigator].

We will collect and store identifiable information from you so that we can contact you if needed during the study. This will include your name, address and contact details. We will keep identifiable information about you for 3 years after the study has finished. We will not pass this information to a third party without your express permission. After 3 years, your identifiable information will be destroyed, but we will store your consent form for 10 years.

The anonymous research data will be stored on a research repository call Enlighten. It will be stored here for 10 years from the time of last data access. Your rights to access, change or move the information we store may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained but will destroy your identifiable data. Once we have anonymised the research data we will be unable to withdraw your data.

Your identifiable information might be shared with people who check that the study is done properly and, if you agree, in coded form with other organisations or universities to carry out research to improve scientific understanding. Your data will form part of the study result that will be published in expert journals, presentations.

The audio recording of your interview(s) will be destroyed within 3 months of the study finishing.

What if I have questions or concerns?

If you have any questions, concerns or issues you would like to raise you can contact either:

1. The Stroke Research Team at Glasgow University who are running the SUSHI trial:
   Telephone - 0141 451 5870
   Email - ggc.srunit@nhs.scot
2. Professor Jesse Dawson who is overseeing the SUSHI trial via switchboard on 0141 201 1100.

What will happen to the results of the study?

Along with the other results of the SUSHI trial, the results of the interviews will be presented at academic meetings and published in medical journals. A report will also be submitted to Chest Heart and Stroke Scotland and the Chief Scientist Office who are funding the research. You will not be identified in any report or publication. We will send a summary of the results to all study participating patients and staff. A copy of the detailed final report will also be available to both patient and staff participants upon request.

What happens now?

The researcher from Glasgow University who is conducting the interviews will telephone you in a few days' time to answer any questions you may have and to ask if you would like to take part. If you decide you would like to take part, she/he will arrange a convenient time and place to conduct the interview(s). You can change your mind at any time, even if it is just before or during the interview(s).

Who is organising and funding the research?

The SUSHI trial is being organised and run by Glasgow University and NHS Greater Glasgow and Clyde. It is funded by Chest Heart and Stroke Scotland and the Chief Scientist Office.

Who has reviewed the SUSHI study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. The study has been reviewed by the West of Scotland Research Ethics Committee.

Thank you for taking the time to read this information sheet.

Consent form

SUSHI Trial	Patient ID ☐☐☐☐☐	Consent Form Interview

Consent form: Interview in SUSHI rehabilitation study

Name of Researchers:
Prof J Dawson (Professor in Stroke Medicine), Ms J Alexander (Senior Research Physiotherapist).

Contact details: [Insert title, name and phone number of principal investigator]

Please read information below and initial boxes

Please initial

1. I confirm that I have read and understand the information sheet about the interviews dated _____ (version) for the above study. ☐
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. ☐
4. I understand the interview will be recorded onto an audio-tape recorder. ☐
5. I understand that the data collected for the interview will be stored securely at Glasgow University. ☐
6. I understand that personal identifiable information will be collected by the SUSHI research team so that they can contact me if needed during the study but that it will be stored securely at Glasgow University and that I will not be identified in any study reports. ☐
7. I understand that any published report of the research may include anonymous quotes from my interview(s) but will not use my name or make my identity known. ☐
8. I agree to take part in this interview. ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of interviewer taking consent	Date	Signature

If the participant is able to give informed consent but unable to sign this consent form (e.g. because of weakness of the dominant hand following stroke), consent should be confirmed orally in the presence of a witness.

_____
Name of patient

_____	_____	_____
Name of witness	Date	Signature

(When completed, 1 for research site file (original), x1 copy for participant (copy), x1 medical notes (copy)

Appendix N – Qualitative study interview guides

Participants

Participants in SaeboGlove Therapy Group

Introduction: Interviewer introduces self and thanks participant for agreeing to be interviewed. Interviewer explains that there are no right or wrong answers to the questions we are asking as we are interested in peoples own individual experiences and thoughts.

Part 1 – How the stroke affected life

Aims:

- To learn about the participant's life before their stroke and how their stroke affected their being / life.
- This will help understand participants views and expectations of their rehabilitation in general and SaeboGlove Therapy specifically.

Plan:

Interviewer explains that we would like to understand how the stroke has affected their life so that we can get a better understanding of how rehabilitation could influence their recovery.

Indicative questions (all to be probed):

1. Can you tell me about your life before you had your stroke?
   - work/leisure/capabilities
2. Can you tell me about your experience of having a stroke and how it has affected you?
   - symptoms/activities/new help needed
3. Can you tell me a little bit about your thoughts about your recovery and how you feel your recovery is going?
   - expectation/what would be a good recovery

Part 2 – Rehabilitation Experience following stroke

Aims:

- To explore participant's thoughts about the support they have received from rehabilitation services following their stroke.
- This will help understand participant's views and expectations of their rehabilitation in general and SaeboGlove therapy specifically.

Plan:

Interviewer explains that we would like to understand how the support they received through their rehabilitation has influenced their recovery after their stroke so that we can get a better understanding of how we can improve rehabilitation support for people after stroke.

Indicative questions (all to be probed):

1. Since having your stroke, what rehabilitation services have you received?
   - stroke inpatient service, CST, GP

2. In general, how do you feel about your experience of these services (or lack of services, if indicated)?
   - Earlier you told me about some of the problems you have experienced as a result of your stroke (give examples). To what extent have your problems been addressed by the services you have received?
   - To what extent has your experience of these services met any expectation you initially had about the care you would receive?
3. What are you still hoping to achieve through rehabilitation?
   - In relation to progress made in SUSHI trial / more generally?
   - What might help/hinder you in making continued progress?

Part 3 – Involvement in SUSHI Trial

Aims:
- To learn about participant's experiences of taking part in the SUSHI Trial.
- This will help understand why participants wanted to get involved in the SUSHI trial.

Plan:

Interviewer explains that we would like to understand why they decided to take part in the SUSHI trial and how their experience being involved in the trial was.

Indicative questions (all to be probed):
1. How did you come to be involved in the SUSHI trial?
   - Can you tell me a little about why you decided to take part?
   - How was it explained to you/who by? (Make sense/unsure about anything/able to ask questions + get information needed to decide)
2. How did you feel about being allocated to SaeboGlove therapy?
3. What has it been like taking part in the trial? (compare to expectations/anything liked or disliked)

Part 4 – SaeboGlove Rehabilitation Experience

Aims:
- To explore participant's thoughts about the SaeboGlove Therapy they received following their stroke and potential barriers and enablers.
- To explore participant's thoughts about the best way to create a self-management SaeboGlove Therapy resource
- This will help understand participant's views on effective SaeboGlove therapy use.

Plan:

Interviewer explains that we would like to find out how the participant found the SaeboGlove therapy and how they feel it has influenced their recovery after their stroke.

Indicative questions (all to be probed):

1. Can you tell me about the SaeboGlove therapy you received in the SUSHI Trial?
   - To what extent have your hand and arm problems been helped by the SaeboGlove Therapy you have received? (movement/daily use in function)
   - To what extent do you feel that the SaeboGlove Therapy has benefited you generally? (personal goals/physical/emotional/social)
   - What were the challenges involved in using the SaeboGlove? (intensity/duration/content/progress/difficulty/likes/dislikes)
   - How did your experience of SaeboGlove Therapy compare with your initial expectations of it? (intensity/duration/content/progress/difficulty/likes/dislikes)
   - What do you feel has contributed most to your hand and arm recovery since you had your stroke? (usual care/SaeboGlove therapy/attitude)
   - How did you find the travelling for the SaeboGlove Therapy?

2. Think about your own experience with the SaeboGlove, how do you think other people with hand opening difficulties would find using it if it were to be made available to them routinely?

3. Based on your experience using the SaeboGlove what would:
   i) Help people to use SaeboGlove therapy successfully?
   - glove itself / therapy content / therapist support / carer support/ goals / self-management book + self-monitoring
   - before / during / after

   ii) Hinder people to use SaeboGlove therapy successfully?
   iii) Improve SaeboGlove therapy for patients?

4. Due to limited resources in the NHS if SaeboGlove therapy is introduced routinely it is likely that it would be offered for a limited time, possibly a 6 week period like in the SUSHI trial. This limited period would help ensure that all people who need it got a chance to use it but some people may be upset at the end of the 6 weeks as they want to use the SaeboGlove for longer.
   i) What do you think could be done to minimise this upset?
   ii) At the end of this study we plan to create a therapy training resource that stroke survivors can use after the initial 6wks of SaeboGlove therapy has ended if they want to. It will aim to teach stroke survivors how to use a SaeboGlove independently so that they can continue to progress their upper limb using a SaeboGlove. What kind of training resource do you think would be most helpful to stroke survivors?

Closing question:

- Is there anything else that you'd like to mention?
- When I am analysing the information I have collected today I may like to ask you a few questions to make sure I have properly understood your experience and thoughts. If this happens would you be willing for me to contact you once more to check this? You would not need to come to an appointment, I would speak to you over the phone.
- Thank participant for their time and effort.

Carers

Carers in SaeboGlove Group

Introduction: Interviewer introduces self and thanks participant for agreeing to be interviewed. Interviewer explains that there are no right or wrong answers to the questions we are asking as we are interested in peoples own individual experiences and thoughts.

Part 1 – Carers involvement with participant and SUSHI Trial

Aims:

- To learn about the carers relationship with participant and their motivation for getting involved in SUSHI Trial

Plan:

Interviewer explains that we would like to understand how the carer knows the participant and why they decided to get involved in the SUSHI Trial.

Indicative questions (all to be probed):

1. Can you tell me about how you know the participant?
2. How do you feel about your experience of the rehabilitation services the participant has received since he/she had his/her stroke?
3. Why did you decide to get involved in the SUSHI Trial?

Part 2 – SaeboGlove Rehabilitation Experience

Aims:

- To explore carers thoughts about the SaeboGlove Therapy they assisted participants to carryout following their stroke and potential barriers and enablers.
- To explore carers thoughts about the best way to create a self-management SaeboGlove Therapy resource
- This will help understand carers views on effective SaeboGlove therapy use.

Plan:

Interviewer explains that we would like to find out how the carer found the SaeboGlove therapy and how they feel it has influenced the participant's recovery after their stroke.

Indicative questions (all to be probed):

1. Can you tell me about how you supported the participant to carry out his/her SaeboGlove Therapy?
2. Can you tell me about your experience with the SaeboGlove therapy the participant carried out in the SUSHI Trial?
   i) To what extent has the participants hand and arm problems been helped by the SaeboGlove Therapy he/she received? (movement/daily use in function)
   ii) To what extent do you feel that the SaeboGlove Therapy has benefited the participant generally? (personal goals/physical/emotional/social)
   iii) What were the challenges you experienced in helping the participant carry out the SaeboGlove therapy? (intensity/duration/content/progress/difficulty/likes/dislikes)

iv) How did your experience of SaeboGlove Therapy compare with your initial expectations of it? (intensity/duration/content/progress/difficulty/likes/dislikes)
v) What do you feel has contributed most to the participants hand and arm recovery since they had their stroke? (usual care/SaeboGlove therapy/attitude)

3. Think about your own experience with the SaeboGlove, how do you think other carers would find supporting people to use it if it were made available to people with hand opening difficulties routinely in the NHS?

4. Based on your experience using the SaeboGlove what would:
   i) Help people to use SaeboGlove therapy successfully?
   - glove itself / therapy content / therapist support / carer support/ goals / self-management book + self-monitoring
   - before / during / after
   ii) Hinder people to use SaeboGlove therapy successfully?
   iii) Improve SaeboGlove therapy for patients?

5. Due to limited resources in the NHS if SaeboGlove therapy is introduced routinely it is likely that it would be offered for a limited time, possibly a 6 week period like in the SUSHI trial. This limited period would help ensure that all people who need it got a chance to use it but some people may be upset at the end of the 6 weeks as they want to use the SaeboGlove for longer.
   i) What do you think could be done to minimise this upset?
   ii) At the end of this study we plan to create a therapy training resource that stroke survivors can use after the initial 6wks of SaeboGlove therapy has ended if they want to. It will aim to teach stroke survivors how to use a SaeboGlove independently so that they can continue to progress their upper limb using a SaeboGlove. What kind of training resource do you think would be most helpful to stroke survivors?

Closing:

- Is there anything else that you'd like to mention?
- When I am analysing the information I have collected today I may like to ask you a few questions to make sure I have properly understood your experience and thoughts. If this happens would you be willing for me to contact you once more to check this? You would not need to come to an appointment, I would speak to you over the phone.
- Thank carer for their time and effort.

Therapists

Therapists with patients who received SaeboGlove therapy

Introduction: Interviewer introduces self and thanks therapist for agreeing to be interviewed. Interviewer explains that there are no right or wrong answers to the questions we are asking as we are interested in peoples own individual experiences and thoughts.

Part 1 – Staff role in stroke service and views on upper limb problems

Aims:

- To learn about therapist's role and their thoughts on the impact of upper limb problems on the lives of stroke survivors.
- This will help understand therapist's views and expectations of rehabilitation in general and SaeboGlove Therapy specifically.

Plan:

Interviewer explains that we would like to understand your role in the stroke service and your thoughts on the impact of upper limb problems on the lives of stroke survivors.

Indicative questions (all to be probed):

1. Can you tell me what your role is in the stroke service and with the stroke survivors you treat?
   - Physio / OT / Inpatient / Community / Specialised / unspecialised
2. How would you describe the impact of upper limb problems on the lives of stroke survivors?
   - symptoms/activities/new help needed
3. Can you tell me a little bit about your thoughts on how well the upper limb recovers after stroke?

Part 2 – Rehabilitation Experience following stroke

Aims:

- To explore therapist's thoughts about the support stroke survivors receive from rehabilitation services following their stroke.
- This will help understand therapist's views and expectations of the rehabilitation stroke survivors receive in general and offered through SaeboGlove therapy specifically.

Plan:

Interviewer explains that we would like to understand how the support stroke survivors receive through their rehabilitation has influenced their recovery after their stroke so that we can get a better understanding of how we can improve rehabilitation support for people after stroke through research that is informed by professionals.

Indicative questions (all to be probed):

1. After having a stroke, what rehabilitation services do patients typically receive in GGC / Lanarkshire?
   - *stroke inpatient service, CST, GP, frequency*
2. In general, how do you feel about these services *(or lack of services, if indicated)*?
   - To what extent are stroke survivors problems addressed by the services they receive?
   - Are there any particular things that you feel we should try to improve upper limb recovery for stroke survivors after stroke? (expectations / new ways of working / self-management)
   - From the perspective of the rehabilitation service the NHS provides in GGC / Lanarkshire, what things help / hinder stroke survivors to make progress?

Part 3 – Involvement in SUSHI Trial

Aims:

- To learn about therapist's experiences of the SUSHI Trial.
- This will help understand why therapist's wanted to get involved in the SUSHI trial.

Plan:

Interviewer explains that we would like to understand why he/she decided to get involved in the SUSHI trial and how his/her experience being involved in the trial has been so far.

Indicative questions (all to be probed):

1. Can you tell me a little about why you decided to get involved in the SUSHI trial?
   - Motivation?
   - How was it explained to you/who by? (Make sense/unsure about anything/able to ask questions + get information needed to decide)
2. What has it been like having a patient you are treating taking part in the trial?
   - Compare to expectations/aware of any advantages or challenges

Part 4 – SaeboGlove Rehabilitation Experience

Aims:

- To explore therapist's thoughts about the support stroke survivors received through the SaeboGlove Therapy following their stroke.
- This will help understand therapist's views and expectations of the SaeboGlove therapy.

Plan:

Interviewer explains that we would like to find out how therapist found the SaeboGlove therapy and how they feel it has influenced the participants' recovery after their stroke.

Indicative questions (all to be probed):

1. Can you tell me about your experience of your patient having a SaeboGlove?
   i) To what extent has the participants hand and arm problems been helped by the SaeboGlove Therapy he/she received? (movement/daily use in function)
   ii) To what extent do you feel that the SaeboGlove Therapy has benefited the participant generally? (personal goals/physical/emotional/social)
   iii) Were there any challenges you experienced because your patients had a SaeboGlove?
   iv) How did your experience of SaeboGlove Therapy compare with your initial expectations of it? (intensity/duration/content/progress/difficulty/likes/dislikes)
   v) What do you feel has contributed most to the participants hand and arm recovery since they had their stroke? (usual care/SaeboGlove therapy/attitude)

2. Think about your own experience with the SaeboGlove, to what extent do you feel that other therapists would find the SaeboGlove a useful tool to improve upper limb recovery?

3. Based on your experience using the SaeboGlove what would:
   i) Help people to use SaeboGlove therapy successfully?
   - glove itself / therapy content / therapist support / carer support/ goals / self-management book + self-monitoring
   - before / during / after
   ii) Hinder people to use SaeboGlove therapy successfully?
   iii) Improve SaeboGlove therapy for patients?

4. Due to limited resources in the NHS if SaeboGlove therapy is introduced routinely it is likely that it would be offered for a limited time, possibly a 6 week period like in the SUSHI trial. This limited period would help ensure that all people who need it got a chance to use it but some people may be upset at the end of the 6 weeks as they want to use the SaeboGlove for longer.
   i) What do you think could be done to minimise this upset?
   ii) At the end of this study we plan to create a therapy training resource that stroke survivors can use after the initial 6wks of SaeboGlove therapy has ended if they want to. It will aim to teach stroke survivors how to use a SaeboGlove independently so that they can continue to progress their upper limb using a SaeboGlove. What kind of training resource do you think would be most helpful to stroke survivors?

Closing:

- Is there anything else that you'd like to mention?
- When I am analysing the information I have collected today I may like to ask you a few questions to make sure I have properly understood your experience and thoughts. If this happens would you be willing for me to contact you once more to check this? You would not need to come to an appointment, I would speak to you over the phone.
- Thank therapist for their time and effort.

Appendix O – Qualitative study Consolidated criteria for reporting qualitative research interviews and focus groups (COREQ)

Table: Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No.	Item	Description
Domain 1: Research team and reflexivity		
Personal characteristics		
1.	Interviewer/facilitator	Chin Soong (CS) / Jen Alexander (JA)
2.	Credentials	Medical student / MSc
3.	Occupation	Medical student / Physiotherapist
4.	Gender	Male / Female
5.	Experience and training	Medical student / Physiotherapist and postdoctoral fellow (PhD) Both attended a training course on qualitative research methods (interview techniques, data collection and analysis), practiced semi-structured interviews using the topic guide on three volunteers (two stroke survivors and a therapy support worker) from other research studies, independently analysed data from the first two interviews in the SUSHI trial then compared patterns and themes with the specialist to enhance training and consistency across all the interviews.
Relationship with interviewees		
6.	Relationship established	CS had no prior relationship with any interviewee. JA delivered therapy reviews to all the stroke survivors/carers interviewed in this process evaluation.
7.	Interviewee knowledge of the interviewer	Participants knew that CS was a medical student helping in the SUSHI trial and that JA was a physiotherapist doing a PhD to try to identify better upper limb interventions and better ways to support people to use the SaeboGlove intervention to improve NHS stroke care.
8.	Interviewer characteristics	CS had no prior experience of stroke care or rehabilitation and was motivated to gain qualitative research experience JA had 16 years stroke rehabilitation experience and had seen little change in upper limb treatment options over her career. She was motivated to try to identify a better upper limb treatment option to help stroke survivors and to better understand the self-management support needs of stroke survivors and carers to inform her clinical / research work.
Domain 2: Study design		

Theoretical framework		
9.	Methodological orientation and Theory	Generic inductive approach using Thematic Analysis (Justified in Chapter 3)
Participant selection		
10.	Sampling	Purposive, iterative
11.	Method of approach	Email/mail
12.	Sample size	18 (7 stroke survivors, 5 carers, 3 physiotherapists, 3 occupational therapists)
13.	Non-participation	No refusals for initial or follow-up interviews and no dropouts
Setting		
14.	Setting of data collection	Private room in hospital typically during stroke survivors' inpatient stay (stroke survivor, carer) or during work hours (therapist)
15.	Presence of non-participants	Invited, consenting carers if stroke survivor and carer preferred to be interviewed together
16.	Description of sample	**Stroke survivors:** To ensure representation of stroke survivors differing in gender (male, female), age (≤65 years, >65 years) time since stroke (≤1 month, >1 month), severity of upper limb disability (ARAT 0-10, 11-28), informal carer support (informal carer / no informal carer) **Informal carers:** To ensure representation of informal carers providing therapy support (acting as sole carer, sharing care with formal carer(s)) to stroke survivors differing in the stroke survivor characteristics sampled **Therapists:** To ensure representation of therapists according to discipline (occupational / physiotherapist), experience (post seniority: band 5 rotational, band 6 rotational, band 6 stroke specialist) and their exposure to stroke survivors differing in carer support (informal carer / no informal carer)

Data collection		
17.	Interview guide	Provided (Appendix N) and piloted
18.	Repeat interviews	No repetition at later time points Two stroke survivors were contacted for a brief follow-up interview to seek clarity/ensure correct interpretation (prolonged engagement)
19.	Audio/visual recording	Audio
20.	Field notes	Yes, written immediately after interviews
21.	Duration	First – 1 hour (individual), 1.5 hour (stroke survivor & carer together) Second – maximum of 30 minutes
22.	Data saturation discussed	Yes, recruited until no new data emerged (saturation) to improve transferability of findings to target population
23.	Transcripts returned	No, transcripts were not returned to participants. A pragmatic view was adopted in the SUSHI study (Chapter 3), assuming that truth is not static but always changing in response to time, place, environment and experience (Johnson and Onwuegbuzie 2004). This is a recognised challenge with member checking as interviewees may wish to reconstruct/change their narrative as they are embarrassed by seeing their words written down or no longer feel this is their truth raising concerns over their truth status e.g. are their words less true when "checked" than they were when they were first spoken or not (Forbat and Henderson 2005; Birt *et al*. 2016). For this reason, transcripts were not returned to interviewees for comment and/or correction.
Domain 3: Analysis and findings		
Data analysis		
24.	Number of data coders	Two first 10 (CS and JA independently), One last 8 (JA)
25.	Description of the coding tree	Yes – 4 themes, 12 subthemes (Table 44)
26.	Derivation of themes	Derived from the data from verbatim transcripts from interviews with stakeholders (stroke survivors, carers, and therapists). This was completed through process of peer review prior to knowing the results of the RCT in the SUSHI trial.
27.	Software	Trint to transcribe data Microsoft word to organise data
28.	Participant checking	Lay summary of findings was sent to interviewees to check for accuracy and resonance with their experiences to explore credibility (Appendix P)

Reporting		
29.	Quotations presented	Yes
30.	Data and findings consistent	Yes, between different methods (field notes, audio recording & transcription), sources (stroke survivors, informal carers & therapists, two health boards) and researchers (JA, CS, LK, JD)
31.	Clarity of major themes	Yes – 4 major themes were reported
32.	Clarity of minor themes	Yes – 12 minor themes. Deviant cases (outliers) were also acknowledged to optimise successful implementation / transferability of findings

ARAT: Action research Arm Test. Table populated with study description from Tong, A., Sainsbury, P. and Craig, J. (2007) 'Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups', Int J Qual Health Care, 19(6), 349-57, available: http://dx.doi.org/10.1093/intqhc/mzm042, by permission of Oxford University Press.

Appendix P – Qualitative study lay findings

SUSHI: SaeboGlove therapy for Upper limb disability and Severe Hand Impairment early after stroke

Summary of the Research

What we did



From: Saebo Ltd

We are **researching a new rehabilitation device called a SaeboGlove**, which **we hope will help people** with **severe hand weakness** after stroke to **recover better**. As part of this research we **wanted to find out how we can best support people** who have just suffered a stroke and severe hand weakness **to self-manage their upper limb recovery**.

The purpose of the research was to **learn the best ways for NHS staff to support people with stroke to use this therapy successfully if** it is beneficial and **introduced into the NHS** routinely.

Glossary:
Self-management: the actions that people take to look after themselves well, to feel confident and in control and to cope with any lasting effects that they experience after a stroke.

Supported self-management: the ways that health and social care professionals encourage, support, and empower people to develop the skills and confidence to self-manage well.

How we did it



From: NHSS Picture Library

We spoke to four groups of people from hospitals in Greater Glasgow & Clyde and Lanarkshire who were involved in this therapy:

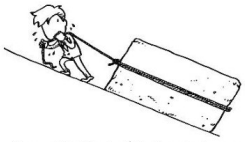
- **stroke survivors** who received this therapy
- **carers** who supported this therapy
- **stroke occupational and physiotherapists** who supported the stroke survivor's overall recovery

We used a method called **Thematic Analysis**. This method helped us **understand things that helped and hindered people to use this therapy** to inform future support provided.

What we found

Our research had four main findings for NHS staff to consider to successfully support stroke survivors to use this therapy. The first three apply to any rehabilitation after stroke including the SaeboGlove therapy and the fourth only applies to the SaeboGlove therapy.

Finding 1: Rehabilitation is hard work



From: Pita Design/Shutterstock.com

All four groups felt that **rehabilitation** after stroke (NHS and SaeboGlove therapy) **is a demanding process**:

- **Physically** – as it requires **sustained physical effort**
- **Emotionally** – as it can **bring up challenging emotions** e.g. sadness, frustration, uncertainty, and fear of trying & failing

One **carer** told us how **striving for progress** in therapy made it **hard work physically** and **emotionally**

'…**every time [we went to a SaeboGlove therapy review**] **we knew** that within the two-week period [between review visits] that was where we we're going to [progress to]…we kind of knew that **the next stage would be difficult**…**we felt a wee bit deflated**…**that there's more hard work**.'

Carer

Finding 2: The rehabilitation effort and help required to support it are greater when stroke survivors have stronger or more stroke symptoms



From: Macrovector/ Shutterstock.com

All four groups felt that **the physical and emotional work and support required** to take part in rehabilitation **is greater when stroke survivors have stronger or more stroke symptoms** (e.g. problems with movement, sensation, mood, memory etc). Besides movement problems, **fatigue** was the **most common symptom** mentioned and was felt to make **balancing rehabilitation with rest and other commitments** more **challenging.**

One **therapist** told us that there are **many symptoms** after stroke that can **make rehabilitation more difficult**

'Obviously with such a significant change [to life after a stroke]…if somebody is quite **low in mood** and lacking motivation **it can be very hard to** get them to **engage** in the whole [rehabilitation] process and…then [i**t can also be hard] if they are unable to follow instruction**…or if they are…**lacking insight** into where they are at [rehabilitation is more challenging]…and then obviously **if their speech has been affected** [and]…quite a big symptom from stroke is **fatigue** so they just can't be in a gym setting with you chucking loads of stuff at them…'

Physiotherapist

Finding 3: More upper limb therapy and motivating therapy tasks are needed/wanted to help regain normality



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All four groups felt that **more upper limb therapy and more motivating therapy tasks were needed/wanted** to improve upper limb recovery as:

- **Regaining normality lost due to upper limb problems** was felt to be **important**
- Although therapy was hard work **therapy opportunities** were **valued to help restore normality**
- Without the SaeboGlove therapy **upper limb rehabilitation time** was felt to be **limited** e.g. sometimes NHS pressures to discharge people home quickly meant that **improving mobility or independence in washing, dressing and meal preparation without using the affected upper limb were prioritised** in hospital. Often **therapy** was **delayed for several weeks after discharge** home. Also, **the limited function** required **in a hospital environment** was felt to **mask how much the affected hand was needed and would normally have been used until** more complex everyday tasks were introduced around **discharge home** e.g. during kitchen practice, when less help was available at home.
- Without the SaeboGlove therapy **rehabilitation tasks were often felt to be too difficult or to lack variety and relevance to the recovery of normal everyday tasks** e.g. involved **cones and marbles instead** of useful everyday objects like **a glass, bottle, hair dryer or cutlery**
- Without the SaeboGlove therapy **upper limb therapy and motivating therapy tasks** were felt to be **particularly limited in stroke survivors who had more severe upper limb problems** and the greatest disruption to normality. This was often because therapists felt that:
    - **There was a real lack of motivating tasks that this group could manage as they had too little movement**

- **Upper limb recovery was often poor compared to the lower limb and mobility, especially when upper limb weakness was more severe, and**
- It was **more useful to divert limited resources** to other types of rehabilitation that were more fruitful e.g. to mobility practice or faster progressing stroke survivors **to facilitate discharge**.

One **stroke survivor** told us that although therapy took effort, he **wanted more therapy** as he **valued** it to **improve his function and normality.** He also expressed that **usual NHS upper limb therapy** was **unspecific** i.e. felt to **lack relevance to** recovery of his **normal everyday tasks**

'**More physiotherapy** [is valuable to my recovery], **I benefit from physiotherapy**…**I want to get back to work**, I want to ride **my bike**…I enjoy it. **It keeps me fit**…I **play with my children**…**gardening**…These are **all drivers** for me [to participate in rehabilitation], big [drivers]…Sometimes **it's [SaeboGlove therapy] a real effort, but I don't hide from that**…[as it] **gives me a better functionality**…I have had some **[usual NHS] arm physiotherapy**…and… **it was vague and unspecific**…It enabled me to **lift a large cone** [or] to **lift a bouncy ball** and put it…in a cone for example…'

Stroke survivor

Three **therapists** told us why they felt **more upper limb therapy was needed/wanted**

'…it [the impact of **upper limb problems** on the lives of the stroke survivors] seems to have a **massive impact [on life]**…But I think when you're **limited in [time and staffing]**…sometimes your **focus is on** obviously **sitting balance…standing, walking** and then you might do a bit of upper limb [therapy] but probably not as much as we should be doing…Yes [I think this reduced prioritisation **impacts upper limb recovery**]…[This trial] has really reiterated…how **important** it is to **spend** a lot of **time on the upper limb'**

Physiotherapist

'…if somebody has got like **no movement at all...you are…limited** [in what you can do in therapy]…**it is…more passive stretches**… kind of [teaching] more **compensatory [one, not two, handed] techniques [instead of upper limb functional recovery]**…how **to get dressed**…**the easiest way basically**…themselves… **discharge planning from the beginning'**

Occupational therapist

'…the **upper limb** is definitely much **harder to get recovery** compared to the lower limb…it can just be quite difficult to work on [the upper limb] if somebody's got a really **dense weakness, you are quite limited to what you can do** with them…**stretching** and good **positioning** of the upper limb and **doing little exercises** if the patient's able to…Whereas [with the **SaeboGlove therapy**] he was able to **spend more time working on his grasp** and his, em, **functional tasks**…it has certainly **come on quite a bit**…' Physiotherapist

Finding 4: The SaeboGlove therapy provided in the trial is acceptable, motivates and supports stroke survivors to self-management their rehabilitation and recovery



ACCEPTABLE

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All four groups felt that the SaeboGlove therapy created positivity and supported ongoing participation. There were four main reasons for this:



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1. **<u>Hope and Expectations</u>: It made sense that the help provided** by the SaeboGlove, carer (if/when needed) and therapist **could make it easier for people with hand opening difficulties to take part in more upper limb therapy and** in **more motivating therapy tasks** that had a clear link **to improving normality** (e.g. tasks to regain the ability to drink, open containers or blow dry hair). This **created renewed hope** and a sense that taking part was an **opportunity for stroke survivors to gain some control over their recovery**.

   All stroke survivors needed assistance to get the SaeboGlove on at first (e.g. due to weakness) and some people from all groups felt that it looked complicated at first sight. However, **some stroke survivors gained independence putting the glove on** due to improved movement or familiarity as therapy progressed **and it was felt to be easy to use the glove after demonstration and first-hand use (with a carer if/when needed)**. Despite any challenges **the SaeboGlove therapy appeared to fulfil or even exceed expectations**.

2. **<u>Efforts were rewarded with progress and through structure</u>: When the SaeboGlove therapy started efforts invested were** felt to be **rewarded with useful progress** that

improved normality and **this maintained hope and motivation to continue** the SaeboGlove therapy.

Examples of progress included: Going from no hand movement to **hand movement**, curled fingers and a droopy wrist to **straight fingers and the ability to move the wrist**, needing the glove on to do an everyday task in therapy to **not needing the glove**, not using the hand in normal everyday life to **using the hand habitually**, doing little movement to **doing more movement before becoming fatigued**, having slow or no progress to having **clearer/faster progress in the recovery of desired movements**.

The structure of the therapy helped to highlight this progress: The **structure of the SaeboGlove therapy was helpful** (use of **everyday objects** during the therapy, providing **harder exercises**, **reducing, or stopping glove use early** as less/no help was needed from it, **recording the daily movement numbers** against a target, **comparing movement quality** against movement advice provided e.g. in take-home instructions). This was because it **supported stroke survivors/carers** to follow the therapy with confidence, overcome difficulties (e.g. recall uncertainties) and **highlighted relevant progress** was being made.

Six weeks was felt to be **long enough to use the glove** as it was stopped before this in most stroke survivors and **progress** was felt to be **possible without it within/after this time**. However, **to stay motivated** to continue therapy **when glove use had stopped it was** felt to be **important that exercises provided** at that point clearly **built on progress already made**. **Increasing glove use to eight weeks** was also **felt to be** a **reasonable** measure **to maintain therapy motivation** if a stroke survivor, **on occasion**, felt that this would be beneficial to their progress.

3. **Physical and emotional support for daily practice:** The **structure of the glove provided physical assistance** which **helped** stroke survivors **make more movement more easily**. **Carers also supported therapy physically** (e.g. to get the glove on) **and emotionally** (e.g. to help remember exercises taught, lead recording of daily movement numbers, highlight progress) **making therapy less challenging**.

4. **<u>Physical and emotional support from therapist experience, alliance, and expertise</u>:** The **previous rehabilitation experience** of the **SaeboGlove therapist** meant that **therapy information/guidance** from her on how rehabilitation and recovery normally worked **was sought and trusted**. This **trust was felt to be increased** when therapy started **as the therapist** demonstrated a **shared effort** with stroke survivors/carers **in their quest for improved normality**.

   The therapist's expertise was important to maintain motivation, coping and positivity by:

   - Providing **guidance on efforts and progress made** to make sure they were 'right' and would be 'worthwhile' as they were expected to lead to desired progress
   - **Linking therapy tasks to desired everyday life tasks**
   - **Setting exercises and repetition targets at** the **'right' difficulty level** and providing **take-home instructions** that all **accommodate individual abilities and preferences**
   - **Providing advice** to help stroke survivors **organise daily therapy** to **manage their fluctuating daily challenges** positively and with confidence (e.g. by altering exercise number, type (easier/harder), timing, order or by staggering or even missing them for a day if there was a good reason to, such as significant fatigue).

One **stroke survivor** told us how the different parts of the **SaeboGlove therapy helped with her rehabilitation and recovery**

'It's [the SaeboGlove therapy] a package…[without the glove on my floppy wrist is] not resembling how my hand would look in the future…I would feel like miles behind…If I had it on…it gave me a sense of [hope like]…I'm getting more towards it [where I want to be]…[But]…what came with the glove was direct instructions…why you would do that particular exercise, what would it lead to.. the dialogue we've had…it's very important, [the research physiotherapist could] tell me what can happen, what will happen…the expertise…the enthusiasm that's come from [her]…praise is given for our attempts. And we began to realise we are getting this right… And then [the research physiotherapist] would help me with a new [harder] set of exercises…And also [my partner] would tell me if I was doing [it] wrong…I couldn't have done the glove [got it on without his help because of], the amount of mobility I had [in my hand] at the start…the repetition, the practise, the record[ing] of movement repetitions], all of that structure will help you…we videoed [the research physiotherapist] helping me…that [video]…was far better [for me] than having written instructions. We just wanted to do it correctly and effectively… And we saw it [progress] daily... I've got enough movement to not feel I want to put the glove on [now]…[I've] starting to write legibly…[I'm] delighted to be part of it…' Stroke survivor

One **carer** told us how the different parts of the **SaeboGlove therapy helped with her partners rehabilitation and recovery**

'…he's so keen to get back to full strength [i.e. he is hopeful]… that he's…welcomed [the]…opportunity…to…take part [in the SaeboGlove therapy]…in terms of motivation, it's really been a good thing because it's given him a goal [that he has hope of achieving]…something [positive] to…focus on…And I think the progress has been great…So emotionally, I find that quite a good thing for him as well as physically…I've been helping him put on his glove…take it off and…with doing the exercises. He's become…more independent [with it] over the last two weeks…I'm just trying to…do what I can to…make things easier and keep us, keep him going… [The research physiotherapist] is very good at…pitching [the therapy] at the right level…tasks…aren't too frustrating and aren't too easy…[she guides us with] how many reps to do…to [accommodate] individual needs and abilities…he [my partner] would get fatigued…and [the research physiotherapist] kind of said you do have to prioritise [balance rest and exercise, ward and SaeboGlove therapy]. So I think we've tried our best to do it…that's improved over time…' Carer

Implications for future

The findings from this project have helped us to **understand** more about **how supported self-management works after stroke** and **what helps and hinders people to do it**.

The findings will help us to develop **recommendations for NHS staff** to **better support people to use this new therapy** early after stroke. It will also inform the **provision of other upper limb self-management approaches** after stroke that are tailored to the needs of stroke survivors and their carers.

Quote from patient and carer advisory group member

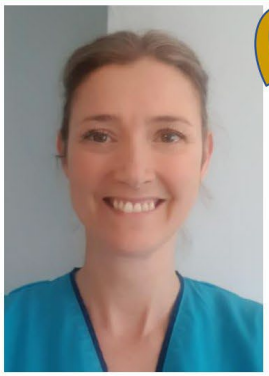




Steven, Angela, Charlie & Pauline considered the therapy provided in the SUSHI trial and reflected on factors that influence a person's ability to self-manage their upper limb recovery early after stroke

'The SaeboGlove…catalysed my progress…I felt nurtured…and was achieving…Goals were set…it [The SaeboGlove Therapy provided] was a joined-up approach, being Team, carer, and the Glove. This provided me with the physical and emotional support I needed…when fatigue was a major issue for me.'

Quote from researcher



Jen Alexander, Physiotherapist and Investigator in the SUSHI study, reflecting on the value of the project findings

'People with severe hand weakness after stroke often have very little hand movement. This can make it very difficult for therapists to offer them motivating upper limb therapy tasks and self-management training opportunities to improve their upper limb recovery.

The SUSHI trial has helped us to understand more about what hinders and helps this group to participate in meaningful upper limb rehabilitation after stroke.

Although this group has severe hand weakness, the SaeboGlove therapy was felt to be an acceptable and supportive treatment. This suggests that it met their rehabilitation support needs.

Going forward, this information will help the NHS develop more accessible and motivating upper limb treatments including self-manage strategies that empower this group to improve their upper limb recovery.'

Glossary

Compensation-based recovery	Recovery that occurs when neural circuits initially disturbed are not restored, and when movement patterns and functional tasks performed prior to stroke are not able to be performed in the same manner i.e. they are performed using abnormal patterns of movement, less frequent use in everyday life tasks and often with the reliance on body parts or aids not previously used.
Complex intervention	An intervention with multiple interacting components and/or where the outcome of the intervention relies on the behaviours of those delivering and receiving it.
Confirmability	The degree to which the findings of the research study could be confirmed by other researchers. Confirmability is concerned with establishing that data and interpretations of the findings are not figments of the inquirer's imagination, but clearly derived from the data.
Confirmatory research	A form of research that confirms or disputes an existing theory / hypothesis e.g. a suspected relationship between two phenomena.
Constraint induced movement therapy	A specialised form of repetitive, functional-based training practiced for six hours a day for two weeks that additionally involves behavioural strategies - constraining the non-paretic arm with a mitt to promote use of the weak arm for 90% of waking hours and training to transfer skills gained in a clinical setting into a real-life environment.
Credibility	The confidence that can be placed in the truth of the research findings. Credibility establishes whether the research findings represent plausible information drawn from the participants' original data and is a correct interpretation of the participants' original views.
Data saturation	The stage in qualitative research when sufficient data have been gathered to allow for appropriate conclusions to be made. Often considered to be the gold standard for determining the end point of qualitative analyse.
Dependability	The stability of findings over time. Dependability involves participants' evaluation of the findings, interpretation and recommendations of the study such that all are supported by the data as received from participants of the study.
Dynamic Hand Orthosis	A rehabilitation aid that is designed to assist digital extension and enable improved access to functional-based upper limb activities.
EMPOWER Help for Hands Programme	A tailored supported self-management programme that aims to improve upper limb functional recovery through the practice of self-

	directed, repetitive, functional-based movements (typically 100 daily) using a dynamic hand orthosis (SaeboGlove) and the transfer of skills gained in therapy into real-life tasks.
Epistemology	The study of what a discipline believes to be acceptable knowledge.
Exploratory research	A form of research that explores a topic to generate a new theory / hypothesis e.g. to understand what factors appear to influence a phenomenon of interest.
External validity	The degree to which findings can be generalized to other settings similar to the one in which the study occurred.
Fidelity of an intervention	The degree to which an intervention programme (e.g. content, dose, reach) is implemented as it was intended by the program developers i.e. the degree that clinician's adherence to and patients' engagement with the intended implementation.
Functional-based training	Training that directly involves the practice of functional everyday life tasks or the practice of movements likely to enhance the performance of functional-based tasks.
Generic inductive approach	An approach to qualitative analysis supported when the focus of the research is to explore the core meanings, or describe the most important themes, evident in the text, relevant to the research objectives.
Graded, repetitive, arm supplementary program	A supplementary upper limb rehabilitation programme involving a combination of range of movement, strengthening and functional based exercises.
Haemorrhagic stroke	A stroke that occurs as a result of a blood vessel bursting either within the brain (intracerebral haemorrhage) or on the surface of the brain (subarachnoid haemorrhage).
Internal validity	The degree to which findings correctly map the phenomenon in question.
International Classification of Functioning, Disability, and Health	A biopsychosocial framework for the classification of health components (impairment of body functions / structures, activities, participation, personal and environmental factors) that influence functioning and disability.
Ischaemic stroke	A stroke that occurs because of an artery or small blood vessel deep in the brain becoming blocked due to the formation of a blood clot or other matter (e.g. fatty deposit) in the circulatory system.
Mixed methods research	The collection and integration of both quantitative and qualitative data to gain a more comprehensive understanding of the research problem.

MRC framework guidance for complex interventions	A framework to help researchers and research funders develop and evaluate complex interventions with a diversity of perspectives and appropriate choice of methods.
Neuroplasticity	A process where neural networks structurally reorganize and develop in response to learning-dependent mechanisms, including therapy experience.
Non-robotic Dynamic Hand Orthosis	A dynamic hand orthosis that is not controlled by a computer program, sensory feedback, or information processing.
Objectivity	The extent to which findings are free from bias.
Ontology	The study of the nature of reality / truth.
Outcome evaluation	A research method that involves measuring the change in a health care outcome of interest in response to an intervention in order to assess if it is effective and by how much.
Peer debriefing	A process in qualitative research that involves peer review to check for researcher bias and to review data and the final themes/subthemes to ensure all interpretations were considered and are true to the data collected.
Process evaluation	A research method that involves understanding the functioning of an intervention (i.e. why, how and in what circumstances it works), by examining implementation, mechanisms of impact, and contextual factors.
Prolonged engagement	A practice in qualitative research where researchers seek sufficient familiarity of the context surrounding a person's experience of interest to ensure correct interpretation.
Qualitative research	The collection of qualitative (i.e. non-numerical) data (e.g. text / audio from interviews or focus groups), and the use of analytical methods that identify common patterns or themes which contribute to the generation of a new hypothesis (inductive reasoning).
Quantitative research	The collection of quantitative (i.e. numerical) data, and the use of statistical techniques to test a theory / hypothesis (deductive reasoning).
Reach of an intervention	The proportion of the intended population that participates in an intervention designed for them.
Reliability	The extent to which findings can be replicated or reproduced by another investigator.
Researcher reflexivity	A gold standard method to determine trustworthiness in qualitative research by giving systematic consideration to the context in which knowledge is constructed, particularly the researchers background and role to influence the study.

Robotic Dynamic Hand Orthosis	A dynamic hand orthosis that is controlled by a computer program, sensory feedback, or information processing.
Self-efficacy	The confidence an individual has that they have the capacity (e.g. knowledge/tools/support) to take worthwhile action to enable them to fulfil their rehabilitation goal(s).
Self-management	A process in which individuals acquire skills, strategies, and knowledge to manage the physical, psychological, emotional, and social effects of a chronic condition.
Spasticity	An intermittent or sustained involuntary activation of muscles resulting from an upper motor neurone lesion.
Stroke	Rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin.
Thematic analysis	A method for analysing qualitative data that aims to identify and understand emerging themes within a dataset using a six stage approach; familiarisation with the data, generating preliminary codes, searching for themes among the codes, reviewing the themes, defining and naming the chosen themes and producing the final report.
Transferability	The degree to which the results of qualitative research can be transferred to other contexts or settings with other respondents. The researcher facilitates the transferability judgement by a potential user by providing a thick description of context.
True recovery	Recovery that occurs when neural circuits initially disturbed are restored, and when movement patterns and functional tasks performed prior to stroke are able to be performed in the same manner i.e. with normal patterns of movement and the same frequency of use in everyday life tasks.

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