

Hunter, Janie Moira (2017) A video intervention to improve treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI): a feasibility study. D Clin Psy thesis.

http://theses.gla.ac.uk/8471/

Copyright and moral rights for this work are retained by the author

A copy can be downloaded for personal non-commercial research or study, without prior permission or charge

This work cannot be reproduced or quoted extensively from without first obtaining permission in writing from the author

The content must not be changed in any way or sold commercially in any format or medium without the formal permission of the author

When referring to this work, full bibliographic details including the author, title, awarding institution and date of the thesis must be given

Enlighten:Theses http://theses.gla.ac.uk/ theses@gla.ac.uk



"A video intervention to improve treatment motivation and selfawareness in people with moderate to severe acquired brain injury (ABI): a feasibility study"

And Clinical Research Portfolio

Janie Moira Hunter

M.A. (Hons)(SocSci)

Submitted in partial fulfilment of the requirements for the degree of

Doctorate in Clinical Psychology

Institute of Health and Wellbeing

College of Medical, Veterinary and Life Sciences

University of Glasgow

September 2017



Declaration of Originality Form

This form **must** be completed and signed and submitted with all assignments.

| Please complete the information bel | ow (using BLOCK CAPITALS). |
|--|---|
| Name JANIE HUNTER | |
| Student Number 0306004H | |
| Course Name | Doctorate in Clinical Psychology |
| Assignment Number/Name | Clinical Research Portfolio |
| An extract from the University read carefully THEN read and s | 's Statement on Plagiarism is provided overleaf. Please sign the declaration below. |

| I confirm that this | assignment is | my own work and | that I have: |
|---------------------|---------------|-----------------|--------------|
|---------------------|---------------|-----------------|--------------|

Read and understood the guidance on plagiarism in the Doctorate in Clinical Psychology Programme Handbook, including the University of Glasgow Statement on Plagiarism

Clearly referenced, in both the text and the bibliography or references, **all sources** used in the work

Fully referenced (including page numbers) and used inverted commas for **all text quoted** from books, journals, web etc. (Please check the section on referencing in the 'Guide to Writing Essays & Reports' appendix of the Graduate School Research Training Programme handbook.)

Provided the sources for all tables, figures, data etc. that are not my own work

Not made use of the work of any other student(s) past or present without acknowledgement. This includes any of my own work, that has been previously, or concurrently, submitted for assessment, either at this or any other educational institution, including school (see overleaf at 31.2)

Not sought or used the services of any professional agencies to produce this work

In addition, I understand that any false claim in respect of this work will result in disciplinary action in accordance with University regulations

DECLARATION:

I am aware of and understand the University's policy on plagiarism and I certify that this assignment is my own work, except where indicated by referencing, and that I have followed the good academic practices noted above

Signature

Date September 2017

ACKNOWLEDGEMENTS

First and foremost I would like to say thank you to all the participants who gave their time to take part in this project. To the service users who shared their experiences, and the staff at Graham Anderson House who helped with recruitment and getting the project off the ground - this research would not have been possible without you.

My sincerest thanks go to my research supervisors Dr Hamish McLeod and Professor Tom McMillan. I have valued your insight, support and wisdom throughout this project, and especially appreciated your reassurance at times when I felt disheartened. Further thanks go to Dr Brian O'Neill for all your guidance in this research, and also imparting your knowledge and humour along the way. I am truly thankful to you all, and I am lucky to have worked with such inspiring experts in this field.

I am most grateful to NHS Education for Scotland and the University of Glasgow, for providing me with this training opportunity. I am especially thankful to my placement supervisors who have provided guidance and support throughout my training. Thank you all for challenging me to continue developing my skills, and helping me learn about the kind of Clinical Psychologist I want to be.

To the DClinPsy class of 2014-2017: You have been the greatest source of motivation, laughter, strength and advice (and a lot of cake) over the past three years, and without doubt have been a highlight of my training experience. I have nothing but amazing memories from our class shenanigans, and have made friends for life. Thank you.

To my friends, family and in-laws who provided me with support and much needed distractions, thank you for your continued encouragement and patience. The past six months especially have been made bearable with an endless supply of doggy cuddles, gifs, gin, and cheerleading; I'm so fortunate to have you all.

A special thank you to my mum Caroline in particular, who has lived every step of my journey with me since long before training, providing unwavering support and enthusiasm. For as long as I can remember she has always believed in me as I strive for my achievements. Mum, I love you, you are the reason I have come so far. Thank you for everything.

Finally, to Garry. You have been an incredible source of love and support, and your unfalteringly belief in me has kept me going when I have felt overwhelmed. Thank you for celebrating my successes with pride, making me smile every day, and sticking with me through this stage of our adventures together. Let's go get married.

TABLE OF CONTENTS

| CHAPTER ONE: SYSTEMATIC REVIEW 5 |
|--|
| "A SYSTEMATIC REVIEW OF EFFICACY OF INTERVENTIONS TO INCREASE MOTIVATION AFTER ACQUIRED BRAIN INJURY (ABI)." |
| CHAPTER TWO: MAJOR RESEARCH PROJECT |
| "A VIDEO INTERVENTION TO IMPROVE TREATMENT MOTIVATION AND SELF-AWARENESS IN PEOPLE WITH MODERATE TO SEVERE ACQUIRED BRAIN INJURY (ABI): A FEASIBILITY STUDY" |
| APPENDIX 1: SYSTEMATIC REVIEW64AUTHOR GUIDELINES FOR SUBMISSION TO NEUROPSYCHOLOGICAL REHABILITATION65COCHRANE RISK OF BIAS - SUMMARY OF BIAS TYPES71COCHRANE RISK OF BIAS - ROBINS-I TOOL SUMMARY OF BIAS TYPES72COCHRANE RISK OF BIAS - FRAMEWORK FOR FORMULATING SUMMARY ASSESSMENTS OF RISK OF73 |
| APPENDIX 2: MAJOR RESEARCH PROJECT |

| MAJOR RESEARCH PROJECT PROPOSAL | |
|---|-------------|
| ETHICS COMMITTEE APPROVAL LETTERS | |
| BIRT APPROVAL LETTER | 94 |
| MOTIVATION FOR TRAUMATIC BRAIN INJURY REHABILITATION QUESTIONNAIRE (MOT-Q | <u>)</u> 96 |
| AWARENESS QUESTIONNAIRE (AQ) – CLINICIAN FORM | 98 |
| AWARENESS QUESTIONNAIRE (AQ) – PATIENT FORM | |
| PITTSBURGH REHABILITATION PARTICIPATION SCALE (PRPS) | 102 |
| THE STRUCTURED ASSESSMENT OF FEASIBILITY MEASURE (SAFE) | |
| INFORMATION SHEET FOR STAFF PARTICIPANTS | 108 |
| CONSENT FORM FOR STAFF PARTICIPANTS | |
| INFORMATION SHEET FOR INPATIENT PARTICIPANTS | 112 |
| CONSENT FORM FOR INPATIENT PARTICIPANTS | 116 |
| GP LETTER | |
| REHABILITATION PREPARATORY VIDEO SCRIPT | 119 |
| RELIABLE CHANGE INDEX CALCULATION METHODS | 122 |
| | |

CHAPTER ONE

SYSTEMATIC REVIEW

"A systematic review of efficacy of interventions to increase motivation after acquired brain injury (ABI)."

Janie Moira Hunter* M.A. (Hons)(SocSci)

Word count (including abstract and references): 9099

* Mental Health and Wellbeing, Institute of Health and Wellbeing, University of Glasgow
Address for correspondence:
Mental Health and Wellbeing
1st Floor, Admin Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Tel: 0141 211 3927

Prepared in accordance with submission requirements for Neuropsychological Rehabilitation (See Appendix 1.1)

ABSTRACT

Background: Motivational problems are commonly observed after acquired brain injury (ABI) and improving motivation is a common challenge faced in ABI rehabilitation settings. We need to know more about how individuals can be engaged more readily in rehabilitation and treatment. Because such motivation difficulties likely arise from varying causes, and are defined and categorised differently across the ABI literature the treatment evidence base needs clarification and analysis.

Aims: To systematically review the different ways in which motivation is understood and to analyse the evidence of the efficacy of interventions for improving motivation in ABI.

Method: A systematic literature search was conducted of electronic databases. Eligibility criteria were devised and included studies were assessed on methodological quality using study-design specific assessment of risk of bias.

Results: Of the seven included studies, all but one were rated as 'high' risk of bias. Methodology and design was disparate across studies. Interventions demonstrating improvement in motivation included those based on behavioural approaches aimed at compensating for frontal/executive dysfunction; the use of feedback to increase selfawareness; the use of technology in interventions; and therapeutic interventions addressing mood and emotional impact of lack of motivation. Approaches towards definitions of motivation also varied, from uni-dimensional to multi-factor representations. Factors implicated include cognitive, affective, behavioural, and selfawareness components.

Conclusions: There is a scarcity of studies with an explicit focus on improving motivation after ABI, and a high degree of variation in the methodology of interventions. Further high quality research is needed, and should hold in a mind a multi-dimensional characterisation of motivation.

INTRODUCTION

Acquired brain injury (ABI) can cause a number of physical, cognitive and behavioural sequelae. Apathy, a deficiency in behavioural, emotional and cognitive components of goal-directed behaviour, is common after ABI; Prevalence rates suggest up to 61% of the TBI population exhibit apathy, 60% of the population who have suffered a focal frontal lesion, and 34.7% of the population who have experienced a stroke (van Reekum et al., 2005). Motivational problems and apathy are difficult to assess and characterise as they can be caused in different ways (Oddy et al., 2008). For example, a primary neuropathological insult may lead to physiological symptoms such as fatigue and physical disability, or affect areas of the brain linked to goal-direction motor functioning, or executive functioning. A lack of insight into ABI sequelae may mean an individual is unaware of the necessity for certain actions or tasks. Additionally, mood and emotional symptoms following ABI, such as depression or anxiety, may lead to a loss of interest, or low self-esteem and lack of belief in abilities to complete tasks. Adjustment to disability and other difficulties may also increase helplessness and dependence, whereby an individual is not motivated to pursue actions, as they rely on others. Thus, we can consider the possibility that a number of diverse pathways may lead to the end 'observable state' of motivational problems. Regardless of the cause, poor motivation as a behavioural problem following ABI leads to a reduction in goaldirected behaviours. This can directly affect engagement in rehabilitation and treatment. As such, individuals may believe it is unnecessary to engage in rehabilitation and may show poor acceptance of compensatory strategies and supports. Poor motivation may therefore delay an individual's progress through inpatient rehabilitation, with consequences for discharge and beyond, including achieving and maintaining independent living and community reintegration, an important outcome of holistic rehabilitation (SIGN-130, 2013). These consequences may also impact on an individual's psychological wellbeing and quality of life, further perpetuating low motivation.

Increasing motivation in people with ABI may therefore be a key target for treatment in inpatient rehabilitation, and a pre-cursor for other outcomes with benefits for rehabilitation (e.g. engagement with rehabilitation and psychological therapy, improved

behavioural functioning, increased activity, distress reduction). Various rehabilitation interventions have been designed to reduce apathy or increase motivation in adults following ABI, however the outcome evidence is limited and there are no well-established clinical guidelines for these specific problems. Questions therefore remain around how best we can enhance motivation for treatment and rehabilitation, to get people engaged more readily and be active collaborators in their recovery. This is also complicated because motivation difficulties following ABI can be viewed as on a continuum (Marin & Wilkosz 2005), whereby impairment can have different presentation of severity. Motivation problems are labelled and talked about differently across contexts, and this causes ambiguity and lack of clarity in the evidence base. Understanding the commonly occurring motivation impairments following ABI helps development of appropriate interventions aiming to remedy these. Additionally it is important to examine the evidence base to inform development of theory-driven interventions specifically focused on modifiable causal and maintenance factors that contribute to impaired motivation in people with ABI.

OBJECTIVES

The rationale for the current review is to contribute to evidence in adult ABI intervention and treatment. There is a particular need to better understand the service needs for individuals with ABI, and the mechanisms underlying difficulties in rehabilitation engagement.

The aim is to systematically review evidence of the efficacy of interventions for improving motivation after ABI, and in particular the different ways in which motivation is understood. Specifically, it will explore:

• Operational definitions of motivation difficulties associated with ABI

- Types/domains of motivation impairments described in intervention studies
- The ways in which these are measured and categorised, and described
- Interventions aiming to increase motivation following ABI
 - What interventions have been developed?
 - Describe the clinically relevant outcomes measured
 - Describe the effectiveness of interventions

METHOD

The search strategy was conducted in accordance with the PRISMA guidelines (Moher et al., 2009; Liberati et al., 2009). A search of the Database of Abstracts of Reviews of Effects (DARE) and the Cochrane Database of Systematic Reviews was completed to ensure no existing or on-going literature reviews, systematic reviews or meta-analyses into this area are identified.

The following databases were searched to identify relevant studies: Medline (via OVID Medline), PsycInfo (via EBSCOhost), Embase (via OVID Embase), CINAHL, and Psychological Database for Brain Impairment Treatment Efficacy (PsycBITE). These searches were carried out from the commencement of the database to 27th April 2017. In order to identify any missed articles, the reference lists and citations of relevant review articles (Brett et al 2015; Lane-Brown & Tate 2009) were hand-searched. The contents lists of Neuropsychological Rehabilitation was also hand searched for further relevant articles (for the last 3 years – May 2014 - May 2017).

The search algorithm was:

- (Motivat* or apath*)
- ((head* or brain*) adj2 (injur* or trauma*))
- (rehab* or intervention* or treatment*)

All search terms were combined with the Boolean operator 'AND'.

INCLUSION CRITERIA

<u>Types of studies:</u> Intervention studies addressing motivation impairments following ABI, where the study design includes at least pre- and post-intervention measurement of outcome.

<u>Types of participants</u>: Adults \geq 18 years of age, who have suffered a moderate-severe ABI (i.e. damage to the brain caused by an external force or physical damage resulting from non-degenerative organic factors such as stroke, aneurysm, neurological disease).

<u>Types of outcome measure</u>: Studies must include a measure of motivation at baseline and post-intervention. These can be self-report or informant-report; standardised measures of motivation; observational assessments; comparison of self-ratings to objective performance. The primary treatment outcome will be a measure of motivation; any other outcomes being reported as indicators of motivation (e.g. selfawareness, engagement with rehabilitation, functional task completion, mood) will be described, in order to further explore the taxonomy of 'motivation' in ABI research.

EXCLUSION CRITERIA

- Non-intervention articles, including non-clinical experimental manipulation
- Published in a language other than English
- Non-peer reviewed articles
- Qualitative research
- Single case reports without empirical data,
- Reviews, Dissertations, Conference Abstracts, and Book Chapters
- Studies including degenerative neurological disorders such as Parkinson's disease, Huntington's disease, motor neurone disease or dementia
- Studies examining surgical or pharmacological interventions

RISK OF BIAS

Criteria for the appraisal of articles will be based on assessment of the methodological risk of bias of included studies, as recommended by The Cochrane Handbook for Systematic Reviews of Intervention (Higgins & Green, 2011) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan et al., 2013). Risk of bias is the degree to which the included studies have a high likelihood of adequate protection against bias (i.e., good internal validity). PRISMA (2009) suggests the use

of the Cochrane Risk of Bias tool (Higgins et al., 2011, Ryan et al., 2013); a component based approach to evaluate the risk of bias within an intervention study with a separate control group (randomised controlled trials [RCTs], non-randomised controlled trials [NRCTs], controlled before-after [CBA] studies). This tool focuses on six areas: 1. Random sequence generation (i.e. selection bias); 2. Allocation concealment (i.e. selection bias); 3. Blinding of participants and personnel (i.e. performance bias); 4. Blinding of outcome assessment (i.e. detection bias); 5. Incomplete outcome data (i.e. attrition bias); 6. Selective reporting (i.e. reporting bias). Items were rated as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins & Green (2011). (See Appendix 1.2 for a summary of the types of bias). Studies will be deemed to be at the highest risk of bias if they are scored as at high or unclear risk of bias for either the sequence generation or allocation concealment domains, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins & Green, 2011). NRCTs are rated and reported as being at a high risk of bias on the random sequence generation item of the risk of bias tool; CBA studies are rated against the same criteria as RCTs but reported as being at high risk of bias on both the random sequence generation and allocation sequence concealment items (Ryan et al. 2013).

As this review is not limited to RCT studies, there may be included study designs that have different issues of bias associated. While criteria used to evaluate the quality of RCTs cannot be applied directly to all studies of other designs that might be included in a review, Sterne et al. (2016) developed a tool for assessment of 'Risk Of Bias In Nonrandomised Studies of Interventions' (ROBINS-I). This tool, funded by the Cochrane Collaboration Methods Innovation Fund and the Medical Research Council, similarly sets out domains of bias. These include: 1. Bias due to confounding; 2. Bias in selection of participants; 3. Bias in classification of intervention; 4. Bias due to deviations from intended interventions; 5. Bias due to missing data; 6. Bias in measurement of outcomes; 7. Bias in selection of the reported result. The latter four domains are substantially similar or overlap with those in the risk of bias assessment for RCTs. Items are rated as being at low, moderate, high, critical, or unclear risk of bias (see Appendix 1.3 for a summary of the types of bias in non-randomised/non-control designs). A study with an outcome judged to be at 'low risk' of bias would be considered to be similar risk of bias as that in a 'high quality' RCT, the gold-standard intervention study design.

The two risk of bias tools utilised in this systematic review use common ratings of low/moderate/high/unclear risk of bias, allowing a comparison across disparate study designs; when exploring such heterogeneous studies it is important to be especially robust in evaluating quality, by using a tool appropriate to each kind of design and related domains of bias. Appendix 1.4 outlines the framework for making summary assessments of the risk of bias for each paper (Ryan et al., 2013).

DATA EXTRACTION

Data from the intervention studies was extracted based upon the Cochrane handbook for systematic reviews of interventions checklist (Higgins et al., 2013). Preliminary synthesis was conducted through tabulation and qualitative description of data, including data related to: study design; setting and participants; intervention description/duration; selected outcome measures; and main outcomes. Details of the definition and/or categorisation of motivation in each study were also recorded.

RESULTS

INCLUDED STUDIES

The PRISMA flow diagram is presented in Figure 1 and Table 1 provides a summary of included studies. From a total of 663 there were seven papers that met inclusion criteria (Cox et al. 2003, Betker et al. 2007, Vanderploeg et al. 2008, Lane-Brown & Tate 2010, Caracuel et al. 2012, Llorens et al. 2015, Skidmore et al 2015).

A range of interventions was described, including motivational counselling techniques; videogames (one incorporating biofeedback); cognitive-didactic versus functional-experiential rehabilitation therapy; motivational interviewing and external compensation; a holistic neuropsychological rehabilitation program; strategy training; and reflective listening. A measure of motivation was a primary outcome measure in six studies, and a secondary measure in the remaining study (Vanderploeg et al., 2008).

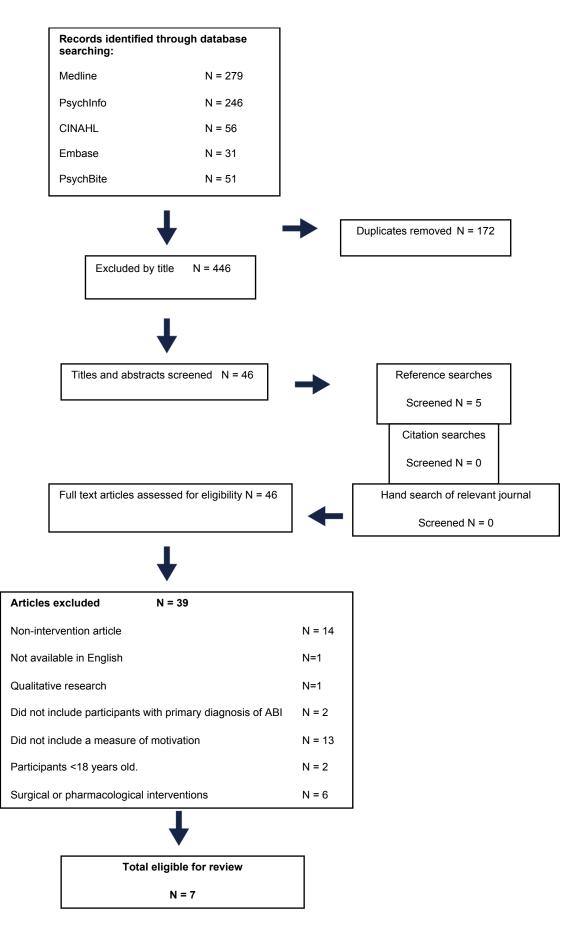


Figure 1: Flow diagram illustrating search process

| Table 1: Summary of | Table 1: Summary characteristics of included studies | ed studies | | | | |
|-----------------------|--|---|-----------------------------|-----------------------|------------------------|---------------------------------|
| Authors, design, & | Participants & setting | Intervention | Outcome measures - | Definition of | Other outcome | Findings |
| bias rating | | | motivation | motivation | measures | |
| 1. Cox et al. 2003 | Intervention n=40, | Intervention - <u>SMC</u> : counseling | MSQ: | Based on | PANAS: | SMC group |
| | recruited from the | technique addressing maladaptive | Name current concerns | motivational model of | Yields separate | improvements in |
| Controlled before and | inpatient and outpatient | motivation | in major life areas. | substance abuse. | positive affect (PA) | motivational |
| after trial | units of a rehabilitation | Comparator – TAU (rehabilitation: | Characterise each | Genetic and other | and negative affect | structure, towards |
| | hospital, USA. | "medical, psychosocial, and | concern along | biological, | (NA) scores. | more adaptive |
| High risk of bias | | vocational support as needed") | dimensions that will | psychological, | | patterns. |
| | Comparison n=54, | | reveal possible | environmental, and | ADI: | |
| | current and former | Method – | resolutions. | societal-cultural | 8 substances of | Significant |
| | patients recruited from | Baseline assessment. | Motivational profile | variables, cause | abuse, the ADI asks | reduction in |
| | different rehabilitation | | drawn to depict | people to form | respondents whether | negative affect |
| | hospital, USA. | SMC treatment. 12 individual | significant features of | expectations about | they currently use the | |
| | | sessions (mean duration = 10.2 | 'motivational structure' | the affective | substance, and if so | Significant |
| | All participants TBI | months, $sd = 4.7$). | i.e. patterns by which | consequences of | how frequently and in | reduction in the |
| | resulting from physical | | they strive for goals. | action vs. not. | what quantity | use of substances |
| | blows to the skull, GOAT | Post-treatment assessment. | Maladaptive patterns | Balance between | | |
| | score >=65. | | might include | people's expected | | No pre-post |
| | | Follow-up assessment. Mean of | characteristics such as | positive and negative | | changes in the |
| | | 9.1 (sd = 4.2) months after SMC. | difficulties with | emotional | | TAU Group. |
| | | | identifying steps for | consequences of | | |
| | | | achievement of goals, | action. | | |
| | | | pessimism about | | | |
| | | | possible attainments, a | | | |
| | | | lack of anticipated | | | |
| | | | benefit or emotional | | | |
| | | | gratification, or conflicts | | | |
| | | | among different goals. | | | |
| 2. betker et al. 2007 | N=3 | Controlled Video Game-based | included the following | rehabilitation | Acceptability of | All participants reported |
| 3x SCEDs | One spina | Exercise Tool: biofeedback principles. | question: 'Did the video | exercises. | intervention | increased |
| | bifida/paraplegia, two | Used with Force- Sensitive | games increase your | | | motivation to |
| High risk of bias | severe TBI. | Applications (FSA) software and | motivation to perform | | Clinical Test of | perform the |
| | | pressure mat. Three games | your exercises?' | | Sensory Interaction | rehabilitation |

Table 1: Summarv characteristics of included studies

| 4. Lane-Brown & Tate 2010 SCED <mark>High</mark> risk of bias | 3. Vanderploeg et al. 2008 RCT with 2 treatment arms High risk of bias |
|--|---|
| N=1 32-year-old man TBI. Outpatient, Australia. | Adult veterans or active duty military service members (N=360) with moderate to severe TBI. Recruited from 4 inpatient rehabilitation units, USA. |
| Motivational interviewing and external compensation (reminder alert set into personal digital assistance device). Identification of 3 target behaviours (. | Randomised, controlled, intent-to- treat trial comparing 2 alternative TBI treatment approaches. MDT inpatient rehabilitation plus either ' <u>Cognitive-didactic'</u> rehabilitation therapy (trial-and-error learning, emphasises building self-awareness) OR ' <u>Functional-experiential</u> ' rehabilitation therapy (errorless learning, focus on developing useful functional abilities) Duration of protocol treatment varied from 20 to 60 days depending on the clinical needs and progress of each participant. |
| <u>AES</u> Apathy subscale of the <u>FrSBe</u> | " Secondary measure: <u>AES</u> (1-year post- protocol) |
| Diminished initiation, sustained activity, and concern about goal directed behaviours. | Functioning – returning to work or school, level of (motivation required to take part in new learning and adaptations needed). |
| Primary measure: behavioural measure of persistence - <u>sustaining activity</u> on 3 target behaviours | Primary measures: <u>functional</u> independence, return to work and/or school (1-year post-protocol) Secondary measures: <u>FIM, DRS</u> (discharge) The Present State <u>Exam,</u> <u>Neurobehavioral</u> <u>Rating Scale, self-</u> rated <u>life satisfaction</u> and <u>change in marital</u> <u>status</u> (1-year post- protocol) |
| Self-rated and clinician-rated FrSBe-A indicated a statistically significant | consequence of practicing exercises. Primary outcome measures showed no between group difference for experimental treatments at 1 year Cognitive treatment arm had better post-treatment cognitive performance than patients in the functional treatment arm (t₃₃₂=2.56, P=.01) No difference in motor performance No differences in secondary outcome measures at 1-year follow-up (incl. motivation) |

| 5. Caracuel et al. 2012 Longitudinal cohort study High risk of bias | High risk of bias |
|---|---|
| N=18 (and their 18 informal caregivers). ABI caused by TBI or stroke. Of these, N=10 'long evolution' i.e. started rehabilitation >6 months after ABI. Recruited from outpatient trauma rehab unit, Spain, in three waves to form three groups of six individuals, one group every six months. | |
| Holistic Neuropsychological Rehabilitation Program: intervention lasted 6 months with three weekly sessions of three hours each. The therapeutic milieu, and vocational therapeutic milieu, and vocational therapy. Carried out routine rehabilitation activities. Relatives attended a caregiver intervention module with a single session of three hours every week where they received training in managing the consequences of ABI and providing emotional support. | (goals) and 3 experimental phases (baseline, treatment, and withdrawal [4 weeks after completion]) allowed controlled examination of the treatment effect over 163 time points. |
| <u>FrSBe</u> (Spanish version) pre- and post- intervention and 12 month follow-up. | |
| Behavioural symptoms derived from damage t oprefrontal circuits. Motivation targeted throughout all elements of Holistic Neuropsychological Rehabilitation Program, but especially vocational module. | Continuum of severity, with apathy at the lesser end, worsening to abulia/akinetic mutism. Range of severity: milder ranges exhibit symptoms of apathy but are still able to live independently in the community. Milder forms of apathy may be defined amotivational syndrome. |
| <u>European Brain</u> Injury Questionnaire (Spanish version) - pre- and post- intervention and 12 month follow-up. | Secondary measures: executive functioning (<u>WAIS-IV</u> Matrix Reasoning/Similaritie s subtests); insight (<u>SADI</u>), leisure activities (<u>NLQ</u>), and participation (<u>M2PI</u>). Control measures: Depression subscale of the <u>DASS; BNIFS</u> |
| Relatives reported improvement between baseline and follow-up in all EBIQ subscales and in the apathy and executive function subscales of the FrSBe Patients reported significant change in the poor social and emotional subscale of EBIQ and the apathy subscale of the FrSBe At follow-up, the short evolution patients achieved | decrease in apathy pre-post treatment SADI indicated significant improvement in ability to set realistic goals No effect on NLQ or M2PI No significant change in WAIS- IV scores |

| 7. Skidmore et al. 2015 Secondary analysis of RCT (Primary analysis examined the feasibility of a strategy training clinical trial, and the impact of strategy training on disability). Low risk of bias | 6. Llorens et al. 2015 Longitudinal study with a pre- and post- assessments. High risk of bias | |
|---|--|--|
| N=30 Acute stroke. Inpatient rehabilitation unit, USA | N=42 Moderate to severe TBI Outpatient rehabilitation, Spain. | |
| Two intervention groups. Routine inpatient rehabilitation, plus one 45- minute research intervention session per day, 5 days per week, for the duration of inpatient rehabilitation. <u>Strategy training</u> : incorporates principles of metacognitive instruction; coaching participants to address their self-selected activity-based goals through self-evaluation of | Group of four pairs of individuals playing a digital board game on a multi-touch screen under the supervision of a neuropsychologist. The objective of the videogame was to move spaces by correctly answering questions about brain injury. Four different types of questions: Knowledge, Reasoning, Action, Cohesion. After an answer was given, the neuropsychologist involved all game participants and alternative answers were discussed. Therapist gave verbal feedback and support with each turn. One-hour game session each week for six months. Two experienced therapists conducted the intervention sessions | |
| <u>AES</u> (baseline, 3 months, 6 months) | AES | |
| Apathy, lack of motivation or interest in goal-directed activities. Three dimensions in motivation: diminished goal directed cognition (lack of interest and value attributed to productivity and | Linked to self- awareness. Social skills and behaviours associated with frontal lobe damage. Intrinsic Motivation - participant interest/enjoyment, pressure, and usefulness of intervention. | |
| Participation in intervention sessions measured post- intervention with <u>PRPS</u> Idiosyncratic measure - Self-rating <u>understanding of the</u> <u>intervention</u> (1. minimal understanding, | <u>SADI</u> SSS, SUS | |
| PRPS - Participants in both groups received and actively participated in the allocated intervention Participants in both groups demonstrated an acceptable | Promoted the acquisition of self-awareness, mainly in perceptions of deficits and the setting of realistic goals. Improvements in development of adequate social and behavioural management skills FrSBe decrease in frontal damage disturbance (x2 = 34.12, p < 0.01). | greater improvements in mood and cognitive functioning than the long evolution patients |

| sst | GOAT: Galveston Orientation and Amnesia Test | GOAT: Galveston Orie | ion Inventory | IMI: Intrinsic Motivation Inventory | Notes: TAU: Treatment as usual | Notes: TAU: 1 |
|---|--|---|---------------|--|--|------------------|
| subjective understanding of the intervention that they received Changes in levels of apathy symptoms differed between strategy training participants over the 3 time points. Strategy training was associated with significantly lower levels of post stroke apathy than was reflective listening | 2. acceptable understanding, 3. understanding) | socialisation); diminished goal directed behaviour (lack of effort, productivity, initiative, or persistence); and diminished emotional responsivity to goal- directed activities (flat affect) (flat | | performance, self-derived strategies to address performance (using a global strategy training method, Goal- Plan-Do-Check) and application of learned principles across self-selected goals. <u>Reflective listening (an attention control condition)</u> : focused on participants' reflecting on their goals and their rehabilitation experiences, facilitated by scripted open-ended questions and active listening skills of therapist (attending, following, and responding). | | |

TAU: Treatment as usual MSQ: Motivational Structure Questionnaire PANAS: Positive Affect Negative Affect Scale

DRS: Disability Rating Scale FrSBe: Frontal Systems Behaviour Scale DASS: Depression, Anxiety and Stress Scale BNIFS: Barrow Neurological Institute Fatigue Scale PRPS: Pittsburgh Rehabilitation Participation Scale

> IMI: Intrinsic Motivation Inventory SMC: Systematic Motivational Counseling AES: Apathy Evaluation Scale FIM: Functional Independence Measure NLQ: Nottingham Leisure Questionnaire M2PI: Mayo-Portland Participation Index SUS: System Usability Scale

GOAT: Galveston Orientation and Amnesia Test ADI: Alcohol and Drug Inventory SCED: Single case experimental design WAIS-IV: Wechsler Adult Intelligence Scale-4th ed SADI: Self-awareness of Deficits Interview PCRS: The Patient Competency Rating Scale SSS: Social Skills Scale

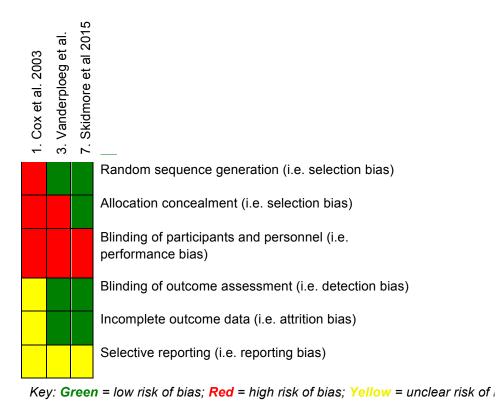


Figure 2: Studies with a separate control group

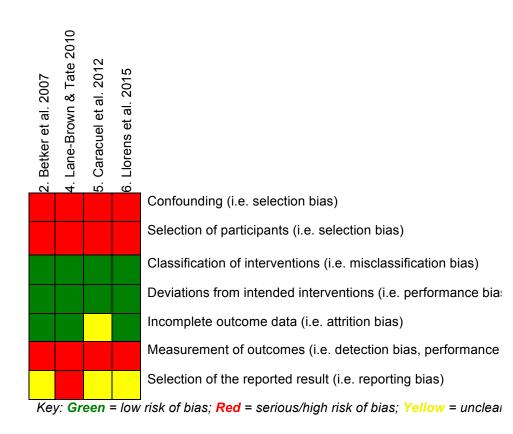


Figure 3: Studies with no separate control group

RISK OF BIAS

Figures 2 and 3 show the risk of bias assigned to each domain in the included studies. Risk of methodological bias was high, with six studies rated as having an overall 'high' risk of bias. While four of these studies achieved the judgment of 'low' risk of bias for three or more risk domains, they were rated as 'high' in the key domains. Only one study could be rated as overall 'low' risk (Skidmore et al., 2015).

In psychological intervention studies it is almost impossible to keep participants blinded to treatment they receive, or therapists to the intervention they provide, and ethical issues would need to be considered if this were pursued. As such, all studies were rated 'high' risk of bias in this domain. Of non-control group studies, there was a high risk of outcome influenced by other confounding variables/historic events during study period. All non-control group studies were also rated as high risk of bias for measurement of outcomes, due to subjectivity of measures and lack of blinding of both participants and assessors.

Due to the time constraints of this review it was not possible to contact the study authors to request access to study protocols. The majority of studies, therefore, were assigned the judgement of 'unclear' risk of bias in the selective reporting domain. It was noted however that these studies did include all expected outcomes, including those that were prespecified in the aims and hypotheses. Lane-Brown & Tate (2010) included post-hoc analysis that was non-specified, and was rated 'high' risk.

While the overall risk of bias in included studies is high, all studies remain included for evaluation. Petticrew (2015) proposes that in areas of emerging evidence it is not beneficial to exclude studies of higher risk of bias, or lower quality; the whole range of evidence may be of value in exploring the range and nature of potential effects, feasibility of interventions, and planning for future studies.

OVERVIEW OF INCLUDED STUDIES

Definitions of motivation

The studies varied in the complexity of definitions provided from uni-dimensional accounts (Betker et al., 2007, Vanderploeg et al., 2008, Caracuel et al., 2012) through to multi-dimensional definitions (Cox et al., 2003, Lane-Brown & Tate, 2010, Llorens et al., 2015, Skidmore et al., 2015).

Skidmore et al. (2015), with the lowest risk of bias rating, provides a multi-dimensional definition of motivation. The study focuses specifically on decreasing apathy after ABI, and defines this as a lack of motivation or interest in goal-directed activities. They propose three dimensions in motivation: cognitive (lack of interest and value attributed to productivity and socialisation); behavioural (lack of effort, productivity, initiative, or persistence); and affective (diminished emotional responsivity to goal-directed activities).

Affect is also implicated in the definition of Cox et al. (2003), positing a multi-dimensional definition based upon substance use literature, whereby genetic and other biological, psychological, environmental, and societal-cultural variables, cause people to form expectations about the affective consequences of action vs. inaction. Motivation therefore is dependent on the balance between people's expected positive and negative affective consequences of taking action to make changes in lifestyle (for example attending rehabilitation). Betker et al. (2007) report a similar affect-driven definition, whereby motivation relates to an individual's desire to perform activities.

A more behavioural pattern of understanding was outlined in Vanderploeg et al. (2008) & Lane-Brown & Tate (2010), specifically relating to levels of independent functioning, the levels of new learning and adaptations required after ABI, and diminished initiation. Lane-Brown & Tate (2010) additionally describe motivation difficulties as presenting on a continuum of severity, with apathy at the lesser end, worsening to abulia/akinetic mutism. The range of severity on this continuum means that those with milder 'symptoms' of amotivation may be able to live more independently.

The neuropathological underpinnings of motivation difficulties are outlined in studies Caracuel et al. (2012) and Llorens et al. (2015), including behavioural symptoms and social impairments associated with damage to prefrontal circuits. This defines amotivation as an observable behavioural consequence following neuropathological insult to prefrontal regions affecting executive functions, whereby the relevant areas of the brain are damaged. Llorens et al. (2015) also refers to the cognitive elements proposed in intrinsic motivation, including participant interest/enjoyment, perceived competence, and perceived usefulness of the action.

Overall, studies represented a total sample of N=548 (range of N=1-360). Regarding study design, this systematic review contained two randomised control trials, one quasi-RCT, four single-case experimental design studies, and two prospective longitudinal cohort studies. The age range, where reported, was 26-71 years. When gender was reported, male participants out-numbered females. Studies were carried out in USA (Cox et al., 2003, Vanderploeg et al., 2008, Skidmore et al., 2015), Canada (Betker et al., 2007), Spain (Caracuel et al., 2012, Llorens et al., 2015), and Australia (Lane-Brown & Tate, 2010). Two of the studies recruited from inpatient rehabilitation units (Vanderploeg et al., 2008, Skidmore et al., 2015), four from outpatient rehabilitation settings (Betker et al., 2007, Lane-Brown & Tate, 2010, Caracuel et al., 2012, Llorens et al., 2015), while Cox et al. (2003) recruited from both inpatient and outpatient service users of a rehabilitation hospital. The rehabilitation hospital in Vanderploeg et al. (2008) was specifically for military veterans or active duty service members. Across the recruited participants, acquired brain injury was as a result of traumatic brain injury (TBI; Cox et al., 2003, Betker et al., 2007, Vanderploeg et al., 2008, Lane-Brown & Tate, 2010, Llorens et al., 2015), stroke (Skidmore et al., 2015), or both (Caracuel et al., 2012). Betker et al. (2007) also included a participant with spina bifida resulting in complete paraplegia and poorly developed lower extremities, as their inclusion criteria was adults with spinal cord and/or head injuries.

Outcome measures: Motivation

Three studies used the Apathy Evaluation Scale (AES) as a measure of the behavioural outputs of motivation (Lane-Brown & Tate, 2010, Skidmore et al., 2015; secondary outcome measure in Vanderploeg et al., 2008). The AES is a clinician-rated structured interview measuring lack of motivation or interest in goal-directed activities. The AES has demonstrated good convergent and divergent validity as well as good intra- and interrater reliability, and has been used to characterise apathy in participants with stroke and traumatic brain injury (Marin et al., 1991). Eighteen items addressing initiative, effort, productivity, emotional responsivity, novelty seeking or curiosity, perseverance, and social engagement are scored on a 4-point Likert scale, indicating the degree to which participant responses are characteristic of motivation or interest. Item scores are summed, with a total score of \geq =37 deemed indicative of apathy. In included studies, Lane-Brown & Tate (2010) case study demonstrated a decrease in apathy from within the clinical range at baseline to below this cut-off; this change was statistically significant and maintained at

follow up. In their secondary analysis of RCT, Skidmore et al (2015) report that in both groups at baseline apathy levels were sub-clinical, however there was a range of apathy symptoms in the sample.

The Frontal Systems Behaviour Scale (FrSBe) was used in three studies (Lane-Brown & Tate, 2010, Caracuel et al., 2012, Llorens et al., 2015). The FrSBe is comprised of three subscales measuring frontal system behavioural profiles associated with three neuroanatomically distinct frontal-subcortical circuits: apathy, disinhibition, and executive dysfunction. The FrSBe is a 46-item questionnaire, with patient and relative forms, and discrepancy between observer and patient scores serves as a measure of these three behavioural syndromes. Scores are converted to T-scores corrected for age, education, and gender; T-scores of 65 or above are considered clinical range. The apathy subscale encompasses general lack of interest, indifference, and motivational loss not attributable to emotional distress. Lane-Brown & Tate (2010) single case study reports self-rated apathy scores in 'borderline clinical' range, clinician rated scores at 'clinical' range, and relative scores at 'not altered' range at baseline. Following intervention, relative ratings did not change, clinician scores decreased but remained in 'clinical' range, and self-rated scores decreased to 'not altered'; the self- and clinician-ratings were significant decreases in ratings of apathy. Participants included in Caracuel et al. (2012) mean scores remained below clinical significance at baseline and follow up, but did demonstrate a reduction. Llorens et al. (2015) report that ten participants from those classified as above clinical range over all subscales at baseline (n = 28) improved from this classification after the intervention.

The Intrinsic Motivation Inventory (IMI) was a further primary measure of motivation used in Llorens et al. (2015). The IMI, grounded in self-determination theory (Ryan & Deci, 2000), is a multidimensional measure intended to assess participants' subjective experience of a target activity or intervention, related to intrinsic motivation and self-regulation (Ryan 1982). Subscales administered in this study assess participant interest/enjoyment, perceived competence, pressure/tension, and value/usefulness. Scores approaching seven in each subscale represent positive values in terms of motivation, with the exception of the pressure/tension subscale, for which high scores represent high levels of tension.

The motivational structure of participants (that is, patterns of behaviour by which an individual strives for identified goals) was used as outcome measure in Cox et al. (2003), using the Motivational Structure Questionnaire (MSQ). Originally designed for use in substance misuse populations (Cox & Klinger, 2011), the MSQ asks participants to choose current concerns and goals they are striving for in 12 major life areas. They then rate and characterise their anticipated resolution of each concern, including for example how likely, and how satisfying it would be. This information allows a motivational profile for each respondent to be drawn that determines maladaptive motivational patterns with regard to particular goals. The patterns might include characteristics such as difficulties with identifying steps for achievement of goals, pessimism about possible attainments, a lack of anticipated benefit or emotional gratification, or conflicts among different goals. Such themes are often heard in brain injury rehabilitation settings.

Finally, Betker et al. (2007) used an informal questionnaire to gather participants' views of the intervention. The questionnaire included the question "Did the video games increase your motivation to perform your exercises?" The idiosyncratic nature of this questionnaire prevents conclusions about whether this is a valid or reliable measure of motivation.

Other Outcome Measures

All seven reviewed studies also reported on measures for constructs other than motivation. These are summarised in Table 1, and included measures of affect, self-awareness, functional independence, participation, and competency. Outcomes/findings are discussed further below.

Interventions and Findings

The included studies suggest a number of ways in which motivation can be improved after ABI, and while the interventions outlined vary, there are some common overarching themes. These included behavioural approaches aimed at compensating for frontal/executive dysfunction and behavioural activation, the use of feedback to increase self-awareness, the use of technology in interventions, and therapeutic interventions addressing mood and emotional impact of lack of motivation.

The current evidence base for ABI rehabilitation supports a holistic approach (e.g. The Matrix 2015) and Caracuel et al. (2012) aimed to explore the long-term effectiveness of a holistic neuropsychological rehabilitation program for ABI outpatients in a Spanish setting.

The therapeutic modules were not defined precisely, however the overarching components incorporated were cognitive rehabilitation, psychotherapy, therapeutic milieu, vocational therapy and a caregiver intervention module. Outcomes were measured pre- and post-intervention and at 12-month follow up using Spanish versions of the FrSBe, and the European Brain Injury Questionnaire, completed by participants and a relative. The authors report long-term outcomes rated by relatives, which showed improvements in cognitive and executive functioning, mood, apathy/motivation and social and emotional self-regulation. The study also supports early intervention following ABI in the form of neuropsychological rehabilitation. The authors state that changes in amotivation were prompted through all elements of the rehabilitation programme, but in particular through the vocational therapy module; this incorporated work-based trials, and gradual experiences of supervised work experience.

A number of novel rehabilitation approaches were explored in the included studies. Skidmore et al. (2015), the only study rated as 'low' in risk of bias, was an RCT in an acute inpatient rehabilitation setting, and results support the use of interventions focused on behavioural strategies for example goal setting and self monitoring, in order to compensate for impairments in executive function. Participants who had suffered ABI due to stroke, and exhibited cognitive impairments, were randomised to receive either strategy training or reflective listening therapeutic interventions. Both groups received one 45minute research intervention session (strategy training or reflective listening) per day, 5 days per week; as such, therapist contact time was balanced across groups. The intervention period continued for the duration of their inpatient admission, in addition to usual inpatient rehabilitation. Strategy training sessions focused on participant-selected goals and participant-derived strategies to address these goals, using a global strategy training method (Goal-Plan-Do-Check). Reflective listening sessions focused on the therapist encouraging participants to reflect on their rehabilitation goals and experiences, facilitated by therapist use of open-ended questions and active listening skills (attending, following, and responding). The AES and PRPS were administered at study admission, 3 months, and 6 months. Findings showed that all participants actively participated in their respective interventions, as determined by scores on PRPS measure of therapeutic engagement. Strategy training was associated with significantly lower apathy scores postintervention than was reflective listening over the first six months of inpatient rehabilitation. The authors proposed that strategy training through its focus on goal-setting and planning, self-monitoring, and problem solving addresses behavioural activation and

perseverance deficits in apathy. This study was a secondary analysis of an RCT intended to explore the effect of strategy training on reducing disability and improving executive cognitive functions in the first 6 months after stroke; as such the authors suggest that it could be that the strategy training related reductions in disability sustain motivation for goal directed behaviour and thus have indirect benefits for apathy and amotivation symptoms.

Another example of alternative rehabilitation approaches was Vanderploeg et al., (2008) RCT in an ABI inpatient facility for military service members and veterans. Participants were randomised to receive either cognitive-didactic (trial-and-error learning, emphasises building self-awareness) or functional-experiential (errorless learning, focus on developing useful functional abilities) rehabilitation therapy. The use of feedback is incorporated in these interventions, and allows us to consider how the style or type of feedback in itself Primary outcomes, measured at one year follow up, were may affect motivation. functional independence and return to work/school at follow up. Secondary measures assessed disability rating, mood, self-perceived memory problems, self-rated life satisfaction, change in marital status, and motivation (AES). Analysis of the primary outcome measures showed long-term functional improvements for both groups but no between group differences for the two experimental treatments at 1 year. Analysis of secondary outcomes showed that those who received the cognitive-didactic treatment had higher cognitive FIM scores at the completion of treatment. Additionally, cognitive arm participants reported lower rates of memory problems at 1-year follow-up. The authors propose that these findings suggest that cognitive treatment not only better enhances cognitive recovery but also lays a stronger foundation for the development of cognitive skills implicated in functional skills. This has implications of the support we may provide to individuals struggling with motivation problems after ABI, who may benefit from the cognitive-didactic treatment components of problem-solving strategies and approaches. In this study it was found that this method of feedback aiming specifically to increase selfawareness had a greater effect on motivation.

Betker et al. (2007) and Llorens et al. (2015) also focussed on interventions aiming to increase self-awareness through use of feedback. Both studies also utlised technology based interventions; Betker et al. (2007) explored the impact of a video game-based exercise, controlled by use of center-of-pressure (COP) signal biofeedback. Biofeedback is the process by which a physical signal is recorded and presented back to an individual in

order to create and strengthen awareness of performance and prompt any alterations. In this study, the feedback came from a pressure mat identifying COP signals, which indicate postural balance and weight shifting. The game comprised graded, dynamic balance exercises, with adjustable difficulty, and software allowing scalability of movement. In these single case experimental reports, participants took part in twelve 30-45 minute sessions per week, and outcomes demonstrated that physical rehabilitative interventions incorporating a functional approach to training and graded balance conditions or disturbances (i.e., sensory feedback) produce substantial improvements in dynamic shortsitting balance. A main observation was that the video game intervention motivated people with chronic spinal cord and traumatic brain injuries to practice dynamic movement tasks, compared to traditional balance exercises. It may be proposed that the use of immediate and frequent physiological feedback made the physical therapy task more interactive, while the video game nature made the exercises more engaging. Llorens et al. (2015) also used a video-game based intervention, exploring its feasibility in improving self-awareness, social skills, and social behaviours in participants with TBI in a cohort study. Findings suggested the videogame-based group therapy can improve these outcomes, and participants rated the approach as effective and motivating. Again, the use of a novel game-based intervention may be viewed as an engaging way to promote learning and feedback for self-awareness of difficulties. Additionally, emerging evidence surrounding the use of technology in ABI (Brunner et al., 2017) suggests that the elements that facilitate improved motivation may include facilitating independence and self-efficacy, and encouraging communication in activities. The nature of technological approaches allows for a consistency in delivery and massed practice, which has implications for the ease of incorporation into wider ABI rehabilitation services.

Cox et al. (2003) and Lane-Brown & Tate (2010) explored interventions using elements of individual talking therapy, or counseling interventions. In a single case experimental design Lane-Brown & Tate (2010) evaluated a novel intervention combining motivational interviewing and external compensation (a reminder alert set into personal digital assistance device), aimed at increasing sustained activity toward cumulative goals. Findings suggest that treatment had a strong and specific effect on goal-directed activity and decreased apathy, as shown by initiation as well as sustaining goal-directed activity. Cox et al. (2003) compared 12 sessions of Systematic Motivational Counseling (SMC) to treatment-as-usual in rehabilitation for participants with TBI. SMC is an individualised counseling technique aiming to address the maladaptive motivational patterns identified in

the Intrinsic Motivation Inventory (IMI), as outlined above. Outcomes were measured pre- and post-treatment and 12 month follow up, and explored motivational structure, affect, and substance use. Findings showed that compared to the TAU group, the SMC group demonstrated improvements in motivational structure, significant reduction in negative affect and in the use of substances. Observed changes in motivation structure were directly related to the SMC components of counseling; the SMC group came to view their anticipated resolutions of their difficulties as attractive outcomes that they wanted to "obtain," or "accomplish," as opposed to unpleasant conditions that were to be "prevented" or "avoided" (i.e., an increase in the Appetitive Action index). They displayed a more relaxed attitude about the immediacy and timeframe within which they had to take action, and more positively emotionally invested in doing something about their current concerns. While the authors make no assessment of post-trial interventions or actions, they do comment that the changes observed in the SMC at follow-up are particularly of note given that participants typically returned to disadvantaged environments without systematic provision of booster sessions. This study however received the most 'high'/'unclear' ratings of all studies, and as such the findings must be considered with caution.

Durability of treatment effects

There was variability within the included studies in terms of follow-up assessment of outcomes. Cox et al. (2003), Vanderploeg et al. (2008) and Caracuel et al. (2012) followed up at 12-months post intervention. The remaining studies had far shorter follow up periods of six months (Skidmore et al. 2015), four weeks (Lane-Brown & Tate, 2010), one week (Llorens et al. 2015), and no post-intervention follow up (Betker et al. 2005). This variation in follow-up intervals may complicate estimations of efficacy, since there may be implications regarding the durability of treatment effects for the interventions.

DISCUSSION

Findings

All seven of the studies reviewed reported improved motivation following treatment. This suggests that apathy and amotivation are not intractable problems following ABI. However, our review also shows that this treatment literature is relatively immature and the types of interventions, outcomes, and research designs varied greatly across papers. As hypothesised, the studies varied in the way they operationalised motivation; in exploring these variations we can see the themes which emerge, and how this influences not only

choice of outcome measure but components of interventions. The different classifications suggest a multi-dimensional understanding of motivation impairments following ABI. One dimension is the neuropathological impact of the injury, with frontal systems implicated. Damage to these regions results in impairment whereby the areas of the brain linking to motivation are no longer working; without the possibility of restoration, compensation is a more appropriate focus. This suggests the use of behavioural interventions aimed at compensatory techniques, cognitive rehabilitation, and practical supports in goal setting such as those for dysexecutive syndromes may be beneficial. Further, there is a proposed cognitive dimension of motivation, encompassing beliefs about self-efficacy, abilities and success in setting and reaching goals; this suggests the use of interventions targeting intrinsic motivation such as those based upon self-determination theory (Ryan & Deci, 2000) may support individuals to adapt beliefs and cognitions around goal-focused tasks. Key targets for intervention may therefore include psychoeducation to impact on attitudes about actions (for example, explaining the role of neurorehabiliation, and encouragement of autonomy), improving self-awareness and metacognitive abilities (for example through developing meaningful goals), and skills based approaches. Affect also emerges as a dimension of motivation, whereby adjustment to injury and mood/emotional sequelae have an impact on motivation to perform tasks or new learning, highlighting the importance of psychological intervention within ABI rehabilitation. Finally, insight and self-awareness into impairment following ABI must be considered; it follows that in order to have the appropriate cognitive, behavioural, emotional and practical capabilities required for goal-directed behaviour and motivation for tasks, and individual needs to be aware of and understand the purpose of such actions.

Limitations

The present review should be considered in light of its limitations. A quality-rating tool designed specifically for assessing risk of bias in single-case experimental designs (SCEDs) was not utilised in this review. One such tool, the revised Risk of Bias in N of 1 Trials scale (RoBiN-T; Tate et al. 2013), is a widely recommended methodological quality-rating tool recommended to measure risk of bias in single-case studies. However, the RoBiN-T uses an ordinal level of measurement whereby items are scored (0,1,2), and all items are weighted equally, despite the fact that the methodological importance of each item inevitably differs. Unlike the Cochrane Risk of Bias tool and ROBINS-I used in this review, the researcher cannot consider particular domains or items as most important based upon empirical evidence. With such differing assessment methods, it would be hard to

compare quality ratings across such tools. However, this may be a point to consider in any future systematic reviews of such diverse literature, particularly given the increase in use of SCEDs within psychological research.

All but one of the included studies was rated as 'high' risk of bias, and therefore of questionable quality, which is important when considering the generalisability of the outcomes. This issue may be related to the immaturity of the literature, and the diversity of intervention strategies that have been trialled so far. Additionally, this lack of homogeneity across samples and measures limits the ability to make comparisons across studies. The only study rated as 'low' risk of bias (Skidmore et al., 2015) included only acute post-stroke participants, rather than a wider ABI population. Most studies utilised questionnaire based measures of motivation, relying on self-reporting of difficulties. There was limited reporting of details on clinically relevant outcomes, for example actual behaviour change, engagement in tasks, or functional task completion. One exception was the additional use of a relative-completed questionnaire (Caracuel et al. 2012). As such, only tentative conclusions can be drawn from this review.

Future research

This systematic review showed there is a scarcity of studies with an explicit focus on improving motivation after ABI. While there are established reviews of interventions targeting apathy (Lane-Brown & Tate, 2009) and engagement in rehabilitation (Brett et al., 2017), this area of research would benefit from establishing clarity around the mechanisms underlying this, and in particular, how these can be combined into appropriate interventions complying with the evidence base for holistic neurorehabilitation (Craig et al., 2013, Wood & McMillan, 2017).

Finally, in order for future studies to develop the evidence base with high quality methodology producing valid and reliable outcomes, design specific sources of bias such as those outlined by The Cochrane Collaboration should be taken into consideration in the protocol planning and implementation stages, and be outlined clearly in the final paper.

Conclusions

As highlighted in this review, there remains variability in the classification and descriptions of motivation difficulties after ABI. As such, when clinicians or researchers talk about 'motivation' they should instead clarify the core facets they are trying to explore, for example goal-directed behaviour, cognitions and self-belief, or the effects of

depression. In being explicit about the underlying area of interest, and holding in mind a multidimensional concept of motivation, we may then move away from an overarching definition to a more nuanced one, allowing the appropriate choices in outcome measures or development of interventions.

This systematic review highlights the need for an improvement of the quality of research conducted in the area of appropriate interventions for motivation impairments following ABI. Understanding the components that contribute to impaired motivation in people with ABI is important in facilitating the development of such theory-driven interventions, and at present the variance in definitions of motivation within the literature is a challenge. Future studies should hold in a mind a multi-dimensional characterisation of motivation, and explore outcomes applicable to real-life clinical practice.

REFERENCE LIST

- Betker, A.L., Desai, A., Nett, C., Kapadia, N. and Szturm, T., 2007. Game-based exercises for dynamic short-sitting balance rehabilitation of people with chronic spinal cord and traumatic brain injuries. *Physical therapy*, *87*(10), pp.1389-1398.
- Brett, C.E., Sykes, C. and Pires-Yfantouda, R., 2017. Interventions to increase engagement with rehabilitation in adults with acquired brain injury: A systematic review. *Neuropsychological rehabilitation*, 27(6), pp.959-982.
- Brunner, M., Hemsley, B., Togher, L. and Palmer, S., 2017. Technology and its role in rehabilitation for people with cognitive-communication disability following a traumatic brain injury (TBI). *Brain injury*, pp.1-16.
- Caracuel, A., Cuberos-Urbano, G., Santiago-Ramajo, S., Vilar-Lopez, R., Coín-Megias, M.A., Verdejo-García, A. and Pérez-García, M., 2012. Effectiveness of holistic neuropsychological rehabilitation for Spanish population with acquired brain injury measured using Rasch analysis. *NeuroRehabilitation*, 30(1), pp.43-53.
- Cox, W.M., Heinemann, A.W., Miranti, S.V., Schmidt, M., Klinger, E. and Blount, J., 2003. Outcomes of systematic motivational counseling for substance use following traumatic brain injury. *Journal of Addictive Diseases*, 22(1), pp.93-110.
- Cox, W.M. and Klinger, E., 2011. Measuring motivation: The motivational structure questionnaire and personal concerns inventory and their variants. *Handbook of motivational counseling: Goal-based approaches to assessment and intervention with addiction and other problems*, pp.159-204.
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. and Petticrew, M., 2013. Developing and evaluating complex interventions: the new Medical Research Council guidance. *International journal of nursing studies*, 50(5), pp.587-592.
- Grace, J. and Malloy, P.F., 2001. Frontal Systems Behavior Scale: Professional Manual. Lutz, FL: Psychological Assessment Resources.
- Higgins, J.P. and Green, S. eds., 2011. Cochrane handbook for systematic reviews of interventions (Vol. 4). John Wiley & Sons. [Online] Available from: <<u>http://handbook.cochrane.org</u>> [Accessed 3rd August 2017]
- Lane-Brown, A.T. and Tate, R.L., 2009. Apathy after acquired brain impairment: a systematic review of non-pharmacological interventions. *Neuropsychological rehabilitation*, 19(4), pp.481-516.

- Lane-Brown, A. and Tate, R., 2010. Evaluation of an intervention for apathy after traumatic brain injury: a multiple-baseline, single-case experimental design. *The Journal of head trauma rehabilitation*, 25(6), pp.459-469.
- Liberati, A., Altman, D.G., Tetzlaff, J., Mulrow, C., Gøtzsche, P.C., Ioannidis, J.P., Clarke, M., Devereaux, P.J., Kleijnen, J. and Moher, D., 2009. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS medicine*, 6(7), p.e1000100.
- Llorens, R., Noé, E., Ferri, J. and Alcañiz, M., 2015. Videogame-based group therapy to improve self-awareness and social skills after traumatic brain injury. *Journal of neuroengineering and rehabilitation*, 12(1), p.37.
- Maher, C.G., Sherrington, C., Herbert, R.D., Moseley, A.M. and Elkins, M., 2003. Reliability of the PEDro scale for rating quality of randomized controlled trials. *Physical therapy*, *83*(8), pp.713-721.
- Marin, R.S., Biedrzycki, R.C. and Firinciogullari, S., 1991. Reliability and validity of the Apathy Evaluation Scale. *Psychiatry research*, *38*(2), pp.143-162.
- Marin, R.S. and Wilkosz, P.A., 2005. Disorders of diminished motivation. *The Journal of head trauma rehabilitation*, 20(4), pp.377-388.
- McIntyre, A., Janzen, S., Richardson, M., Kwok, C. and Teasell, R., 2015. An overview of acquired brain injury rehabilitation randomized controlled trials. *The Journal of head trauma rehabilitation*, 30(6), pp.E47-E53.
- Moher, D., Liberati, A., Tetzlaff, J., Altman, D.G. and Prisma Group, 2009. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS medicine*, 6(7), p.e1000097.
- Oddy, M., Cattran, C. and Wood, R., 2008. The development of a measure of motivational changes following acquired brain injury. *Journal of clinical and experimental neuropsychology*, 30(5), pp.568-575.
- Petticrew, M., 2015. Time to rethink the systematic review catechism? Moving from 'what works' to 'what happens'. *Systematic reviews*, *4*(1), p.36.
- Ross, K.A., Dorris, L. and McMillan, T., 2011. A systematic review of psychological interventions to alleviate cognitive and psychosocial problems in children with acquired brain injury. *Developmental Medicine & Child Neurology*, 53(8), pp.692-701.

- Ryan, R.M., 1982. Control and information in the intrapersonal sphere: An extension of cognitive evaluation theory. *Journal of personality and social psychology*, *43*(3), p.450.
- Ryan, R.M. and Deci, E.L., 2000. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American psychologist*, 55(1), p.68.
- Ryan R, Hill S, Prictor M, McKenzie J; Cochrane Consumers and Communication Review Group. Study Quality Guide. 2013 [PDF] Available from: <<u>https://cccrg.cochrane.org/sites/cccrg.cochrane.org/files/public/uploads/StudyQual</u> ityGuide_May%202013.pdf> [Accessed 3rd August 2017]
- Schulz, K.F., Altman, D.G. and Moher, D., 2010. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC medicine*, 8(1), p.18.
- Scottish Intercollegiate Guidelines Network. Brain injury rehabilitation in adults. Edinburgh: SIGN 2013 (SIGN Guideline 130). [PDF] Available from: <<u>http://www.sign.ac.uk/pdf/sign130.pdf</u>> [Accessed 3rd August 2017]
- Skidmore, E.R., Whyte, E.M., Butters, M.A., Terhorst, L. and Reynolds, C.F., 2015. Strategy training during inpatient rehabilitation may prevent apathy symptoms after acute stroke. *PM&R*, 7(6), pp.562-570.
- Sterne, J.A., Hernán, M.A., Reeves, B.C., Savović, J., Berkman, N.D., Viswanathan, M., Henry, D., Altman, D.G., Ansari, M.T., Boutron, I. and Carpenter, J.R., 2016. ROBINS-I: a tool for assessing risk of bias in nonrandomised studies of interventions. *Bmj*, 355, p.i4919.
- Tate, R.L., Perdices, M., Rosenkoetter, U., Wakim, D., Godbee, K., Togher, L. and McDonald, S., 2013. Revision of a method quality rating scale for single-case experimental designs and n-of-1 trials: The 15-item Risk of Bias in N-of-1 Trials (RoBiNT) Scale. *Neuropsychological Rehabilitation*, 23(5), pp.619-638.
- The Matrix: A Guide to Delivering Evidence-Based Psychological Therapies in Scotland, 2: Evidence Tables, *'Neurological Disorders'*. 2015. [PDF] Available from:

<<u>http://www.nes.scot.nhs.uk/media/3325330/matrix_-_neurologicaltables.pdf</u>> [Accessed 3rd August 2017]

 Vanderploeg, R.D., Schwab, K., Walker, W.C., Fraser, J.A., Sigford, B.J., Date, E.S., Scott, S.G., Curtiss, G., Salazar, A.M., Warden, D.L. and Defense and Veterans Brain Injury Center Study Group, 2008. Rehabilitation of traumatic brain injury in active duty military personnel and veterans: Defense and Veterans Brain Injury Center randomized controlled trial of two rehabilitation approaches. *Archives of physical medicine and rehabilitation*, *89*(12), pp.2227-2238

• van Reekum, R., Stuss, D.T. and Ostrander, L., 2005. Apathy: why care?. *The Journal of neuropsychiatry and clinical neurosciences*, *17*(1), pp.7-19.

CHAPTER TWO

MAJOR RESEARCH PROJECT

"A video intervention to improve treatment motivation and selfawareness in people with moderate to severe acquired brain injury (ABI): a feasibility study"

> Janie Moira Hunter* M.A. (Hons)(SocSci)

Word count (including abstract and references): 7768

* Mental Health and Wellbeing, Institute of Health and Wellbeing, University of Glasgow
Address for correspondence:
Mental Health and Wellbeing
1st Floor, Admin Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Tel: 0141 211 3927

Prepared in accordance with submission requirements for Neuropsychological Rehabilitation (See Appendix 1.1)

PLAIN ENGLISH SUMMARY

Background: Acquired Brain Injury (ABI) is often associated with poor awareness into ongoing symptoms following damage to the brain. A multi-disciplinary rehabilitation programme is recommended to help with such symptoms. However, without self-awareness of difficulties, people with ABI can have poor motivation to take part. In order to improve treatment engagement, some research suggests that showing people a video before they begin can help increase motivation.

Aims: Before conducting a clinical trial, feasibility studies are recommended to assess whether an intervention can be carried out. This study aims to investigate the feasibility of using a preparatory video about ABI rehabilitation, by exploring whether staff find supporting participants to view the video easy to incorporate into routine practice. The study also aims to explore whether showing people the video has an effect on selfawareness of difficulties, and their motivation to take part in rehabilitation.

Procedure: Participants were recruited from a brain injury inpatient unit, and randomly allocated to a group who began taking part straight away or one that started after two weeks. They were supported by staff to watch a short video two/three days a week, over four weeks. The video aimed to improve understanding of the kinds of emotional and/or practical difficulties they may be experiencing, and to inform about what rehabilitation might be like. Participants completed questionnaires relating to motivation for rehabilitation and awareness of difficulties before and after the four-week period. The staff members that supported the participants also completed an evaluation of how they found delivering the video, and questionnaires about participants' level of engagement in their rehabilitation sessions.

Results: Staff rated the use of the video as feasible, and reported they plan to continue using the video. There were indications of change in some individuals' motivation, awareness of deficits, and rehabilitation behaviour, however these effects should only be viewed as an introduction for future studies.

Conclusions: The video intervention was rated by staff as feasible for use in clinical practice, and future studies, which should further explore the effects of preparatory video information on motivation, awareness of difficulties, and rehabilitation attendance and engagement in inpatients with ABI. Further research should consider the difficulties in recruitment and presenting the video intervention encountered in this study.

ABSTRACT

Background: Individuals who suffer acquired brain injury (ABI) commonly demonstrate deficits in awareness. This may contribute to poor motivation for participation in neurorehabilitation, as a result of problems with self-regulation, goal-setting, and risk awareness. Research has suggested that preparing individuals for therapeutic interventions can improve engagement and promote more accurate expectations of interventions. For example, recent evidence suggests that providing structured information about treatment rationale and therapy tasks can increase treatment engagement motivation (Campbell et al. 2017).

Objectives: To determine feasibility of providing a video of preparatory information within ABI inpatient services, and to investigate the use of this video in increasing insight, motivation, and rehabilitation behaviour (attendance and engagement).

Method: Participants (N=11) were recruited from a brain injury inpatient unit, and randomised to immediate or lagged exposure to the video. A preparatory video aimed at improving insight and increasing motivation was shown regularly over a period of four weeks. Multi-disciplinary clinical staff evaluated the feasibility of delivering the video intervention using structured ratings Additionally, pre- and post-trial measures of motivation for rehabilitation, insight and rehabilitation behaviours were recorded.

Results: Staff rated the use of the video as feasible, in terms of the intervention itself, resource consequences, and evaluation. In addition, management and senior staff reported intent to continue use of the video. Preliminary exploration of secondary measures of motivation, awareness of deficits, and rehabilitation behaviour suggests there were some indicators of change at individual levels. Due to the main study focus on feasibility, these clinical effects are to be treated as highly preliminary.

Conclusions: Further piloting of this preparatory information video intervention is recommended to further explore the effects of such intervention on the motivation and awareness of deficits in people with ABI. There is a need for future trials to include formal process evaluation.

INTRODUCTION

Awareness and motivation

Acquired brain injury (ABI) is damage to the brain caused by an external force or pathophysiological damage resulting from non-degenerative organic factors such as stroke, aneurysm or neurological disease. Traumatic brain injury (TBI; damage occurring by external force) is the most common cause of ABI, and up to 45% of individuals who suffer moderate to severe TBI demonstrate deficits in their awareness of cognitive and behavioural sequelae (Flashman & McAllister 2002). Multiple biopsychosocial factors can cause problems with self-awareness: influences of psychological factors such as coping style; neuropathology relating to the ABI; and social factors such as interactions, values, and cultural diversity (FitzGerald et al., 2012). The outcomes after ABI are broad, as damage to the brain can vary widely (e.g. focal versus diffuse damage) resulting in different clinical presentations. Patients may also lack the insight necessary to set realistic goals, all of which may contribute to poor participation in rehabilitation. In creation of rehabilitation interventions, Oddy et al., (2008) emphasise the importance of considering improved awareness as a primary goal of intervention, not just a by-product of rehabilitation. For example, if a patient is unaware of their cognitive deficits, one main objective of their rehabilitation should be to address this unawareness.

However caution must be exercised when considering benefits of improved awareness. Schrijnemaekers et al., (2014) review of interventions for unawareness of deficits after ABI suggests that greater self-awareness and symptoms of depression are both associated with poorer self-reported quality of life. Thus increased insight into difficulties may lead to a negative change in mood, which in itself can decrease motivation. Shields et al., (2015) studied emotional distress following TBI and found that emotion dysregulation was related to depression and global distress, and that those reporting greater emotion dysregulation had greater difficulties engaging in goal-directed behaviour. Consequently mood regulation may be an important mediating factor when exploring the link between awareness and motivation for rehabilitation.

Apathy, a deficiency in behavioural, emotional and cognitive components of goal-directed behaviour, is a common effect of ABI and should be considered when assessing an individual's problems with motivation. Prevalence rates suggest up to 61% of the TBI

40

population exhibit apathy, 60% of the population who have suffered a focal frontal lesion, and 34.7% of the population who have experienced a stroke (van Reekum et al., 2005). Motivational problems and apathy are difficult to assess and characterise, as they can be caused in different ways (Oddy et al., 2008). The observable behaviour of lack of goal pursuit may result from a number of factors. For example, the primary neuropathological insult may lead to physiological symptoms of fatigue, or impaired executive functioning meaning a failure to set goals or poor execution of goal pursuits. There may be motivation difficulties arising from lack of insight, whereby an individual is unaware of their deficits and therefore the need to take action. Additionally, other factors associated with ABI such as depression and anxiety may lead to a loss of interest in activity, or low self-esteem and lack of belief in abilities to complete tasks. Adjustment to disability and other difficulties may also increase learned helplessness and dependence, whereby an individual is not motivated to pursue actions, as they rely on others. Regardless of the basis, with the presence of apathy as a behavioural presentation following ABI we are likely to see a reduction in goal-directed behaviours; one such behaviour is engagement in rehabilitation.

Rehabilitation guidelines

Reviews of the current evidence base for ABI treatment recommend a holistic rehabilitation programme to address neurobehavioural and psychosocial difficulties (The Matrix 2015, SIGN-130 2013, McMillan 2013). Fundamental to the holistic approach is working with the whole individual rather than single areas of difficulty. Successful outcomes are associated with intensive and prolonged interventions involving multidisciplinary working aimed at physical, cognitive, emotional and behavioural difficulties with the aim of improving functioning in meaningful everyday activities, including community integration. Therefore the holistic approach suggests that a key task is to identify and respond to individual needs. Considering the high prevalence of impaired awareness and motivation, addressing 'motivational hooks' may be important targets for improving engagement. In addition to this individually tailored approach, there is a need for scaleable and generalisable approaches that are relevant to many people with ABI, and can be widely utilised within rehabilitation services. These more universal approaches can then help establish a foundation making patients more prepared for individualised care.

Engagement

A major barrier to holistic neurorehabilitation is lack of engagement. ABI can severely affect an individual's motivation to take part in activities, and also the ability to recognise problems and understand possible solutions, therefore reducing the likelihood of taking part in rehabilitation. A systemic review of interventions aimed at improving rehabilitation engagement by Brett et al., (2015) found that behavioural strategies such as contingent rewards (e.g. a token economy, Corrigan & Bogner, 2007) improved compliance with rehabilitation, however more cognitive interventions aiming to equip clients with the skills required for self-directed rehabilitation (e.g. Skidmore et al., 2011) facilitated an increase in motivation and engagement. The cognitive interventions that demonstrated the greatest success were those that empowered clients to play an active role in their rehabilitation, which is in line with SIGN-130 guidance for collaborative client-centred goal planning.

Studies examining the effect of preparatory information within non-ABI adult mental health settings (Deane et al., 1992, Johansen et al., 2011) suggest that pre-intervention information can improve engagement, reduce anxiety and promote more accurate expectations of interventions. Within an ABI population, Pegg et al., (2005) found that providing personalised information on ABI and the rehabilitation progress increased patients' effort in subsequent physical therapy and cognitive rehabilitation. Results suggest that despite variability in the participants' ability to understand the information presented to them, the very act of receiving information enhanced their perception of involvement in their own care. Campbell et al. (2017) also found a significant increase in motivation for a compassion-focussed imagery task in ABI inpatients following exposure to videopresented general preparatory information. It is proposed that while preparatory information alone is not enough to encourage engagement, by reducing fear, confusion and avoidance it may hasten the speed with which an individual can be engaged in holistic neurorehabiliation. Difficulties commonly associated with ABI include memory problems, slowed processing speed, and mood dysregulation, as well as a general lack of familiarity with rehabilitation concepts; these are factors to bear in mind when devising preparatory information for this population. Information should be kept simple and short, and it will likely be necessary to repeat the information to support consolidation and understanding. Holding in mind that increased awareness into deficits may impact on mood (Schrijnemaekers et al., 2014), information should be put in terms that are not only easily understood but also non-threatening.

There is much to be learned about how to improve engagement in inpatient ABI rehabilitation in a way that is effective, generalisable, and scaleable. Previous findings (Campbell et al. 2017) suggest a role for video-based preparatory information, and a cost-effective and parsimonious approach to new complex intervention development is to follow The Medical Research Council (MRC) framework for developing complex interventions. This emphasises the importance of conducting feasibility and pilot work prior to conducting a large-scale study of efficacy (Craig et al., 2013). Eldridge et al. (2017) developed a conceptual framework for the definition of studies where feasibility is an overarching concept in assessing whether future studies, interventions or developments can be done; this study is a feasibility study in line with these recommendations.

Aims

- To investigate the feasibility of using a repeatable preparatory protocol in moderatesevere ABI in an inpatient neurorehabilitation service.
- To design, implement and investigate the usefulness of preparatory material for moderate-severe ABI patients as a way of increasing motivation, awareness, and engagement in rehabilitation.

Hypotheses

- Presentation of generalised preparatory information is a feasible intervention as part of a general protocol for ABI inpatient services.
- Exposure to preparatory information will increase self-reported motivation to engage in rehabilitation interventions.
- Preparatory information will improve awareness of difficulties and rehabilitation needs.
- Preparatory information will facilitate a change in behaviour, as demonstrated by increased activity attendance and staff ratings of engagement at rehabilitation sessions.

METHOD

Ethical approval

Ethical approval was obtained from the West of Scotland Research Ethics Committee (reference number 16/WS/0232), and ethical and management approval from the Brain Injury Rehabilitation Trust (BIRT) (Appendix 2.2).

Design

The study setting was Graham Anderson House [GAH] (a service run by BIRT), which is a post-acute independent hospital that specialises in assessment and rehabilitation of people with complex needs following ABI. BIRT adopt a neurobehavioural rehabilitation approach, combining evidence-based methods of changing behaviour with an understanding of neuropsychological changes associated with ABI (Worthington et al., 2017). On-site multi-disciplinary teams deliver interventions, and each client has a structured holistic rehabilitation programme (as recommended by SIGN 130) involving individual sessions and group treatments.

The study is a feasibility trial of a preparatory video intervention for use in inpatient neurorehabilitation for people with ABI. This study aims to estimate the important parameters needed to design future studies of preparatory information, by observing the integrity of the protocol via exploring numbers of eligible participants, feedback on intervention, response rates, adherence/compliance rates, and the ease of data collection. Arain et al. (2010) expand further by making formal distinctions between feasibility and pilot studies, whereby a pilot study is focussed on the processes of a wider study, and reflects a more rigorous methodological adherence to a main study "in miniature". This feasibility design reflects strategies that could be used in future randomised trials, including more rigorous pilot studies. It is a repeated-measures design, with a delayedviewing (lagged-exposure) group. During the delay period, the lagged-exposure group continued to receive usual care from BIRT rehabilitation staff. The preparatory video was presented to all participants, who also completed pre/mid/post-trial measures. The primary outcome is the assessment of the feasibility of the preparatory material as an intervention (SAFE; Bird et al., 2014). Secondary outcomes are motivation for rehabilitation (MOT-Q: Chervinsky et al., 1998), awareness (AQ: Sherer, 2004) and rehabilitation behaviour change (PRPS: Lenze et al., 2004, attendance statistics).

Sample size aims

This is a preliminary feasibility study aiming to model recruitment and procedure, and to detect patterns rather than effects. Current best practice regarding feasibility studies (Arain et al. 2010) suggests that the usual power calculation should not be undertaken, and instead the sample size should be adequate to estimate the critical parameters for the study objectives, for example estimation of eligible participants and recruitment rate. It was anticipated (taking into account number of beds in inpatient unit, possible discharges

during trial period, and previous rates of participation in research conducted at BIRT that 20 inpatient participants in total (ten per group) would be eligible for recruitment in the time available. This sample size is comparable to therapeutic studies within a brain injury population (e.g. Hodgson et al., 2005, RCT n=12; Hsieh et al., 2012, RCT n=27).

Participants

Participants were recruited from GAH. Primary participants were service users and secondary participants were members of the GAH professional multidisciplinary clinical team. Led by a consultant in neuropsychology and rehabilitation, the MDT includes clinical psychologists, assistant psychologists, speech and language therapists, physiotherapists, and occupational therapists.

Eligibility criteria

Service users were current inpatients at GAH with a moderate-severe ABI, aged >18 years. Only participants considered to have capacity to consent by professionals responsible for their care were approached. Individuals were ineligible if they had communication difficulties that might affect ability to consent to or understand/comply with test procedures, were not fluent in English, were experiencing severe mental illness/challenging behaviour that would prevent meaningful participation in the study, or had a planned discharge date within the trial period. Information regarding eligibility for recruitment was provided by BIRT professionals responsible for their care.

Inclusion criteria for staff participants were that they worked directly with participants, and had commenced employment at BIRT prior to first assessment. Only patient's key therapists from the MDT clinical team participated in test procedures.

Recruitment

The study enrolment window was 7th-19th April 2017, during which 19 inpatients met the inclusion criteria. All participants (patients and staff) who met inclusion criteria were provided with an information sheet and at least 24 hours to consider participation (Appendices 2.10, 2.12). Four patients who met inclusion criteria declined to participate. Once the researcher obtained consent (Appendices 2.11, 2.13), baseline measures were completed with patients and staff. The same measures were completed mid- and post-intervention (weeks 2, 6). The key therapists of these service user participants were recruited to complete staff measures (seven staff participants). In line with BIRT policy

regarding service users taking part in research, details regarding the study and their participation were included in their care plans.

Eleven service users completed all assessments (intervention, N=5; lagged-exposure N=6). Of the remainder, one withdrew before completion of baseline measures, one self-discharged before completion of baseline measures, one was withdrawn in week 2 due to increasing frustration when presented the video due to slowed processing speed, and one was discharged in week 6 before completion of final measures could take place. A further six inpatients were admitted to GAH throughout May/June during the trial period (not checked against eligibility criteria).

Participants who completed baseline measures were a mixed group of 13 adults with acquired brain damage: seven with traumatic brain injury with CT evidence for intracranial bleeding or cerebral contusions, five with stroke or cerebral hypoxia and one with alcohol related brain damage also confirmed by CT. It was noted that two had a history of experiencing psychotic symptoms, however these were not evident during their admission to GAH.

Measures

Demographic information

Demographic details were gathered regarding each participant, including: age; gender; highest level of education; postcode (to translate to social deprivation, SIMD 2012); nature of ABI; measure of level of disability (Glasgow Outcome at Discharge Scale). In addition, information regarding a cognitive profile was gathered. The information available in GAH records varied between participants, owing to differences in stage of assessment. Cognitive domains of memory, executive functioning, complex attention/processing speed, language, and perceptual-motor function were considered, and recorded if the participant had been assessed to demonstrate impairments in this domain.

Primary outcome measures: intervention implementation and the process of intervention delivery

• The <u>Structured Assessment of Feasibility measure (SAFE)</u> (Bird et al., 2014) is a 16item measure, which assesses blocks/enablers of routinely implementing an intervention (in this case, the preparatory video), and was completed by MDT clinicians within GAH. Feasibility is defined as the cumulative impact of these blocks/enablers. Bird et al., (2014) reported excellent inter-rater (0.84) and testretest reliability (0.89) assessed by Cronbach's alpha.

• Data regarding the percentage of scheduled videos actually delivered to each participant was collected to consider the feasibility of regular delivery of the intervention.

Secondary outcome measures

- Motivation: Motivation for traumatic brain injury rehabilitation questionnaire -MOT-Q (Chervinsky et al., 1998). This Likert-scale questionnaire assesses factors that facilitate or act as barriers to motivation to engage in rehabilitation, including denial of illness, anger, compliance with treatment, and medical information seeking behaviour. This scale has good reliability (Cronbach's alpha = 0.91).
- Insight into difficulties: The <u>Awareness Questionnaire AQ</u> (Sherer, 2004). This is

 a 17-item questionnaire designed to assess self-awareness in ABI. There are three
 versions of the AQ, one for staff, one for a family member and one for service
 users. Two of these (staff and service user questionnaires) were adopted in this
 feasibility study. Sherer et al., (1998a) reported good internal consistency for the
 AQ (Cronbachs alpha = 0.88), and good validity. The awareness score is calculated
 as the difference between patient and staff scores, indicating the degree to which
 the patient has similar insight to that of the professional view.
- Behaviour changes: After a rehabilitation session at each time point staff participants completed a rehabilitation engagement measure, <u>The Pittsburgh Rehabilitation Participation Scale PRPS.</u> This is a single item instrument measuring participation on a 6- point Likert scale, and demonstrates good interrater reliability (0.91) and validity (Lenze et al., 2004). The rating points consider therapy attendance and effort in therapy, as well as interest in activities and future therapy. Rating of engagement in rehabilitation activities (including 1:1 or group sessions) was used as outcome measure. In addition, participation statistics routinely collected by GAH record the number of rehabilitation sessions offered that are attended. This information was gathered for the pre-, mid- and post-trial weeks.

Intervention process

Construction of preparatory video

Review of the literature and information from professionals working within BIRT (Consultant Clinical Psychologist, Clinical Psychologists, Speech and Language Therapist) informed creation of the preparatory video, which was aimed at increasing psychological readiness for neurorehabilitation. Video content was tailored for an ABI population, allowing for common difficulties such as impairments in memory/attention, executive functioning, and processing speed.

The main information targets of the video were information about ABI (i.e. various mechanisms for sustaining ABI, common sequelae, reference to common shared goals and values within inpatient neurorehabilitation, orientation to inpatient admission), and information about the acute rehabilitation offered within BIRT (see Appendix 2.15 for script).

Evidence from research into wider health behaviour change areas (including alcohol and substance abuse, obesity, HIV/AIDS prevention, medication compliance, and smoking cessation) support these as potentially important elements in preparing individuals for action, with 'consciousness raising' as an experiential process important in supporting individuals through a continuum of motivational readiness as explained in the Transtheoretical Model of Stages of Change (Prochaska et al., 2008). Additionally, reference to shared goals and experiences aims to enhance intrinsic motivation by tapping into the innate human need for relatedness, while explanation of the person-centred and collaborative goal planning within neurorehabilitation supports the tenets of the need for autonomy and competence, as outlined in self-determination theory (Ryan & Deci 2000).

The preparatory video was recorded on an encrypted laptop, downloaded onto GAH iPads, and then uploaded on to a password protected video sharing website (Vimeo). The final video was seven minutes in length, and can be viewed online at https://vimeo.com/214526226 (password: rehabvideo).

Intervention phase

Participants were randomly assigned by stratified block sampling to intervention or laggedexposure groups. In order to control for covariates participants were stratified by time since admission, and motivation for rehabilitation as measured by the MOT-Q; this was to ensure that the possible influences of longer previous exposure to rehabilitation and baseline motivation level were balanced across groups. The randomisation process was undertaken using an online statistical computing web programme (www.sealedenvelope.com).

The aim was that all participants would be shown the preparatory video in a 1:1 delivery by a member of BIRT staff (RSWs), and this allocated as a daily task by nursing staff. The presentation was planned to be 3-4 times per week for 4 weeks, with the lagged-exposure group having a delayed exposure of two weeks. Due to some implementation issues, the presentation of the video was in fact facilitated by clinical team members, incorporated into planned sessions with service users. This new timetable was planned to facilitate each participant viewing the video ten times over their four-week intervention period, with the lagged-exposure group remaining on delay of two weeks. The lagged-exposure group continued to receive routine care throughout this delay period. BIRT staff recorded the number of videos watched by each participant. As a result of these issues, the trial began three weeks later than intended.

Presentation of the video was facilitated using GAH's iPad electronic tablets, and participants were able to view the video in their own rooms or in quiet lounge areas, supported by a member of the clinical team. Outcome measures were completed in private clinical rooms, quiet lounge areas, or in patient bedrooms when requested.

The primary outcome measure, regarding feasibility of the video intervention, was completed post-trial (week 6) by staff participants. Secondary outcome measures of motivation, awareness, and behaviour change, were completed pre-, mid- and post- trial (weeks 0, 2 and 6) with inpatient and staff participants. The researcher completed measures with inpatient participants, and staff participants were sent weekly email reminders with measures attached, in addition to researcher prompting when in the unit.

Inpatient participant mood was monitored throughout the trial through observation and clinician feedback; this allowed consideration of possible mediating effects of the intervention, and any appropriate response.

Analysis

Missing data

At the mid-point (week 2; intervention group = video, lagged-exposure = no video) the

MOT-Q was not completed for two participants (one refused on a number of attempts, and another was on a home pass). The AQ clinician-form was not completed for five participants, and the PRPS was not completed by any staff participants at the mid-point. One inpatient participant was on extended home pass for the final three weeks of the trial period, and discharged in week 6 before post-trial measures could be completed.

Feasibility

Each SAFE item was identified from implementation research, and classified as either a block (eight items) or an enabler (eight items) of implementation. Findings of the SAFE questionnaire are summarised into visual feasibility profiles. While 'acceptability' is often declared a focus of feasibility studies, the current study did not formally assess this. The MRC guidance for developing complex interventions (2010) includes acceptability as a factor, however it provides no definition of this, nor clear instructions on how to assess it. Bowen et al., (2009) propose that understanding the acceptability of an intervention requires consideration of how "satisfying or attractive" it is to both those delivering and receiving, and outcomes may include comments upon the interventions as well as intent to continue use; such comments are reported descriptively. Data regarding the number of planned video presentations facilitated are presented.

Treatment effects

In line with current guidance in the reporting of feasibility studies (Arain et al. 2010, Lancaster et al., 2004), analysis of the trial is mainly descriptive, to avoid inappropriate emphasis on hypothesis testing. As such data are explored to evaluate promise of efficacy in a larger sample, however there should not be undue significance placed upon these results and they should be treated as only preliminary.

Descriptive statistics (mean, standard deviations) are presented for each measure for participants completing assessments at both time points (N=11). Statistical investigation of the data was completed using IBM SPSS version 22.

Odds ratios are used to express the relative likelihood of improvement in motivation, awareness and rehabilitation behaviour in each condition (intervention/video vs. lagged-exposure/no video).

Sensitivity analysis was conducted on the secondary outcome measures (MOT-Q, AQ, PRPS), to test for clinically significant change after the video intervention trial period, for those completing assessments pre-, and post-video trial. The Reliable Change Index (RCI) determines whether the magnitude of change for an individual participant is statistically reliable (i.e. RCI <-1.96 or > 1.96; Evans, Margison, & Barkham, 1998). Calculations were based on estimates of internal reliability (see Appendix 2.15).

- MOT-Q: Chervinsky et al., 1998 (Bains et al., 2007 α=0.86 [ABI population])
- AQ: Sherer et al., (1998; α=0.88)
- PRPS: Lenze et al. (2004; intraclass correlation coefficient (ICC) =0.91)

RESULTS

Implementation

In preparation for the intervention period, there were some issues that led to delays in starting the study, which speak to feasibility. There initially arose a number of unexpected delays in staff recruitment, owing to staffing changes and a need for clarification about key therapists. Further to this, when the planned trial period began there were complications whereby the video was not being presented as planned. On exploring this, a number of unusual situational factors were discovered (including new staff systems, changes to routine timetable, and service user issues), suggesting that idiosyncratic circumstances may have an impact on the feasibility of a wider application of the video protocol in future studies

Demographic variables

Characteristics of the sample can be seen in Table 1.

Table 1: Participant Characteristics for overall sample at baseline (N=13); mean (SD) and range or N and percentage.

| | | Treatme | ent group |
|---|---|---|---|
| | | Intervention (N=6) | Lagged-exposure (N=7) |
| Age | | 44 (11.94); 28–63 | 52.8 (14.58); 32–70 |
| Gender: | Male; Female | 5 (83%); 1 (17%) | 6 (86%); 1 (14%) |
| Time since admission (in weeks): | | 38.6 (53.6); 3-142 | 46.8 (55.17); 1-162 |
| Nature of ABI: | TBI Stroke/hypoxia Alcohol related brain damage | 3 (50%) 3 (50%) 0 | 3 (43%) 3 (43%) 1 (14%) |
| Glasgow Outcome Discharge Scale-Extended | Lower severe disability Upper severe disability | 4 (66%) 2 (34%) | 4 (57%) 2 (29%) |
| Rating: | Lower moderate disability | | 1 (14%) |
| Measure of social deprivation (SIMD quintile): | Q1 (most deprived) Q2 Q3 Q4 Q5 (least deprived) | 3 (50%) 2 (34%) 0 1 (16%) 0 | 2 (28.5%) 1 (14.5%) 2 (28.5%) 0 2 (28.5%) |
| Cognitive impairments: | Memory Complex attention Executive function Language Perceptual-motor | 6 (100%) 4 (67%) 4 (67) 0 2 (33%) | 6 (86%) 4 (57%) 4 (57%) 2 (28%) 0 |
| Highest level of education: | Secondary school College Higher education | 1 (17%) 4 (66%) 1 (17%) | 2 (28.5%) 3 (43%) 2 (28.5%) |

Experimental Analyses

• Is presentation of generalised preparatory information video a feasible intervention as part of a general protocol for ABI inpatient services?

SAFE questionnaire results

The SAFE was completed by six staff participants; the response options available were "yes", "partial", "no" and "unable to rate". A visualisation of the proportion of reported blocks and enablers for SAFE items is shown in Table 2. Regarding efficacy, the staff respondents showed some variation in their responses: one respondent rated there was "partial" evidence for use of the video, and commented to the researcher this was based on reports from service users who found the video informative. Three further respondents rated "yes", and they commented to the researcher that while there is currently no established evidence base for the intervention it was their clinical judgment that the video

would likely be effective within the context of GAH. The final two respondents, both clinical psychologists, were "unable to rate" the efficacy of the video, stating there is not yet enough evidence. This range of responses may reflect differences between professional groups in their definition of how efficacy can be measured.

Acceptability

In addition to formal feedback by clinicians in the SAFE, informal feedback on the video intervention was positive from clinicians and service users. Inpatient participants said that they recognised their own experiences in examples from the video; that they remembered more information each time they saw the video; and that it was not taxing to watch. Management and senior staff at GAH reported they would use the video on GAH iPads for orientation purposes and intend to use the video for staff training and on their webpage.

Scheduled videos presented.

The planned timetable for video presentation allocated ten viewings over the four-week intervention period (3x in two of the intervention weeks, 2x in the further two weeks). For the intervention group, the mean number of video presentations was 7, and this is 70% of those planned. During the final two weeks of the trial period the issues that arose within the unit limited the number of presentations. For this reason the number of planned videos shown to the lagged-exposure group averaged 5 (SD=17.9) equating to 50% of the planned total.

Table 2: Visual profiles of implementation blocks and enablers

| Block/Enabler | Staff 1 | Staff 2 | Staff 3 | Staff 4 | Staff 5 | Staff 6 |
|---|------------|------------|------------|------------|------------|------------|
| B1—Training: Do staff require specific training to deliver the intervention? | Ν | N | N | N | N | Ν |
| B2—Complexity: Is the intervention complex? | N | N | N | N | N | N |
| B3—Time: Is the intervention time- consuming to provide? | N | N | N | N | N | N |
| B4—Support: Does the intervention include/require ongoing support and supervision? | N | N | N | N | N | N |
| B5—Personnel: Does the intervention require additional human resources? | Р | Р | Р | Р | N | N |
| B6—Material: Does the intervention require additional material resources? | Р | Ρ | Р | Р | Р | Р |
| B7—Costs: Is the intervention costly? | Ν | N | N | N | N | N |
| B8—Harms: Are there any known serious or adverse events associated with the intervention? | N | N | N | N | N | N |
| E1—Population: Is the intervention applicable to the population of interest? | Y | Y | Y | Y | Y | Y |
| E2—Manualisation: Is the intervention manualised? | N | U | N | N | N | N |
| E3—Flexibility: Is the intervention flexible? | N | Р | Р | Y | Ν | N |
| E4—Effectiveness: Is the intervention likely to be effective? | U | Y | Y | U | Р | Y |
| E5—Saving: Is the intervention cost-saving? | U | Y | Y | Р | U | Υ |
| E6—Goals: Do the intended goals of the intervention match the prioritised goals of the NHS? | U | Y | Y | Y | U | Y |
| E7—Pilot: Can the intervention be piloted? | Υ | Y | Y | Y | Υ | Y |
| E8—Reversibility: Is the intervention reversible? | Y | Y | Y | Y | Y | Y |

Y= Yes; P= Partial; N = No; U = Unable to rate

• Does a change in self-reported motivation to engage in rehabilitation interventions, awareness of difficulties, and/or engagement behaviour occur following presentation of preparatory information video?

There was indication of some positive change in awareness of impairment, and rehabilitation behaviour pre- to post-intervention although variance is high (see Table 3). Change was marginal for motivation for intervention.

| | Pre-video i | ntervention | Post-video | intervention |
|---|---------------|----------------|---------------|--------------|
| | Mean (SD) | Median (IQR) | Mean (SD) | Median (IQR) |
| Motivation for rehabilitation (MOT-Q) | 20.07 (27.36) | 21 (2.5-45) | 20.81 (29.43) | 29 (7-40) |
| Awareness (AQ) | 9.69 (16.56) | 14 (-8.5-25.5) | 10 (13.67) | 13 (3-22) |
| Engagement in rehabilitation (PRPS) | 3.84 (1.51) | 4 (3-5) | 4.25 (1.6) | 4 (4-6) |
| Attendance in rehabilitation (%age - BIRT stats) | 73.41 (30.51) | 80 (62.5-100) | 81 (27.9) | 95 (70-100) |

• Exploration of treatment effects (see Table 4)

(a) Motivation

In pre- and post-trial comparisons of scores on the MOT-Q measure using RCI, one intervention group participant exhibited significantly improved motivation.

At week 2 midpoint (i.e. video vs. no video), the odds ratio for improved MOTQ scores in intervention group compared to lagged-exposure group = 1 (95% CI 0.08-12.56). This suggests there was no difference between the groups.

(b) Awareness

In pre- and post-trial comparisons of scores on the AQ using RCI, one lagged-exposure group participant improved significantly in self-awareness. His score also moved from a negative score, indicating he was overestimating his difficulties, to a positive score, indicating more underestimation of difficulties.

Due to missing data, awareness scores could not be calculated for all participants at midpoint. Of the data gathered (n=7), all participants in each group showed an improvement in awareness as measured by AQ. As such, an odds ratio could not be calculated (ratio=infinity).

(c) Rehabilitation behaviour (attendance and engagement)

In pre- and post-trial comparisons of scores on the PRPS using RCI, three intervention group participants and two lagged-exposure participants exhibited significantly improved engagement in a rehabilitation session. One intervention participant (Participant 3) demonstrated significantly deteriorated engagement.

At week 2 midpoint the odds ratio for improved attendance in intervention group compared to lagged-exposure group = 1.5 (95% CI 0.07-31.58). This demonstrates percentage attendance at rehabilitation sessions was 1.5 times more likely to have increased in the intervention group; however the confidence interval suggests this is not a significant difference between group.

Rel = Reliability of the measure, taken from ABI populations for the calculation of RCI. Mean and SD were calculated from the intervention/lagged-exposure group data. Bold and * = RCIs Reliable according to the Reliable Change Index RCI; <-1.96 or >1.96. Higher MOT-Q scores indicate improved motivation. AQ scores moving towards 0 indicate increased awareness. Higher PRPS scores indicate improved engagement in rehabilitation session Notes:

| PRPS 0.91 | AQ 0.88 | MOT-Q 0.86 | |
|----------------|----------------|------------|------|
| 1 3.84 | 3 9.69 | 3 20.07 | |
| 1.51 | 16.56 | 27.36 | |
| - | 27 | -36 | ۲re |
| 4 | 25 | -46 | Post |
| *6 <u>.</u> 66 | -0.35 | -0.98 | RCI |
| വ | -9 | 42 | Pre |
| сл | -2 | 39 | Post |
| 0 | 1.22 | -0.29 | RCI |
| ω | 27 | 15 | ۲re |
| ω | 24 | 17 | Post |
| 0 | 0.52 | 0.19 | RCI |

| Measure Rel | Rel | Mean at SD at | SD at | Lagge | Lagged-exposure 4 | ire 4 | Lagge | Lagged-exposure | ıre 5 | Lagge | ged-exposure 6 | re 6 |
|-------------|------|---------------|----------|-------|-------------------|-------|-------|-----------------|-------|-------|----------------|-------|
| | | baseline | baseline | | | | | | | | | |
| | | | | Pre | Post | RCI | Pre | Post | RCI | Pre | Post | RCI |
| MOT-Q | 0.86 | 20.07 | 27.36 | -36 | -46 | -0.98 | 42 | 98 | -0.29 | 15 | 17 | 0.19 |
| ٥O | 88 U | 090 | 95 91 | 70 | 22 | -0.35 | 6- | c- | 1 22 | 70 | 24 | 0 7 N |

| Measure | Rel | Mean at | SD at | Interve | Intervention 5 | | Lagge | Lagged-exposure | ure 1 | Lagge | Lagged-exposure 2 | ure 2 | Lagge | Lagged-exposure 3 | sure 3 |
|---------|------|----------|----------|---------|----------------|------|-------|-----------------|-------|-------|-------------------|-------|-------|-------------------|--------|
| | | baseline | baseline | | | | | | | | | | | | |
| | | | | Pre | Post | RCI | Pre | Post | RCI | Pre | Post | RCI | Pre | Post | RCI |
| MOT-Q | 0.86 | 20.07 | 27.36 | 22 | 33 | 1.07 | 15 | 29 | 1.37 | 49 | 40 | 0.88 | -10 | μ | -0.49 |
| AQ | 0.88 | 9.69 | 16.56 | 8 | 8 | 0 | 22 | 22 | 0 | 8 | 7 | *2.6 | 19 | 20 | 0.17 |
| PRPS | 0.91 | 3.84 | 1.51 | 4 | 4 | 0 | З | 4 | *2.2 | 6 | 6 | 0 | 2 | 2 | 0 |

| Measure | Re | Mean at | SD at | Interve | Intervention 1 | | Interve | ntervention 2 | | Interve | Intervention 3 | | Interve | Intervention 4 | |
|---------|------|----------|----------|---------|----------------|---------------|---------|---------------|-------|---------|----------------|--------|---------|----------------|-------|
| | | baseline | baseline | | | | | | | | | | | | |
| | | | | Pre | Post | RCI | Pre | Post | RCI | Pre | Post | RCI | Pre | Post | t RCI |
| MOT-Q | 0.86 | 20.07 | 27.36 | 58 | 61 | 0.29 | -13 | 8 | *2.05 | 48 | 46 | -0.19 | 15 | 7 | -0.78 |
| AQ | 0.88 | 9.69 | 16.56 | -9 | З | -1.05 | 14 | 13 | -0.17 | -19 | -20 | 0.17 | 24 | 20 | 0.70 |
| PRPS | 0.91 | 3.84 | 1.51 | 4 | 6 | 44. 4* | ε | <u>л</u> | *4.44 | 5 | 1 | 68'8-* | Сī | 6 | *2.22 |

Table 4: Reliable Change scores

DISCUSSION

Findings

This feasibility study examined the use of a brief preparatory information video for adults with ABI admitted to a specialist inpatient rehabilitation unit. The main objective was to inform future research into the use of interventions aimed at improving engagement with inpatient rehabilitation, in part by targeting the mechanisms of self-awareness and motivation.

Inpatient multi-disciplinary clinical staff rated the intervention positively, with particular comments upon the ease of integration into routine rehabilitation and care. They rated the use of the video overall as feasible, in terms of its complexity, resource demands, and alignment with NHS aims. In addition, management and senior staff reported plans to continue using the intervention video in future for inpatients and staff, which speaks to the views regarding acceptability from those involved in the day to day implementation of neurorehabilitation. In particular, this study provides valuable information that speaks to the refinement and delivery of the intervention, and the integration of the intervention into routine rehabilitation practice.

There were some indicators of change in the secondary measures of motivation, awareness of deficits, and rehabilitation behaviours (attendance and engagement in sessions). These were explored at individual levels, due to the small sample size. After the intervention trial period, one individual demonstrated significantly improved motivation, one demonstrated significantly improved self-awareness of deficits, and five demonstrated improved engagement in rehabilitation sessions. One participant demonstrated significantly deteriorated engagement. In comparisons of the groups at a point when the lagged-exposure group had not yet viewed the video intervention, rehabilitation behaviour (i.e. attendance at rehabilitation sessions) was more likely to have increased in the intervention group; however confidence intervals suggest this change was not significant.

The preparatory information video intervention used here did not replicate the significant increase in motivation for treatment reported by Campbell et al. (2017). In exploring the effect upon self-compassion of a brief compassion focused imagery intervention compared to a relaxation imagery intervention, the authors discovered a main effect that the general

preparatory video shown to both groups increased their motivation to engage with the imagery task. Despite modification of this procedure, by tailoring the video content to ABI and rehabilitation, and increasing the 'dose' i.e. number of presentations, the current study did not find comparable outcomes.

Strengths and limitations

The video intervention presented in the present study was inexpensive to develop, and straightforward to deliver using resources already available in the rehabilitation unit. Overall, compliance with viewing the video was good, and informal feedback was positive with no participants expressing a wish to withdraw. The sample included within this study was comparable to previous studies with a focus on preparatory information for ABI participants (Campbell et al., 2017, O'Neill & McMillan, 2012) in terms of cause of injury and proportion of male and female, suggesting that the sample was representative. The use of electronic tablets for video presentation is in line with the emerging evidence for use of assistive technology in ABI rehabilitation (Brunner et al., 2017). The use of electronic devices for other elements of neurorehabilitation, such as communication or augmentative and assistive aids, suggests that widening the role of such electronic devices to include the easy access of preparatory information for rehabilitation would fit with resources currently being provided and encouraged. Additionally, the nature of this as a feasibility study allows exploration of interventions relating to the 'real world' of ABI neurorehabilitation, and is subject to the issues faced by clinicians day to day.

The sample size was small in comparison to other studies in an ABI population, and comparison with other research suggest that significantly larger sample sizes would be required to accurately test the effects of preparatory information. Due to human error and issues arising within the unit there is missing data, whereby some comparisons could not be explored. These factors are important to consider when addressing feasibility of future studies. Finally, as addressed in the results section, there were a number of practical issues arising in the implementation of the study protocol; these are important concerns to bear in mind in consideration of the amendments to delivery, and how this speaks to feasibility of incorporating such a video-based preparatory intervention into 'routine use' within inpatient rehabilitation units. Current best practice regarding feasibility and pilot studies in preparation for randomised controlled trials (Arain et al. 2010, Eldridge et al. 2016), is in line with the definition that is used by the National Institute of Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre (NETSCC). This defines feasibility

studies as pieces of research that are carried out before a main study in order to estimate important parameters that are needed to design the main study and to determine whether the study can be done. Thus, the study findings relating to participant recruitment, video implementation, and data collection procedures were more important than exploration of effects.

Future research

A key feature of feasibility studies is to contribute insights into challenges encountered, in order to alleviate such risks in future studies. Further studies should address the practical issues of implementation arising in establishing a new intervention, insofar as they can be predicted. Future studies may benefit from a wider recruitment population, for example inclusion of other BIRT inpatient units across the UK, which would hopefully translate to a larger sample size. They may also benefit from a 'rolling recruitment' strategy in order to increase sample size and allow for attrition.

The lack of comparable outcome to Campbell et al. (2017) with regards to increasing motivation raises interesting questions about the role of mere information (i.e. general rehabilitation preparatory video) versus information about the self (i.e. video aimed at developing self-compassion, preparation for compassionate imagery task). It may be that knowledge alone is not enough to facilitate insight or increased motivation, but that there is also a need to instil an attitude of self-compassion. This speaks to the importance of carrying out feasibility and pilot trials. More investigation into the mechanisms of motivation and engagement in rehabilitation is required, to establish the important and active components of preparatory information in ABI, before a RCT can be recommended.

Conclusions

The current study suggests that use of a video-based preparatory intervention protocol is feasible for use within an ABI inpatient rehabilitation setting. While there are some indicators of change in the underlying mechanisms of self-awareness, motivation, and behaviour change, the small sample size precluded exploration of effect sizes. Further feasibility and pilot studies will refine such interventions, with particular focus on acceptability, implementation, and efficacy.

REFERENCE LIST

- Arain, M., Campbell, M.J., Cooper, C.L. and Lancaster, G.A., 2010. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC medical research methodology*, 10(1), p.67.
- Bird, V.J., Le Boutillier, C., Leamy, M., Williams, J., Bradstreet, S. and Slade, M., 2014. Evaluating the feasibility of complex interventions in mental health services: standardised measure and reporting guidelines. *The British Journal of Psychiatry*, 204(4), pp.316-321.
- Bowen, D.J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., Bakken, S., Kaplan, C.P., Squiers, L., Fabrizio, C. and Fernandez, M., 2009. How we design feasibility studies. *American journal of preventive medicine*, 36(5), pp.452-457.
- Brett, C.E., Sykes, C. and Pires-Yfantouda, R., 2017. Interventions to increase engagement with rehabilitation in adults with acquired brain injury: A systematic review. *Neuropsychological rehabilitation*, 27(6), pp.959-982.
- Brunner, M., Hemsley, B., Togher, L. and Palmer, S., 2017. Technology and its role in rehabilitation for people with cognitive-communication disability following a traumatic brain injury (TBI). *Brain injury*, pp.1-16.
- Campbell, I.N., Gallagher, M., McLeod, H.J., O'Neill, B. and McMillan, T.M., 2017. Brief compassion focused imagery for treatment of severe head injury. *Neuropsychological rehabilitation*, pp.1-11.
- Chervinsky, A.B., Ommaya, A.K., Spector, J., Schwab, K. and Salazar, A.M., 1998. Motivation for traumatic brain injury rehabilitation questionnaire (MOT-Q): Reliability, factor analysis, and relationship to MMPI-2 variables. *Archives of Clinical Neuropsychology*, *13*(5), pp.433-446.
- Corrigan, J.D. and Bogner, J., 2007. Interventions to promote retention in substance abuse treatment. *Brain Injury*, *21*(4), pp.343-356.
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. and Petticrew, M., 2013. Developing and evaluating complex interventions: the new Medical Research Council guidance. *International journal of nursing studies*, 50(5), pp.587-592.
- Deane, F.P., Spicer, J. and Leathem, J., 1992. Effects of videotaped preparation information on expectations, anxiety, and psychotherapy outcome. *Journal of Consulting and Clinical Psychology*, 60(6), p.980.

- Eldridge, S.M., Lancaster, G.A., Campbell, M.J., Thabane, L., Hopewell, S., Coleman, C.L. and Bond, C.M., 2016. Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. *PLoS One*, *11*(3), p.e0150205.
- Evans, C., Margison, F. and Barkham, M., 1998. The contribution of reliable and clinically significant change methods to evidence-based mental health. *Evidence-Based Mental Health*, 1(3), pp.70-72.
- FitzGerald, M.C., Carton, S., O'Keeffe, F., Coen, R.F. and Dockree, P.M., 2012. Impaired self-awareness following acquired brain injury: current theory, models and anatomical understanding. *The Irish Journal of Psychology*, *33*(2-3), pp.78-85.
- Flashman, L.A. and McAllister, T.W., 2002. Lack of awareness and its impact in traumatic brain injury. *NeuroRehabilitation*, *17*(4), pp.285-296.
- Hodgson, J., McDonald, S., Tate, R. and Gertler, P., 2005. A randomised controlled trial of a cognitive-behavioural therapy program for managing social anxiety after acquired brain injury. *Brain Impairment*, 6(3), pp.169-180.
- Hsieh, M.Y., Ponsford, J., Wong, D., Schönberger, M., Taffe, J. and Mckay, A., 2012. Motivational interviewing and cognitive behaviour therapy for anxiety following traumatic brain injury: A pilot randomised controlled trial. *Neuropsychological Rehabilitation*, 22(4), pp.585-608.
- Johansen, A.B., Lumley, M. and Cano, A., 2011. Effects of video-based therapy preparation targeting experiential acceptance or the therapeutic alliance. *Psychotherapy*, 48(2), p.163.
- Lancaster, G.A., Dodd, S. and Williamson, P.R., 2004. Design and analysis of pilot studies: recommendations for good practice. *Journal of evaluation in clinical practice*, 10(2), pp.307-312.
- Lenze, E.J., Munin, M.C., Quear, T., Dew, M.A., Rogers, J.C., Begley, A.E. and Reynolds, C.F., 2004. The Pittsburgh Rehabilitation Participation Scale: reliability and validity of a clinician-rated measure of participation in acute rehabilitation. *Archives of physical medicine and rehabilitation*, 85(3), pp.380-384.
- The Matrix: A Guide to Delivering Evidence-Based Psychological Therapies in Scotland, 2: Evidence Tables, '*Neurological Disorders*'. 2015. [PDF] Available from: <<u>http://www.nes.scot.nhs.uk/media/3325330/matrix_-_neurologicaltables.pdf</u>>
 [Accessed 2nd August 2017

- McMillan, T.M., 2013. Outcome of rehabilitation for neurobehavioural disorders. *NeuroRehabilitation*, 32(4), pp.791-801.
- National Institute of Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre (NETSCC) Glossary [ONLINE] Available from: <<u>http://www.nets.nihr.ac.uk/glossary</u>> [Accessed: 2nd August 2017]
- O'Neill, M. and McMillan, T.M., 2012. Can deficits in empathy after head injury be improved by compassionate imagery? *Neuropsychological rehabilitation*, 22(6), pp.836-851.
- Oddy, M., Cattran, C. and Wood, R., 2008. The development of a measure of motivational changes following acquired brain injury. *Journal of clinical and experimental neuropsychology*, 30(5), pp.568-575.
- Pegg Jr, P.O., Auerbach, S.M., Seel, R.T., Buenaver, L.F., Kiesler, D.J. and Plybon, L.E., 2005. The Impact of Patient-Centered Information on Patients' Treatment Satisfaction and Outcomes in Traumatic Brain Injury Rehabilitation. *Rehabilitation Psychology*, 50(4), p.366.
- Prochaska, O. et al., "The Transtheoretical Model and Stages of Change" 2008. In Glanz, K., Rimer, B.K. and Viswanath, K. eds., 2008. *Health behavior and health education: theory, research, and practice*. John Wiley & Sons.
- Ryan, R.M. and Deci, E.L., 2000. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American psychologist*, 55(1), p.68.
- Schrijnemaekers, A.C., Smeets, S.M., Ponds, R.W., van Heugten, C.M. and Rasquin, S., 2014. Treatment of unawareness of deficits in patients with acquired brain injury: a systematic review. *The Journal of head trauma rehabilitation*, 29(5), pp.E9-E30.
- Scottish Intercollegiate Guidelines Network. Brain injury rehabilitation in adults. Edinburgh: SIGN 2013 (SIGN Guideline 130). [PDF] Available from: <<u>http://www.sign.ac.uk/assets/sign130.pdf</u>> [Accessed 2nd August 2017]
- Shields, C., Ownsworth, T., O'Donovan, A. and Fleming, J., 2016. A transdiagnostic investigation of emotional distress after traumatic brain injury. *Neuropsychological rehabilitation*, 26(3), pp.410-445.
- Skidmore, E.R., Holm, M.B., Whyte, E.M., Dew, M.A., Dawson, D. and Becker, J.T., 2011. The feasibility of meta-cognitive strategy training in acute inpatient stroke rehabilitation: case report. *Neuropsychological rehabilitation*, 21(2), pp.208-223.

- Smeets, S.M., Ponds, R.W., Verhey, F.R. and van Heugten, C.M., 2012. Psychometric properties and feasibility of instruments used to assess awareness of deficits after acquired brain injury: a systematic review. *The Journal of head trauma rehabilitation*, 27(6), pp.433-442.
- van Reekum, R., Stuss, D.T. and Ostrander, L., 2005. Apathy: why care?. *The Journal of neuropsychiatry and clinical neurosciences*, *17*(1), pp.7-19.
- Worthington, A., Wood, R. and McMillan, T., "Neurobehavioural disability over the past four decades." In Wood, R.L. and McMillan, T., eds., 2017. *Neurobehavioural disability and social handicap following traumatic brain injury*. Psychology Press.

APPENDIX 1: SYSTEMATIC REVIEW

- 1.1 Guidelines for submission to 'Neuropsychological Rehabilitation'
- 1.2 Cochrane Risk of Bias Summary of bias types
- 1.3 Cochrane Risk of Bias ROBINS-I Tool summary of bias types
- 1.4 Cochrane Risk of Bias Framework for formulating summary assessments of risk of bias

Author guidelines for submission to Neuropsychological <u>Rehabilitation</u>

This journal uses ScholarOne Manuscripts (previously Manuscript Central) to peer review manuscript submissions. Please read the <u>guide for ScholarOne authors</u> before making a submission. Complete guidelines for preparing and submitting your manuscript to this journal are provided below.

About the journal

Neuropsychological Rehabilitation is an international, peer reviewed journal, publishing high-quality, original research. Please see the journal's <u>Aims & Scope</u> for information about its focus and peer-review policy.

Please note that this journal only publishes manuscripts in English.

This journal accepts the following article types: original (regular) articles, scholarly reviews, and book reviews.

Peer review

Taylor & Francis is committed to peer-review integrity and upholding the highest standards of review. Once your paper has been assessed for suitability by the editor, it will then be double blind peer-reviewed by independent, anonymous expert referees. Find out more about what to expect during peer review and read our guidance on publishing ethics.

Preparing your paper

All authors submitting to medicine, biomedicine, health sciences, allied and public health journals should conform to the <u>Uniform Requirements for Manuscripts Submitted to</u> <u>Biomedical Journals</u>, prepared by the International Committee of Medical Journal Editors (ICMJE).

We also refer authors to the community standards explicit in the <u>American Psychological</u> Association's (APA) Ethical Principles of Psychologists and Code of Conduct.

Structure

Your paper should be compiled in the following order: title page; abstract; keywords; main text; acknowledgements; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figure caption(s) (as a list).

Word limits

Please include a word count for your paper. There are no word limits for articles in this journal.

Style guidelines

Please refer to these <u>style guidelines</u> when preparing your paper, rather than any published articles or a sample copy.

Please use British -ize spelling style consistently throughout your manuscript.

Please use double quotation marks, except where "a quotation is 'within' a quotation". Please note that long quotations should be indented without quotation marks.

The style and format of your paper should conform to the specifications given in the *Publication Manual of the American Psychological Association* (6th ed.).

Formatting and templates

Papers may be submitted in any standard format, including Word and LaTeX. Figures should be saved separately from the text. To assist you in preparing your paper, we provide formatting templates.

A <u>LaTeX template</u> is available for this journal.

<u>Word templates</u> are available for this journal. Please save the template to your hard drive, ready for use.

If you are not able to use the templates via the links (or if you have any other template queries) please contact <u>authortemplate@tandf.co.uk</u>

References

Please use this <u>reference style guide</u> when preparing your paper. An <u>EndNote output</u> <u>style</u> is also available to assist you.

Checklist: what to include

1.

Author details. Please ensure everyone meeting the International Committee of Medical Journal Editors (ICMJE) requirements for authorship is included as an author of your paper. Please include all authors' full names, affiliations, postal addresses, telephone numbers and email addresses on the title page. Where available, please also include <u>ORCID identifiers</u> and social media handles (Facebook, Twitter or LinkedIn). One author will need to be identified as the corresponding author, with their email address normally displayed in the article PDF (depending on the journal) and the online article. Authors' affiliations are the affiliations where the research was conducted. If any of the named co-authors moves affiliation during the peer-review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after your paper is accepted. <u>Read more on authorship</u>.

- 67
- 2. A non-structured **abstract** of more than 150 and no more than 200 words. Read tips on <u>writing your abstract</u>.
- 3. You can opt to include a **video abstract** with your article. <u>Find out how these can help your work reach a wider audience</u>, and what to think about when filming.
- 4. Up to five **keywords**. Read <u>making your article more discoverable</u>, including information on choosing a title and search engine optimization.
- 5. Funding details. Please supply all details required by your funding and grant-awarding bodies as follows: For single agency grants: This work was supported by the [Funding Agency] under Grant [number xxxx]. For multiple agency grants: This work was supported by the [funding Agency 1]; under Grant [number xxxx]; [Funding Agency 2] under Grant [number xxxx]; and [Funding Agency 3] under Grant [number xxxx].
- 6. **Disclosure statement**. This is to acknowledge any financial interest or benefit that has arisen from the direct applications of your research. <u>Further guidance on what is a conflict of interest and how to disclose it</u>.
- 7. **Geolocation information.** Submitting a geolocation information section, as a separate paragraph before your acknowledgements, means we can index your paper's study area accurately in JournalMap's geographic literature database and <u>make your article more discoverable to others</u>.
- 8. **Supplemental online material.** Supplemental material can be a video, dataset, fileset, sound file or anything which supports (and is pertinent to) your paper. We publish supplemental material online via Figshare. Find out more about <u>supplemental material and how to submit it with your article</u>.
- 9. **Figures.** Figures should be high quality (1200 dpi for line art, 600 dpi for grayscale and 300 dpi for color, at the correct size). Figures should be saved as TIFF, PostScript or EPS files. More information on how to prepare artwork.
- 10. **Tables.** Tables should present new information rather than duplicating what is in the text. Readers should be able to interpret the table without reference to the text. Please supply editable files.
- 11. **Equations**. If you are submitting your manuscript as a Word document, please ensure that equations are editable. More information about <u>mathematical symbols and equations</u>.
- 12. Units. Please use <u>SI units</u> (non-italicized).

Using third-party material in your paper

You must obtain the necessary permission to reuse third-party material in your article. The use of short extracts of text and some other types of material is usually permitted, on a limited basis, for the purposes of criticism and review without securing formal permission. If you wish to include any material in your paper for which you do not hold copyright, and which is not covered by this informal agreement, you will need to obtain written permission from the copyright owner prior to submission. More information on requesting permission to reproduce work(s) under copyright.

Disclosure statement

Please include a disclosure of interest statement, using the subheading "Disclosure of interest." If you have no interests to declare, please state this (suggested wording: *The authors report no conflicts of interest*). For all NIH/Wellcome-funded papers, the grant number(s) must be included in the disclosure of interest statement. <u>Read more on declaring conflicts of interest</u>.

Clinical Trials Registry

In order to be published in a Taylor & Francis journal, all clinical trials must have been registered in a public repository at the beginning of the research process (prior to patient enrolment). Trial registration numbers should be included in the abstract, with full details in the methods section. The registry should be publicly accessible (at no charge), open to all prospective registrants, and managed by a not-for-profit organization. For a list of registries that meet these requirements, please visit the <u>WHO International Clinical Trials</u> <u>Registry Platform</u> (ICTRP). The registration of all clinical trials facilitates the sharing of information among clinicians, researchers, and patients, enhances public confidence in research, and is in accordance with the <u>ICMJE guidelines</u>.

Complying with ethics of experimentation

Please ensure that all research reported in submitted papers has been conducted in an ethical and responsible manner, and is in full compliance with all relevant codes of experimentation and legislation. All papers which report *in vivo* experiments or clinical trials on humans or animals must include a written statement in the Methods section. This should explain that all work was conducted with the formal approval of the local human subject or animal care committees (institutional and national), and that clinical trials have been registered as legislation requires. Authors who do not have formal ethics review committees should include a statement that their study follows the principles of the <u>Declaration of Helsinki</u>.

Consent

All authors are required to follow the <u>ICMJE requirements</u> on privacy and informed consent from patients and study participants. Please confirm that any patient, service user, or participant (or that person's parent or legal guardian) in any research, experiment, or clinical trial described in your paper has given written consent to the inclusion of material pertaining to themselves, that they acknowledge that they cannot be identified via the paper; and that you have fully anonymized them. Where someone is deceased, please ensure you have written consent from the family or estate. Authors may use this <u>Patient</u> Consent Form, which should be completed, saved, and sent to the journal if requested.

Health and safety

Please confirm that all mandatory laboratory health and safety procedures have been complied with in the course of conducting any experimental work reported in your paper. Please ensure your paper contains all appropriate warnings on any hazards that may be involved in carrying out the experiments or procedures you have described, or that may be involved in instructions, materials, or formulae.

Please include all relevant safety precautions; and cite any accepted standard or code of practice. Authors working in animal science may find it useful to consult the <u>International</u> <u>Association of Veterinary Editors' Consensus Author Guidelines on Animal Ethics and Welfare and Guidelines for the Treatment of Animals in Behavioural Research and Teaching.</u> When a product has not yet been approved by an appropriate regulatory body for the use described in your paper, please specify this, or that the product is still investigational.

Submitting your paper

This journal uses ScholarOne Manuscripts to manage the peer-review process. If you haven't submitted a paper to this journal before, you will need to create an account in the submission centre. Please read the guidelines above and then <u>submit your paper in the relevant author centre</u> where you will find user guides and a helpdesk.

If you are submitting in LaTeX, please convert the files to PDF beforehand (you may also need to upload or send your LaTeX source files with the PDF).

Please note that *Neuropsychological Rehabilitation* uses $Crossref^{TM}$ to screen papers for unoriginal material. By submitting your paper to *Neuropsychological Rehabilitation* you are agreeing to originality checks during the peer-review and production processes.

On acceptance, we recommend that you keep a copy of your Accepted Manuscript. Find out more about <u>sharing your work</u>.

Publication charges

There are no submission fees or page charges for this journal.

Color figures will be reproduced in color in your online article free of charge. If it is necessary for the figures to be reproduced in color in the print version, a charge will apply.

Charges for color figures in print are £250 per figure (\$395 US Dollars; \$385 Australian Dollars; €315). For more than 4 color figures, figures 5 and above will be charged at £50 per figure (\$80 US Dollars; \$75 Australian Dollars; €63). Depending on your location, these charges may be subject to local taxes.

Copyright options

Copyright allows you to protect your original material, and stop others from using your work without your permission. Taylor & Francis offers a number of different license and reuse options, including Creative Commons licenses when publishing open access. <u>Read</u> more on publishing agreements.

Complying with funding agencies

We will deposit all National Institutes of Health or Wellcome Trust-funded papers into PubMedCentral on behalf of authors, meeting the requirements of their respective open access (OA) policies. If this applies to you, please tell our production team when you receive your article proofs, so we can do this for you. Check funders' OA policy mandates <u>here</u>. Find out more about <u>sharing your work</u>.

Open access

This journal gives authors the option to publish open access via our <u>Open Select publishing</u> <u>program</u>, making it free to access online immediately on publication. Many funders mandate publishing your research open access; you can check <u>open access funder policies</u> and mandates here.

Taylor & Francis Open Select gives you, your institution or funder the option of paying an article publishing charge (APC) to make an article open access. Please contact <u>openaccess@tandf.co.uk</u> if you would like to find out more, or go to our <u>Author Services website</u>.

For more information on license options, embargo periods and APCs for this journal please search for the journal in our journal list.

My Authored Works

On publication, you will be able to view, download and check your article's metrics (downloads, citations and Altmetric data) via <u>My Authored Works</u> on Taylor & Francis Online. This is where you can access every article you have published with us, as well as your <u>free eprints link</u>, so you can quickly and easily share your work with friends and colleagues.

We are committed to promoting and increasing the visibility of your article. Here are some tips and ideas on how you can work with us to promote your research.

Article reprints

You will be sent a link to order article reprints via your account in our production system. For enquiries about reprints, please contact the Taylor & Francis Author Services team at reprints@tandf.co.uk. You can also order print copies of the journal issue in which your article appears.

Queries

Should you have any queries, please visit our <u>Author Services website</u> or contact us at authorqueries@tandf.co.uk.

Updated November 2016

Appendix 1.2

| Type of bias | Description | Relevant domains in the Collaboration's 'Risk of bias' tool |
|------------------|--|---|
| Selection bias | Biased allocation to treatment. Systematic differences between baseline characteristics of the groups that are compared. | Sequence generation.Allocation concealment. |
| Performance bias | Bias due to knowledge of the allocated interventions by participants and personnel. Systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest. | Blinding of participants and personnel. Other potential threats to validity. |
| Detection bias | Bias due to the knowledge of allocated interventions by outcome assessors. Systematic differences between groups in how outcomes are determined. | Blinding of outcome assessment. Other potential threats to validity. |
| Attrition bias | Bias due to amount, nature of handling of incomplete outcome data. Systematic differences between groups in withdrawals from a study. | • Incomplete outcome data |
| Reporting bias | Bias due to selective outcome reporting. Systematic differences between reported and unreported findings. | • Selective outcome reporting |

Cochrane Risk of Bias - Summary of bias types

Appendix 1.3

Cochrane Risk of Bias – ROBINS-I Tool summary of bias types

| Type of bias | Description | Relevant domains | | |
|---|---|--|--|--|
| Confounding | Baseline confounding, when one or more prognostic variables (factors that predict the outcome of interest) also predict the intervention received at baseline. | Selection biasAllocation bias | | |
| Selection of participants | Bias due to exclusion of some eligible participants, or the initial follow up time of some participants, or some outcome events | Selection bias | | |
| Classification of Bias introduced by either differential or non-differential misclassification of intervention status | | Recall biasMeasurement biasObserver bias | | |
| Deviations from intended interventions | • Performance bias | | | |
| Missing data | Bias that arises when later follow-up is missing for individuals initially included and followed, or due to exclusion of individuals with missing information about intervention status or other variables such as confounders. | • Attrition bias | | |
| Measurement of outcomes | Bias introduced by either differential or non-differential errors in measurement of outcome data. Such bias can arise when outcome assessors are aware of intervention status, if different methods are used to assess outcomes in different intervention groups, or if measurement errors are related to intervention status or effects. | Detection bias Recall bias Information bias Misclassification bias Observer bias Measurement bias | | |
| Selection of the reported result | Selective reporting of results in a way that depends on the findings. | Outcome reporting bias Analysis reporting bias | | |

Appendix 1.4

Cochrane Risk of Bias - Framework for formulating summary assessments of risk of bias

| Risk of bias | Interpretation | Within article |
|--------------|--|--|
| Low | Bias, if present, is unlikely to alter the results seriously | Low risk of bias for all key domains |
| Unclear | Risk of bias that raises some doubt about the results | Low or unclear risk of bias for all key domains |
| High | Bias may alter the results seriously | High risk of bias for one or more key domains |

APPENDIX 2: MAJOR RESEARCH PROJECT

- 2.1 Major Research Project Proposal
- 2.2 Ethics Committee approval letters
- 2.3 BIRT approval letter
- 2.4 Motivation for Traumatic Brain Injury Rehabilitation questionnaire (MOTQ)
- 2.5 Awareness Questionnaire (AQ) clinician form
- 2.6 Awareness Questionnaire (AQ) patient form
- 2.7 Pittsburgh Rehabilitation Participation Scale (PRPS)
- 2.8 The Structured Assessment of FEasibility measure (SAFE)
- 2.9 Information sheet for staff participants
- 2.10 Consent form for staff participants
- 2.11 Information sheet for inpatient participants
- 2.12 Consent form for inpatient participants
- 2.13 GP letter
- 2.14 Video script
- 2.15 Reliable Change Index calculation methods

Appendix 2.1

Major Research Project Proposal



Institute of Health & Wellbeing

DOCTORATE IN CLINICAL PSYCHOLOGY

SUBMISSION COVER PAGE

Matriculation Number: 0306004

Name of Assessment: Major Research Project Proposal

Title of Project: Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI)

Date of Submission: 17/02/17

Version Number: 12

Word Count, including reference list (excluding appendices): 4414

Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI).

1. Abstract

Background: Individuals who suffer acquired brain injury (ABI) commonly demonstrate deficits in awareness of injury sequelae. This may contribute to poor participation in neurorehabilitation, as a result of problems with self-regulation, goal-setting, and risk awareness. Research has suggested that preparing individuals for therapeutic interventions can improve engagement and promote more accurate expectations of interventions. In an ABI population, emerging evidence has found that providing information on ABI and the rehabilitation process increased patients' effort in subsequent tasks.

Aims: To determine whether providing preparatory information is feasible as part of a general protocol for ABI inpatient services. To investigate the use of preparatory material in increasing insight, motivation, and engagement in rehabilitation.

Methods: Participants will be recruited from a brain injury inpatient unit in Glasgow, and shown a video aimed at improving insight and increasing motivation, and complete pre- and post-trial measures of insight and motivation for intervention. Additionally, staff will evaluate the feasibility of delivering the protocol. The study will be a repeated-measures design, with a lagged control group, allowing within-and between-subjects analysis.

Applications: If successful, this study may be used in development of future ABI rehabilitation protocols, which focus on improving motivation for engagement and insight into difficulties.

Introduction

1.1 Awareness and motivation

Up to 45% of individuals who suffer moderate to severe traumatic brain injury demonstrate deficits in their awareness of cognitive and behavioural sequelae (Flashman & McAllister 2002). Multiple biopsychosocial factors could cause problems with self-awareness: influences of psychological factors such as coping style and emotions; neuropathology relating to the acquired brain injury (ABI); and social factors such as interactions, values, and cultural representations of ABI (FitzGerald et al., 2012). ABIs are heterogeneous, as neuropathological damage to the brain can vary widely, and neuropathologIcal differences can present in clinically different ways; the nature of damage may differ when ABI is due to focal damage, stroke, or infection such as encephalitis. Lack of awareness may present as problems with self-regulation, decision-making, and poor risk awareness. Patients may also lack the insight necessary to set realistic goals, all of which may contribute to poor participation in rehabilitation. In creation of rehabilitation interventions, Oddy et al., (2008) emphasise the importance of considering improved awareness as a primary goal of intervention, not just a by-product of rehabilitation; for example if a patient is unaware of their cognitive deficits, one main objective of their rehabilitation should be to increase awareness of this.

However we must exercise caution when considering benefits of improved awareness. Schrijnemaekers et al., (2014) review of interventions for unawareness of deficits after ABI suggests that higher self-awareness and symptoms of depression are both significantly associated with self-reports of poor quality of life. Thus an increased insight into difficulties may lead to a negative change in mood, which in itself can produce decreased motivation. A study by Shields et al., (2015) into emotional distress following TBI found that levels of emotion dysregulation were independently related to levels of depression and global distress, and that those reporting higher levels of emotion dysregulation had difficulties engaging in goal-directed behaviour. Consequently mood regulation may be an important mediating factor when exploring the link between awareness and motivation for rehabilitation.

Apathy, a deficiency in behavioural, emotional and cognitive components of goal-directed behaviour, is a common effect of ABI and is a basis to consider in an individual's motivation. Prevalence rates summarised by van Reekum et al., (2005) suggest up to 61.4% of the TBI population exhibit apathy, 60% of those who suffered a focal frontal lesion, and 34.7% following stroke. Motivational problems and apathy are difficult to assess and characterise as they can arise in different ways (Oddy et al., 2008). For example, the primary neuropathological insult leading to decreased motivation, a secondary problem arising from lack of insight, or a tertiary deficit resulting from other factors associated with ABI

such as depression, anxiety, low self-esteem, and learned helplessness. Regardless of the basis, with the presence of apathy as a behavioural presentation following ABI we are likely to see a reduction in goal-directed behaviours; one such behaviour is engagement in rehabilitation.

1.2 Rehabilitation guidelines

Reviews of the current evidence base for ABI treatment recommend a holistic rehabilitation programme addressing neurobehavioural and psychosocial difficulties. Fundamental to the holistic approach is working with the whole individual rather than single areas of difficulty. Successful outcomes are associated with intensive and prolonged interventions involving multidisciplinary working aimed at physical, cognitive, emotional and behavioural difficulties with the aim of improving functioning in meaningful everyday activities, including community integration (The Matrix 2015, SIGN-130 2013, McMillan 2013).

The holistic approach suggests a key task is identifying and responding to individual needs within the context of a focus on returning to participation in meaningful activities. Considering the high prevalence of impaired awareness and motivation, these may be important targets for improving engagement. In addition to this individually tailored approach, there is a need for scalable and generalizable approaches that can be relevant to many people with ABI, and so can be widely utilised within rehabilitation services. These more universal approaches can then help establish a foundation making patients more prepared for individualised care.

1.3 Engagement

A systemic review of interventions aimed at improving rehabilitation engagement by Brett et al., (2015) found that behavioural strategies such as contingent rewards (e.g. a token economy) were beneficial in improving compliance, however more cognitive interventions aiming to equip clients with the skills required for self-directed rehabilitation (e.g. motivational interviewing) facilitated increased motivation and engagement. The cognitive interventions that demonstrated the greatest success were those that empowered clients to play an active role in their rehabilitation, which is in line with SIGN-130 guidance for collaborative client-centred goal planning.

Studies examining the effect of preparatory information within non-ABI adult mental health settings (Deane et al., 1992, Johansen et al., 2011) suggest that pre-intervention information can improve engagement, reduce anxiety and promote more accurate expectations of interventions. Within an ABI population, Pegg et al., (2005) found that providing personalised information on ABI and the rehabilitation progress increased patients' effort in subsequent physical therapy and cognitive

rehabilitation. Results suggest that despite variability in the participants' ability to understand the information presented to them, the very act of receiving information enhanced their perception of involvement in their own care. Gallagher (2014) also found a significant increase in ABI inpatients' motivation for a compassion-focussed imagery task following general preparatory information. This study aims to examine the effect of preparatory information within this population in a feasibility trial, generalising beyond the foci of the previous studies. The Medical Research Council (MRC) framework for developing complex interventions emphasises the importance of conducting feasibility and pilot work prior to conducting a large-scale study of efficacy.

2. Aims

2.1 Aims

- A feasibility study of a repeatable preparatory protocol for moderate-severe ABI inpatient neurorehabilitation services, that examines whether preparatory material is suitable for wider dissemination across inpatient ABI neurorehabilitation services.
- To design, implement and investigate the use of preparatory material for moderate-severe ABI patients as a way of increasing motivation, awareness, and engagement in rehabilitation.

2.2 Hypotheses

- 5) Presentation of generalised preparatory information will be a feasible intervention (for staff and service users) as part of a general protocol for ABI inpatient services.
- Exposure to preparatory information will increase self-reported motivation to engage in rehabilitation interventions.
- Preparatory information will improve self-reported and staff-reported awareness of difficulties.
- 8) Preparatory information will facilitate a change in behaviour, demonstrated by increased attendance and staff rating of engagement at rehabilitation sessions.

3. Plan

3.1 Participants and Setting

Participants will be recruited from Graham Anderson House [GAH] (a specialist service run by the Brain Injury Rehabilitation Trust [BIRT]), a post-acute independent hospital specialising in assessment and rehabilitation of people with complex needs following ABI. BIRT adopt a neurobehavioural rehabilitation approach, combining evidence-based methods of changing behaviour with an understanding of neuropsychological changes associated with ABI (Wood & Worthington, 2001). On-

site multi-disciplinary teams deliver interventions, and each client has a structured holistic rehabilitation programme (as recommended by SIGN 130) involving individual sessions and group attendance.

3.2 Inclusion criteria

Primary participants will be current inpatients at GAH with a moderate-severe ABI (i.e. damage to the brain caused by an external force or pathophysical damage resulting from non-degenerative organic factors such as stroke, aneurysm, neurological disease), aged >18 years. Length of time as BIRT inpatient will not be pertinent. Only participants considered to have capacity to consent by professionals responsible for their care will be approached.

Secondary participants will be members of the Graham Anderson House professional multidisciplinary clinical team. Led by a consultant in neuropsychology and rehabilitation, the MDT includes clinical psychologists, assistant psychologists, speech and language therapists, physiotherapists, nurses, and occupational therapists.

3.3 Exclusion criteria

Individuals with communication difficulties that might affect ability to consent to or understand/comply with test procedures, not fluent in English, severe mental illness or challenging behaviour that would prevent meaningful participation in the study, or a discharge date within the trial period will be ineligible. This information regarding participants eligible for exclusion will be provided by BIRT professionals responsible for their care.

Only BIRT staff from the MDT clinical team will participate in test procedures. Rehabilitation support workers will not complete research questionnaires, even if they facilitate rehabilitation sessions.

3.4 Recruitment

BIRT MDT staff will approach potential participants and provide the study information sheet. Potential participants will give permission for staff to notify the researcher of their details. A researcher will contact interested individuals to answer any further questions and arrange participation. Written consent will be obtained. In line with BIRT policy regarding service users taking part in research, a care plan will be drawn up incorporating their participation in the study.

3.5 Measures (see Appendix 2)

1. Information obtained from BIRT:

 Demographics: age; gender; education; postcode (to translate to social deprivation, SIMD 2012); nature of ABI; Glasgow Coma Scale score at time of injury; measure of level of disability (Glasgow Outcome at Discharge Scale) at time of BIRT admission.

- A cognitive profile will be gathered. A cognitive screen (ACE-III) is usually completed preadmission to BIRT. In addition a comprehensive assessment of cognitive functioning is completed during the assessment period following admission, therefore scaled scores will be available from cognitive measures across domains (selected subtests from WAIS-IV, TEA, BADS, RBMT-3).
- BIRT patient participation statistics record number of rehabilitation sessions offered, sessions attended, and sessions refused.

2. Primary outcome measure: Measure of intervention implementation and the process of intervention delivery

- The <u>Structured Assessment of Feasibility measure (SAFE)</u> (Bird et al., 2014) a 16-item measure, which aims to assess blocks/facilitators of implementing the preparatory DVD as an intervention, to be completed by MDT clinicians within GAH. Bird et al., (2014) reported excellent inter-rater (0.84) and test-retest reliability (0.89) assessed by Cronbach's alpha.
- Data regarding the percentage of scheduled videos actually delivered to each participant; this allows consideration of how feasible regular delivery intervention is in practice.

3. Secondary outcome measures

- Motivation: <u>Motivation for traumatic brain injury rehabilitation questionnaire MOT-Q</u> (Chervinsky et al., 1998). This Likert-scale questionnaire assesses factors that facilitate or act as barriers to motivation to engage in rehabilitation, including denial of illness, anger, compliance with treatment, and medical information seeking behaviour. This scale has good reliability (Cronbach's alpha = 0.91).
- Insight into difficulties: Smeets et al., 2012 recommend the <u>Awareness Questionnaire AQ</u> (Sherer, 2004). This is a 17-item questionnaire designed to assess self-awareness in ABI. There are three versions of the AQ, one for staff, one for a family member and one for service users. Two of these (staff and service user questionnaires) will be adopted in this feasibility study. Sherer et al., (1998a) reported good internal consistency for the AQ (Cronbachs alpha = 0.88), and good validity.
- Behaviour changes: After each rehabilitation activity BIRT staff (from the GAH clinical MDT) who are blind to the preparatory condition will complete a rehabilitation engagement measure, <u>The Pittsburgh Rehabilitation Participation Scale – PRPS.</u> This is a single item instrument measuring participation on a 6- point Likert scale, and demonstrates good inter-rater reliability (0.91) and validity (Lenze et al., 2004). The rating points consider therapy attendance and

effort in therapy, as well as interest in activities and future therapy. Rating of engagement in rehabilitation activities (including 1:1 or group sessions) will be used as outcome measure. In addition, participation statistics routinely collected by BIRT will record the number of rehabilitation sessions offered, sessions attended, and sessions refused.

4. The <u>Hospital Anxiety and Depression Scale (HADS)</u> (Zigmond and Snaith 1983) will be utilised as a safety measure. This 14-item scale has good internal consistency for both the anxiety (Cronbachs alpha = 0.8) and the depression subscales (Cronbachs alpha = 0.81). This measure has been validated for use with ABI patients (Schönberger & Ponsford, 2010).

BIRT staff administers HADS fortnightly. Monitoring mood throughout the trial allows the researchers to recognise any possible mediating effects of the intervention, and respond accordingly. HADS outcomes will not be reported.

3.6 Design:

Repeated-measures design, with a delayed-viewing [lagged] control group. During the delay period, the control group will continue to receive care as normal from BIRT rehabilitation staff. All participants will watch the preparatory video and complete pre//mid/post-trial measures. The primary outcome variable is motivation for rehabilitation (MOT-Q). Secondary measures include measures of awareness (AQ) and behaviour change (time use diaries and participation statistics). Tertiary outcomes are the assessment of the feasibility of the preparatory material as an intervention (SAFE).

3.7 Procedures;

3.7.1 Construction of preparatory video

Review of the literature and information from professionals working within BIRT (Consultant Clinical Psychologist, Clinical Psychologists) will inform creation of a generalised preparatory video, around five minutes in length, aimed at increasing psychological readiness for rehabilitation. Video content will be tailored to an ABI population, allowing for common difficulties such as impairments in memory/attention, executive functioning, and processing speed (see Appendix 3).

The main information targets of the video will include information about ABI (i.e. various mechanisms for sustaining ABI, common sequelae, reference to common shared goals and values within an inpatient population, orientation to inpatient admission), and details about the acute rehabilitation offered within BIRT (including generalizable metaphors of purpose of rehabilitation e.g. "physio rehabilitation for your brain").

Evidence from research into wider health behaviour change areas (including alcohol and substance abuse, obesity, HIV/AIDS prevention, medication compliance, and smoking cessation) support these as potentially important elements in preparing individuals for action, with 'consciousness raising' as an

experiential process important in supporting individuals through a continuum of motivational readiness as explained in the Transtheoretical Model of Stages of Change (Prochaska et al., 2008).

3.7.2 Intervention phase (See Appendix 4)

Participants will be randomised into two groups; intervention and control. In order to control for covariates randomisation will be stratified by time since admission, and motivation for rehabilitation as measured by the MOT-Q; this is to ensure that the possible influences of longer previous exposure to rehabilitation and baseline motivation level are balanced across each of the two groups. Thus the randomisation process will be by stratified block sampling.

All participants will view the preparatory video in a 1:1 delivery by a member of BIRT staff an average of 3 times per week over a period of 4 weeks, with the control group on delayed exposure of 2 weeks. The control group will continue to receive routine care throughout this delay period. BIRT staff will record the number of videos scheduled and watched by each participant. Primary and secondary outcome measures will be completed pre-, mid- and post- trial to allow exploration of effects by within-group comparisons, and between-group comparison with control group. Tertiary outcome measures will be completed post-trial. Data for unexpectedly discharged patients will be retained for analysis.

3.8 Data Analysis (see appendix 5);

Dependent t-tests will be used to assess change in pre-post video measures. Independent t-tests will compare scores between video and control groups. Pearson correlations will examine the relationships between variables (motivation for intervention, awareness of difficulties, participation in rehabilitation). Non-parametric alternatives will be employed wherever parametric assumptions cannot be met.

3.9 Sample size;

The present study will be treated as a feasibility study following on from previous research, and will follow similar sample size considerations (Gallagher 2014, n=24, O'Neill and McMillan 2012, n=24). It is anticipated (taking into account number of beds in inpatient unit, possible discharges during trial period, and previous rates of participation in research conducted at BIRT) that 20 inpatient participants in total (ten per group) will be recruited in the time available. This sample size is comparable to other therapeutic studies within a brain injury population (e.g. Hodgson et al., 2005, RCT n=12; Hsieh et al., 2012, RCT n=27), although is smaller than studies examining the effect of preparatory information within a non-head injury adult mental health setting (Johansen et al., 2011, n=105).

With 80% power to detect a medium effect size (dz=0.5), and alpha set at .05, it is estimated that a sample size of 27 participants would be required to find a significant effect of changes in primary outcome measure MOT-Q (G*Power 3; Faul, Erdfelder, Lang & Buchner, 2007). Given that this is a preliminary feasibility study aiming to model recruitment and detect patterns over large effect size, a

more conservative effect size may considered to be adequate. Post-hoc calculations of effect sizes for different outcomes will be beneficial for future studies. In addition, methodological factors in this study may inflate the power; compared to a previous preparatory video study (Gallagher 2014) this trial will not only compare pre- and post-video measures, but the repeated nature of the video presentation to participants (increased exposure to intervention) may also enhance effect sizes reported in the previous study.

3.10 Settings and Equipment

The preparatory video will be uploaded to a password protected video sharing website (such as Vimeo). GAH is available as a setting for recording the video.

Presentation of the video to participants will be facilitated using GAH's electronic tablets or participants' own Smartphone. Participants will view the video and complete outcome measures within the BIRT unit, where private clinical rooms are available.

For administration and analysis, necessary equipment will be copies of outcome measures and an encrypted laptop to carry out statistical analysis

4. Health and Safety Issues

4.1 Participant health and safety

Due to the nature of ABI participants may suffer from fatigue, or other co-morbid physical problems that may cause discomfort over the course of participating. Presentation of the video will involve no further demands than general exposure to other inpatient rehabilitation they would be receiving and so participation is not an additional risk for individuals to experience these problems. Participants included will have been assessed as fit for intensive rehabilitation and inclusion in this study, so this is unlikely to be an issue, however this will be managed by offering regular breaks, and close liaison with professionals involved in participant's care to ensure they remain physically and psychologically able to take part. Regular monitoring of mood will allow the researcher to identify any negative changes in affect and take appropriate action to prevent harm or unnecessary distress.

4.2 Researcher health and safety

In this population there is the risk of challenging behaviour/aggression, and difficulties with emotional regulation. Therefore it will be necessary to adhere to all local safety protocols.

5. Ethics

5.1 Approval

Sponsorship will be provided by University of Glasgow, and ethical approval will be obtained from the West of Scotland Research Ethics Committee. Ethical and management approval will be sought from BIRT. Written consent will be obtained from all participants. Participants will be informed that they are able to stop or break from the intervention, and that they can withdraw from the study at any point.

5.2 Confidentiality

- Data protection rules outlined by BIRT and by University of Glasgow will be adhered to.
- A laptop encrypted to NHS standards will be used for data collection, storage, and analysis. The data will be anonymised: each participant will be assigned an identifier code, which will allow comparison of outcome measures pre- and post-trial. This identifier code will be held separately from research data.
- During the study data will be backed up on a password-protected folder on the University of Glasgow Server. All anonymous raw data will be kept on the University of Glasgow Server for 10 years before being destroyed, as per University guidance.
- Manual files for each participant (including signed consent forms and outcome measures) will be stored in separate folders, each labeled with the identifier assigned to that participant. These files will be stored in a locked drawer within GAH psychology office, and will not be accessed by anyone other than the research team. Outcome measures will be shredded following completion of data analysis.
- The primary investigator will have access to personal data relevant to the study throughout the trial period. This data will be held within routine care records within BIRT, and will not be accessed by anyone else out with the direct care team. Participants will be informed of this, and consent sought.
- Representatives of the study sponsor, University of Glasgow, may access personal data for audit purposes.

5.3 Dissemination

The study will be undertaken for the purposes of obtaining award of Doctorate in Clinical Psychology, University of Glasgow. Results of the study will be reported within the Clinical Research Portfolio, a required piece of assessed work in part fulfilment of the award. The study report will be presented in the form of journal submissions, with the intention of submitting for publication in a peer reviewed scientific journal.

Interested participants will be provided a summary sheet of the findings. In addition, findings will be distributed to the inpatient unit involved, who will also let participants know where they can access the results.

6. Financial Issues

See Appendix 1.

7. Timetable

2017:

February - Ethics amendments, create final video

March - Recruitment, baseline data collection, randomisation

April - May – Data collection

May - Analysis

May - July - Drafts written

July - Submit research portfolio

8. Practical Applications

Little is known about how to support the use of psychological interventions to improve awareness after ABI. This study will explore whether it is useful to prepare individuals for rehabilitation interventions, including whether this can make people more motivated for engagement and more insightful to the need for rehabilitation. In addition, this study may provide a greater understanding of specific factors influencing engagement with rehabilitation, and may be used in consideration of future ABI rehabilitation protocols.

9. References

All references are included in the MRP Project Paper (Chapter Two).

Ethics Committee approval letters

WoSRES West of Scotland Research Ethics Service

Dr Hamish McLeod Institute of Mental Health and Wellbeing Gartnavel Royal Hospital Glasgow G12 0XH



West of Scotland REC 3 West of Scotland Research Ethics Service West Glasgow Ambulatory Care Hospital (former Royal Hospital for Sick Children Yorkhill) Dalnair Street Glasgow G3 8SW

www.nhsggc.org.uk

Date 12th January 2017 Your Ref Our Ref Direct line 0141 232 1805 E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr McLeod

| Study title: | Improving treatment motivation and self-awareness in |
|------------------|--|
| | people with moderate to severe acquired brain injury |
| | (ABI) |
| REC reference: | 16/WS/0232 |
| IRAS project ID: | 208077 |

Thank you for your recent response to the Favourable Opinion with Conditions letter. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 05 December 2016

Documents received

The documents received were as follows:

| Document | Version | Date |
|---|---------|------------------|
| Other [script v2] | 2 | 17 November 2016 |
| Participant information sheet (PIS) [Inpatient participant information sheet] | 7 | 05 January 2017 |
| Participant information sheet (PIS) [Staff participant information sheet] | 6 | 22 December 2016 |
| Research protocol or project proposal [MRP proposal v11] | 11 | 17 December 2016 |

Approved documents

The final list of approved documentation for the study is therefore as follows:

| Document | Version | Date |
|---|---------|-------------------|
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Client Information Letter Clinical Trials] | | 04 August 2016 |
| GP/consultant information sheets or letters [GP letter] | 3 | 26 August 2016 |
| Other [Dr O'Neill CV] | | 07 September 2016 |

| Other [script v2] | 2 | 17 November 2016 |
|---|-----|------------------|
| Participant consent form [Staff participant consent form] | 3 | 26 August 2016 |
| Participant consent form [Inpatient participant consent form] | 3 | 26 August 2016 |
| Participant information sheet (PIS) [Inpatient participant information sheet] | 7 | 05 January 2017 |
| Participant information sheet (PIS) [Staff participant information sheet] | 6 | 22 December 2016 |
| REC Application Form [REC_Form_31102016] | | 31 October 2016 |
| Research protocol or project proposal [MRP proposal v11] | 11 | 17 December 2016 |
| Summary CV for Chief Investigator (CI) [Dr H McLeod CV] | | 19 August 2016 |
| Summary CV for student [Janie Hunter CV] | 1 | 26 August 2016 |
| Summary CV for supervisor (student research) [Prof McMillan CV] | | |
| Validated questionnaire [MOT-Q] | | |
| Validated questionnaire [AQ clinician] | | |
| Validated questionnaire [AQ patient] | | |
| Validated questionnaire [PRPS] | | |
| Validated questionnaire [SAFE] | 1.1 | |
| Validated questionnaire [HADS] | | |
| | | |

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/WS/0232

Please quote this number on all correspondence

Yours sincerely

Ling Jamien

Liz Jamieson REC Manager

Copy to: Ms Emma-Jane Gault



Dr Hamish McLeod Institute of Mental Health and Wellbeing Gartnavel Royal Hospital Glasgow G12 0XH

WOSRES West of Scotland Research Ethics Service

> West of Scotland REC 3 West of Scotland Research Ethics Service West Glasgow Ambulatory Care Hospital (former Royal Hospital for Sick Children Yorkhill) Dalnair Street Glasgow G3 8SW www.nhsggc.org.uk

Date 10th March 2017 Your Ref Our Ref Direct line 0141 232 1805 E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr McLeod

| Study title: | Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI) |
|-------------------|--|
| REC reference: | 16/WS/0232 |
| Amendment number: | AM01 |
| Amendment date: | 28 February 2017 |
| IRAS project ID: | 208077 |

Thank you for submitting the above amendment, which was received on 01 March 2017. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Summary of Amendment

Reduce trial period from 18 weeks to 6 weeks. This is to facilitate recruitment and to reduce the impact on staff and inpatient participants by making the project more manageable for the site to implement.

In accordance with up to date literature it is reasonable to reduce the period of video presentation to a 'one off' viewing.

Documents received

The documents to be reviewed are as follows:

| Document | Version | Date |
|--|---------|------------------|
| GP/consultant information sheets or letters | 4 | 17 February 2017 |
| Notice of Substantial Amendment (non-CTIMP) | AM01 | 28 February 2017 |
| Participant consent form [Inpatients] | 4 | 25 January 2017 |
| Participant consent form [Staff] | 4 | 25 January 2017 |
| Participant information sheet (PIS) [Inpatients] | 8 | 25 January 2017 |
| Participant information sheet (PIS) [Staff] | 7 | 25 January 2017 |
| Research protocol or project proposal | 12 | 17 February 2017 |

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <u>http://www.hra.nhs.uk/hra-training/</u>

Please quote this number on all correspondence

Yours sincerely

16/WS/0232:

Ling Jamein

Liz Jamieson REC Manager

Copy to:

Ms Emma-Jane Gault, University of Glasgow



Dr Hamish McLeod Institute of Mental Health and Wellbeing Gartnavel Royal Hospital Glasgow G12 0XH

WOSRES West of Scotland Research Ethics Service

> West of Scotland REC 3 West of Scotland Research Ethics Service West Glasgow Ambulatory Care Hospital (former Royal Hospital for Sick Children Yorkhill) Dalnair Street Glasgow G3 8SW www.nhsggc.org.uk

Date 16 March 2017 Your Ref Our Ref Direct line 0141 232 1805 E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr McLeod

| Study title: | Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI) |
|-------------------|--|
| REC reference: | 16/WS/0232 |
| Amendment number: | AM01 |
| Amendment date: | 28 February 2017 |
| IRAS project ID: | 208077 |

The above amendment was reviewed by the Sub-Committee in correspondence.

Summary of Amendment

Reduce trial period from 18 weeks to 6 weeks. This is to facilitate recruitment and to reduce the impact on staff and inpatient participants by making the project more manageable for the site to implement.

In accordance with up to date literature it is considered reasonable to reduce the period of video presentation to a 'one off' viewing.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee agreed that the amendment did not present any ethical issues.

Approved documents

The documents reviewed and approved at the meeting were:

| Document | Version | Date |
|--|---------|------------------|
| GP/consultant information sheets or letters | | 17 February 2017 |
| Notice of Substantial Amendment (non-CTIMP) | AM01 | 28 February 2017 |
| Participant consent form [Inpatients] | 4 | 25 January 2017 |
| Participant consent form [Staff] | 4 | 25 January 2017 |
| Participant information sheet (PIS) [Inpatients] | 8 | 25 January 2017 |
| Participant information sheet (PIS) [Staff] | 7 | 25 January 2017 |

| Research protocol or project proposal | 12 | 17 February 2017 |
|---------------------------------------|----|------------------|
|---------------------------------------|----|------------------|

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <u>http://www.hra.nhs.uk/hra-training/</u>

16/WS/0232: Please quote this number on all correspondence

Yours sincerely

Lin Jamein

Liz Jamieson REC Manager On behalf of Mrs Rosie Rutherford, Alternate Vice Chair

Enclosures: List of names and professions of members who took part in the review

Copy to:

Ms Emma-Jane Gault, University of Glasgow

Appendix 2.3

BIRT approval letter

32 Market Place **Burgess Hill** West Sussex RH15 9NP Tel: 01444 239123 Fax: 01444 244978 Email: info@thedtgroup.org



Ms Janie Hunter c/o Institute of Health & Wellbeing University of Glasgow 1st Floor, Administration Building Gartnavel Royal Hospital 1055 Great Western Road Glasgow G120X

08 February 2017

Dear Ms Hunter,

THE DISABILITIES TRUST RESEARCH ETHICS COMMITTEE (DTREC) APPROVAL

Study Title: Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI).

We are pleased to inform you that the DTREC has APPROVED the abovementioned project.

The documents reviewed are:

- a) DTREC Brief Form
- b) Response to request for clarification
- c) Summary of investigation, dated 06 February 2017
- d) Participant Information Sheet, dated 06 February 2017
- e) Staff Participant Information Sheet, dated 06 February 2017
 f) Letter of approval from the West of Scotland Research Ethics Service, dated 05 December 2016
- Letter of approval from the West of Scotland Research Ethics Service (Site g) Specific Assessment), dated 25 January 2017

The approval period is from 08 February 2017 to 07 February 2018.

The Terms and Conditions attached to this letter are to be observed upon DTREC approval.

On behalf of the DTREC, I would like to wish you the best with your study.

Yours sincerely,

Q (0)

Dr Sue Copstick **Clinical Director** Graham Anderson House 1161 Springburn Road Glasgow G21 1UU

Cc: Dr Brian O'Neill, Consultant Clinical Psychologist, Graham Anderson House

Patron: Her Grace The Duches of Northumberland | Vice Patrons: The Rt Hon Lord Robertson of Port Ellen KT GCMG honFRSE PC, Gabby Logan Life President: Stephen E, Love MA | Life Vice-Presidents: Barbara Besant-Hutchins, Graham Anderson

Founded in 1979, a company limited by guarantee incorporated in England and Wales under registration number 2334589 and registered as a charity in England and Wales under and in Scotland under registration number SC038972. Incorporating The Brain Injury Rehabilitation Trust, Hamilton Lodge Trust, Registered office: 32 Market Place, Burgess Hill, W r 800797



r 800797

TERMS AND CONDITIONS OF ETHICAL APPROVAL

08 February 2017

Ethical approval given by The Disabilities Trust Research Ethics Committee ("DTREC") to Dr Janie Hunter ("the applicant") based within the University of Glasgow, Institute of Mental Health and Wellbeing, for the project entitled Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI)., is subject to the following conditions.

- 1) Researchers who are not current DT staff members are required to provide a copy of a valid Disclosure and Barring System (DBS) certificate before commencement of the study.
- The study will be conducted in accordance with Trust's relevant policies. 2)
- Any adverse events or new information that may affect the risk to the participants 3) or the conduct of the study must be reported to the DTREC within 24 hours of their occurrence, via Dr Brian O'Neill, Consultant Clinical Psychologist, Graham Anderson House, 1161 Springburn Road, Glasgow, G21 1UU, Telephone 0141 4046060.
- The Researcher should promptly report the DTREC of: 2)
 - i. Changes in the planned duration of the study
 - ii. Deviations from, or changes to the protocol
 - iii. Date of first participant recruited
 - iv. Date of last participant recruited v. Completion of the study.
- 3) A Study Status Report should be submitted for the following: i. Study completion or termination: the Final Report is to be submitted within three months of study completion or termination.
- 4) Any dissemination of the findings should acknowledge the support of The Disabilities Trust and of the appropriate Trust's divisions.
- This approval and right of access to DT services will lapse if the named DT 5) supervisor leaves the employment of the Trust during the course of this approval.
 - The Disabilities Trust reserves the right to withdraw access to its services if

Founded in 1979, a company limited by guarantee incorporated in England and Wales under registration number 2334889 and registered as a charity in England and Wales under registration number & and in Scotland under registration number SC038972. Incorporating The Brain Injury Rehabilitation Trust, Hamilton Lodge Trust, Registered office: 32 Market Place, Burgess Hill, West Sussex Reli5 9NP

i. The applicant fails to comply with the present Terms and Conditions. ii. There are alterations in the service's operational capacity to host the study.

Patron: Her Grace The Duchess of Northumberland | Vice Patrons: The Rt Hon Lord Robertson of Port Ellen KT GCMG honFRSE PC, Gabby Logan Life President: Stephen E, Love MA | Life Vice-Presidents: Barbara Besant-Hutchins, Graham Anderson

Motivation for Traumatic Brain Injury Rehabilitation questionnaire (MOT-Q)

MOT-Q Motivation for Traumatic Brain Injury Rehabilitation Questionnaire Defense and Veterans Head Injury Progaram, Walter Reed Army Medical Center, Bldg. 7, Rm. 224, Washington, D.C. 20307 (202) 782-7281, FAX (202) 782-4400 / / Today'sDate (Mo'Dayy'Yr) Participant code: Please rate your agreement with the following statements by placing an X in an appropriate square. Rehabilitation programs are designed to help injured persons recover from their illness. Rehabilitation includes: physical therapy, speech therapy, counseling or psychotherapy, occupational therapy, vocational services, and cognitive therapy. For Office Use Only Disagree Undecided Strong) Ages LD Disas Amo 1 If it was recommended, I would see a rehabilitation therapist. 2 Given a choice I would spend more time in therapy. 3 Rehabilitation will probably help me. 4 Rehabilitation is very useful. 5 At first I had some problems, but I'm fine now. 6 I'm better now than I ever was 7 Rehabilitation therapists can't help me with my problems. 8 Rehabilitation has nothing to do with my needs. 9 I have always had the problems I'm having BOW. 10 I have some problems, but I'm doing fine. 11 Rehabilitation therapists would probably treat me like a child. 12 I'm very excited about getting treatment as soon as possible. 13 There is nothing wrong with me. 14 I'll be the same if I get treatment or not. 15 Therapists would have me do things that are irrelevant. 16 The head injury had minimal effect on my abilities. 17 Rehabilitation is useful, but I don't think I need it. For Office Use Only Subtotal Page 1

| | | Strongly | Disagree | Undecided | Agroc | Strongly | | | e Use (| |
|-------|--|----------|----------|-----------|----------|------------|----|----|---------|------|
| _ | | Disagree | Somewhat | | Somewhat | Agree | LD | IR | LA | RI |
| 18 | I rely on doctors to help me with my problems. | 4 | | | | 1 | | | | |
| 19 | I don't have any problems worth mentioning. | 1 | 1 | | 4 | 4 | | | | |
| 20 | I'd ask my therapists to do extra therapy tasks. | 4 | 14 | | 1 | 1 | | | | Γ |
| 21 | I always follow medical orders because I think they'll help me. | 4 | 4 | | 1 | 3 | | | | T |
| 22 | Doctors know what I need and I'll do what they say. | 4 | | | | 1 | | | | Γ |
| 23 | I'd do what a therapist tells me even if it doesn't make sense. | 4 | 4 | | 1 | 3 | | | | |
| 24 | I'm very interested in rehabilitation, but it's not for me. | 1 | 1 | | 4 | 4 | | | | 1000 |
| 25 | I don't have time for rehab. | 1 | 1 | 9 | 4 | 4 | | | | |
| 26 | It's fine to see a rehabilitation therapist. | 4 | 9 | t. | 1 | 3 | | | | Γ |
| 27 | My problems are my own business. | 1 | 1 | * | 4 | 4 | | | | |
| 28 | I don't like people prying too deeply. | 1 | ' | | 4 | 4 | | | F | |
| 29 | Therapists would waste my time. | 1 | | 9 | - 4 | 4 | | | t | |
| 30 | Going through rehabilitation will help me get (or keep) a job. | 4 | 24 | 9 | 1 | 1 | | | | |
| 31 | Doctors shouldn't say I have problems without knowing how I was before my injury. | 2 | 1 | | 4 | 4 | | | Γ | 1000 |
| For O | flice Use Only | | | | Subto | tal Page 2 | | | | |
| | | | | | Subto | tal Page 1 | | | | |
| | | | | | | Total | | | | |

Awareness Questionnaire (AQ) – clinician form

Participant Code: Date: 1 2 3 4 5 a little much a little about the much worse same better better worse How good is the patient's ability to live independently now as compared 1. to before his/her injury? 2. How good is the patient's ability to manage his/her money now as compared to before his/her injury? How well does the patient get along with people now as compared to 3. before his/her injury? 4. How well can the patient do on tests that measure thinking and memory skills now as compared to before his/her injury? How well can the patient do the things he/she wants to do in life now as 5. compared to before his/her injury? 6. How well is the patient able to see now as compared to before his/her injury? How well can the patient hear now as compared to before his/her injury? 7. How well can the patient move his/her arms and legs now as compared to 8. before his/her injury? 9. How good is the patient's coordination now as compared to before his/her injury? 10. How good is the patient at keeping up with the time and date and where he/she is now as compared to before his/her injury?

Awareness Questionnaire Clinician Form

| 1 | l | 2 | 3 | 4 5 | | | | | |
|----------|--------|--|---|---------------------|----------------|--|--|--|--|
| mu wo | | a little worse | about the same | a little better | much better | | | | |
| | 11. | How well can the pat injury? | How well can the patient concentrate now as compared to before his/her injury? | | | | | | |
| | 12. | How well can the pat compared to befo | tient express his/h pre his/her injury? | er thoughts to othe | rs now as | | | | |
| | 13. | | How good is the patient's memory for recent events now as compared to before his/her injury? | | | | | | |
| | 14. | How good is the patient at planning things now as compared to before his/her injury? | | | | | | | |
| | 15. | How well organized is the patient now as compared to before his/her injury? | | | | | | | |
| | 16. | How well can the patient keep his/her feelings in control now as compared to before his/her injury? | | | | | | | |
| | 17. | How well adjusted emotionally is the patient now as compared to before his/her injury? | | | | | | | |
| | | | | | | | | | |
| 1 | l | 2 | 3 | 4 | 5 | | | | |
| comp | letely | severely | moderately | minimally | not at all | | | | |
| | _18. | To what extent is the patient's accurate self-awareness impaired by brain injury? | | | | | | | |

Awareness Questionnaire (AQ) – patient form

Awareness Questionnaire Patient Form

| P | articipa | nt Code: | | | | | | |
|-----|----------|---|--|----------------------|-------------|--|--|--|
| D | ate: | | | | | | | |
| 1 | | 2 | 3 | 4 | 5 | | | |
| mue | h | a little | about | a little | much | | | |
| wor | se | worse | the same | better | better | | | |
| | 1. | How good is your ability to live independently now as compared to before your injury? | | | | | | |
| | 2. | | How good is your ability to manage your money now as compared to before your injury? | | | | | |
| | 3. | How well do you get injury? | How well do you get along with people now as compared to before your injury? | | | | | |
| | 4. | How well can you do on tests that measure thinking and memory skills now as compared to before your injury? | | | | | | |
| | 5. | How well can you do the things you want to do in life now as compared to before your injury? | | | | | | |
| | 6. | How well are you ab | How well are you able to see now as compared to before your injury? | | | | | |
| | 7. | How well can you he | How well can you hear now as compared to before your injury? | | | | | |
| | 8. | How well can you move your arms and legs now as compared to before your injury? | | | | | | |
| | 9. | How good is your co | ordination now as co | mpared to before yo | our injury? | | | |
| | 10. | How good are you at keeping up with the time and date and where you are now as compared to before your injury? | | | | | | |
| | 11. | How well can you co | oncentrate now as cor | npared to before you | ır injury? | | | |
| | 12. | | How well can you express your thoughts to others now as compared to before your injury? | | | | | |
| | 13. | How good is your m your injury? | emory for recent ever | nts now as compared | to before | | | |

| 1 | 2 | 3 | 4 | 5 |
|---------------|--|----------------------|--------------------|-------------------|
| much worse | a little worse | about the same | a little better | much better |
| 14. | How good are you a injury? | at planning things n | ow as compared | to before your |
| 15. | How well organized | l are you now as co | mpared to before | your injury? |
| 16. | How well can you keep your feelings in control now as compared to before your injury? | | | |
| 17. | How well adjusted of injury? | emotionally are you | 1 now as compare | ed to before your |

Pittsburgh Rehabilitation Participation Scale (PRPS)

Pittsburgh Rehabilitation Participation Scale - PRPS

Participant code: ______Admission date: _____

Instructions to therapist: for each therapy session, please circle one of each of the following to assess the patient's participation (effort and motivation as perceived by you) in the therapy session. Please rate as follows:

- None: patient refused entire session, or did not participate in any exercises in session. (see Note below)
- Poor: patient refused or did not participate in at least half of session.
- Fair: patient participated in most or all of activities but did not show maximal effort or finish most activities, or required much encouragement to finish activities.
- **Good:** patient participated in all activities with good effort and finished most but not all activities and passively followed directions (rather than actively taking interest in activities and future therapy).
- Very good: patient participated in all activities with maximal effort and finished all activities, but passively followed directions (rather than actively taking interest in activities and future therapy).
- Excellent: patient participated in all activities with maximal effort, finished all activities and actively took interest in activities and/or future therapy sessions.

Note: if patient was unable to attend therapy because of medical test, bed rest order, illness, or scheduling conflict, do not mark any score.

Note: in cases of doubt, choose the lower rating, eg, "good" rather than "very good."

| Session Number | Date | Therapist Initials | None | Poor | Fair | Good | Very good | Excellent |
|-------------------|------|-----------------------|------|------|------|------|--------------|-----------|
| 1 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 2 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 3 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 4 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 5 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 6 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 8 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 9 | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 10 | | | 1 | 2 | 3 | 4 | 5 | 6 |

PARTICIPATION:

NOTE. Available as an electronic file from the corresponding author by request.

The Structured Assessment of FEasibility measure (SAFE)

Structured Assessment of FEasibility (SAFE) Version 1.1

SAFE assesses the extent to which an intervention is feasible for implementation in menta health services in the National Health Service (NHS) in England.

The reference for this measure is:

Bird V, Le Boutillier C, Leamy M, Williams J, Bradstreet S, Slade M (2014) Evaluating the feasibility of complex interventions in mental health services: standardised measure and reporting guidelines, British Journal of Psychiatry, 204, 316-321.

SAFE Version 1.1 (this document) and the SAFE Version 1.1 rating manual can be www.researchintorecovery.com/safe downloaded at

The measure comprises two sub-scales: Blocks (8 items) and Enablers (8 items). Circle one answe for each item.

BLOCKS SUB-SCALE

These items are blocks to implementation.

1. Do staff require specific training to deliver the intervention?

| Yes | Partial | No | Unable to rate |
|--|------------------------------|------------------------------------|---|
| Yes: Partial: No: Unable to rate: | The interven The interven | tion requires u tion does not i | our hours or more of training Ip to four hours of training require any specific training ovided to rate item |

2. Is the intervention complex?

| Yes | Partial | No | Unable to rate |
|--|------------------------------|------------------------------------|---|
| Yes: Partial: No: Unable to rate: | The interven The interven | tion contains t tion only has c | p of more than three separate components wo or three separate components one component ovided to rate item |

3. Is the intervention time consuming to provide?

| Yes | Partial | No | Unable to rate |
|------------------------|--------------|------------------------------------|--|
| Yes: | client) | | wo hours or more per week of work (per |
| Partial: | | tion requires h week (per clier | alf an hour or more but less than two hours |
| No: Unable to rate: | The interven | tion requires le | ess than half an hour per week (per client) ovided to rate item |

4. Does the intervention include/require ongoing support and supervision?

| Yes | Partial | No | Unable to rate |
|-----------------|-------------------------|------------------|--|
| Yes: | The interver session | ntion requires a | an extra weekly supervision or support |
| Partial: | The interver session | ntion requires a | an additional monthly supervision or support |
| No: | | ntion does not | require any additional support sessions or |
| Unable to rate: | | information pr | ovided to rate item |

5. Does the intervention require additional human resources?

| r |
|-------|
| eded. |
| |
| |
| |
| |
| |

6. Does the intervention require additional material resources?

| Yes | Partial | No | Unable to rate |
|-----------------|----------------------------|----|---|
| Yes: | which staff v | | sizeable resources or special equipment Ily have access to e.g. a specially equipped erials |
| Partial: | The interver computers, | | additional but readily available resources e.g. |
| No: | The interver | | require any additional resources that staff cess to |
| Unable to rate: | | | ovided to rate item |

7. Is the intervention costly?

| Yes | Partial | No | Unable to rate |
|-----------------|-------------------------|--------------------|--|
| Yes: | The interver funding | ntion is likely to | be too costly to provide without extra |
| Partial: | The interver | ntion is likely to | require other costs to be de-prioritised |
| No: | The interver | ntion cost is low | V |
| Unable to rate: | Not enough | information pr | ovided to rate item |

8. Are there known serious or adverse events associated with the intervention?

| Yes | Partial | No | Unable to rate |
|----------------|---------------------------|--------------|---|
| Yes: | There are interventio | | ious adverse events associated with the |
| Partial: | There are | known adv | erse events associated with the intervention |
| No: | There are intervention | | serious or adverse events associated with the |
| Unable to rate | : Not enoug | gh informati | on provided to rate item |

ENABLERS SUB-SCALE

These items are enablers of implementation.

9. Is the intervention applicable to the population of interest (e.g. adults using community mental health teams)

| Yes | Partial | No | Unable to rate |
|------------------------|--------------|-----------------|--|
| Yes: | The interven | tion has been (| designed for the population of interest |
| Partial: | | | designed for a general mental health ed to be applicable to the population of |
| No: Unable to rate: | | | icable to the population of interest vided to rate item |

10. Is the intervention manualised?

| Yes | Partial | No | Unable to rate |
|--|----------------------------|-------------------------------------|---|
| Yes: Partial: No: Unable to rate: | Some compo The interven | onents of the in tion is not man | vention are manualised Itervention are manualised Jualised Ivided to rate item |

11. Is the intervention flexible (i.e. can it be tailored to the context and situation)?

| Yes | Partial | No | Unable to rate |
|------------------------------------|---------------------------|-------------------|--|
| Yes: | The interver situation | ntion is flexible | and can be tailored to the context and |
| Partial: No: Unable to rate: | The interver | ntion cannot be | on can be tailored to the context and situation e tailored to the specific context ovided to rate item |

12. Is the intervention likely to be effective (i.e. evidence based and expected to produce positive outcomes)?

| Yes | Partial | No | Unable to rate |
|------------------------|---------|-------------------------------------|--|
| Yes: | | established ev tion (e.g. clinic | idence base regarding the effectiveness of al trials) |
| Partial: | | ne evidence fo s but no clinica | r the effectiveness of the intervention (e.g. I trials) |
| No: Unable to rate: | | | for the intervention ovided to rate item |

13. Is the intervention cost saving?

| Yes | Partial | No | Unable to rate |
|-----------------|------------|--------------|--------------------------------------|
| Yes: | The interv | ention has | been demonstrated to save costs |
| Partial: | The interv | ention has | been demonstrated to be cost-neutral |
| No: | The interv | ention incu | rs more costs |
| Unable to rate: | Not enoug | gh informati | on provided to rate item |

14. Do the intended goals of the intervention match the prioritised goals of the NHS?

| Yes | Partial | No | Unable to rate |
|-----------------|--|---|--|
| Yes: | improving r recovery, pr satisfaction, | nental health ar romoting good reducing stign | ervention match valued NHS outcomes e.g. ad wellbeing, supporting clinical and personal physical health, improving service na and discrimination [Taken from No Health 11, Department of Health] |
| Partial: | The second outcomes | ary aims of the | intervention match the current valued |
| No: | | and secondar | y aims of the intervention do not match the f the NHS |
| Unable to rate: | Not enough | information pro | ovided to rate item |

15. Can the intervention be piloted?

| Yes | Partial | No | Unable to rate |
|-----------------|--------------|-----------------|---|
| | | | |
| Yes: | The interver | ntion can be pi | loted by a few members of staff AND with |
| | only a few s | ervice users | |
| Partial: | The interver | ntion can be pi | loted by a few members of staff OR with a |
| | few service | users | |
| No: | The interver | ntion cannot be | e piloted |
| Unable to rate: | Not enough | information pr | ovided to rate item |

16. Is the intervention reversible?

| Yes | Partial | No | Unable to rate |
|------------------------|---------------------------|----------------------------------|--|
| Yes: | lt is possible effects | to stop the in | tervention without harmful, or unwanted, |
| Partial: | | to stop the in Inwanted, effe | tervention, but there are likely to be some cts |
| No: Unable to rate: | It is not pos | sible to stop th | e intervention without serious adverse effects ovided to rate item |

Scoring

It is recommended that no overall summary score is used, as barriers and facilitators differ in their importance depending on the context. See the SAFE paper (reference given on page 1) for further discussion of using SAFE ratings.

Information sheet for staff participants



Study title:

Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI).

Information sheet

My name is Janie Hunter. I am a trainee clinical psychologist conducting a research project as part of my course. You are being invited to take part in this project as part of my research study. Please take time to read this information about the study carefully. Please ask if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We would like to find out about the effects of a short video about rehabilitation for acquired brain injury (ABI) in an inpatient setting. The study will be submitted as part of a research portfolio for a Doctorate in Clinical Psychology at the University of Glasgow.

Why have I been invited?

You have been asked to participate as you are a member of the Graham Anderson House clinical multi-disciplinary rehabilitation team. In order to examine whether the video is feasible for use in improving motivation for rehabilitation an inpatient setting, we wish to collect feedback from staff involved in rehabilitation sessions. Additionally, in order to measure any effects of the video on patients' awareness and motivation, we would like to collect observer/informant information from staff members working with them.

What does taking part involve?

Your participation will all take place at Graham Anderson House, and the trial will last 6 weeks. Taking part firstly involves completing questionnaires about no more than four inpatient participants; you will be asked to complete two short questionnaires about each patients' awareness, on three occasions; pre-trial, week 4 and week 6. The total time taken for questionnaires should be no longer than 20 minutes on each occasion (five minutes per patient).

You will also be asked to record details about these patients' participation in your rehabilitation sessions on three occasions; pre-trial, week 4 and week 6. This will be information you already record about session participation but in a different format, and should only take a minute more than your routine data collection.

At the end of the trial you will be asked to complete a final questionnaire about the experience of the use of the video intervention, and this will take five minutes.

Who is conducting the research?

Janie Hunter, a Trainee Clinical Psychologist from the University of Glasgow, is carrying out this study. Dr. Hamish McLeod and Professor Tom McMillan, also from the University of Glasgow, are supervising the study.

Do I have to take part?

No; participation is voluntary and it is up to you to decide. If you want to take part, you will be asked to sign a consent form to show you have agreed. You would also be free to withdraw from the study at any time, and you would not have to give a reason for this.

What happens to the information gathered?

Your identity and personal information will be kept completely confidential and known only to the researchers. The study Sponsor (University of Glasgow) may audit the conduct of the study so would also have access to participant information. The information will be stored securely; paper files will be kept within a locked filing cabinet in Graham Anderson House, and electronic information will be anonymised and stored on an encrypted laptop. Data collected will be anonymised and unique numerical codes will be used as identifiers. The data will be held in accordance with the Data Protection Act, which means that we will keep it safely and will not reveal it to other people without your permission or unless we are obliged to for legal reasons.

What are the possible benefits of taking part?

By taking part in this research you will be providing valuable information on how we can best support people who have experienced a head injury to take part in rehabilitation programmes. Results of the study will be made available to Graham Anderson House.

Who has reviewed the study?

The NHS West of Scotland Research Ethics Committee, and the Brain Injury Rehabilitation Trust (BIRT) Ethics Committee have reviewed this study.

What do I do now?

If you are interested in taking part in the study, please contact Dr Brian O'Neill, Consultant in Neuropsychology and Rehabilitation at Graham Anderson House, or you may contact me directly. The Research Team will then contact you by telephone to answer any other questions that you may have about the study. If you are still interested in taking part following this, we will discuss when the trial will begin. When we meet you will be asked to sign a consent form to show that you have read and understood the information provided to you and that you agree to take part in the study.

What will happen to the results of the study?

The results of the study will be written into a report and submitted to the University of Glasgow as part of the requirements for the Doctorate in Clinical Psychology. It is possible that this report will also be published in an academic journal. A summary of this report will be distributed to Graham Anderson House.

If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact **Dr Sue Turnbull**, Research Tutor, University of Glasgow, Institute of Health and Wellbeing, email: <u>s.turnbull@clinmed.gla.ac.uk</u>, tel no: 0141 211 3927.

If you have a complaint about any aspect of the study?

We value the time you will take to participate in the study and will try to ensure you are comfortable with all aspects of your participation. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint through the University of Glasgow who are acting as the research sponsor. Please contact the Chief Investigator, Dr Hamish McLeod, in the first instance, on the contact details below.

Contact Details:

Main Researcher (Trainee Clinical Psychologist): Janie Hunter University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow G12 0XH <u>i.hunter.1@research.gla.ac.uk</u> 0141 211 3920

Research Supervisors: Dr. Hamish McLeod University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow G12 0XH <u>Hamish.McLeod@glasgow.ac.uk</u> 0141 211 3922

Professor Tom McMillan University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow G12 0XH <u>Thomas.McMillan@glasgow.ac.uk</u> 0141 211 0354

Thank you for taking the time to read this Information Sheet and forconsidering taking part in this study.

Appendix 2.10

Consent form for staff participants



Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI)

Contact details: Janie Hunter (Trainee Clinical Psychologist) University of Glasgow, Section of Psychological Medicine, 1055 Great Western Road, Glasgow, G12 0XH Email: <u>i.hunter.1@research.gla.ac.uk</u> 0141 211 3920

Please initial the BOX

I confirm that I have read and understand the information sheet (version 7, dated 25thJanuary 2017) for the above study.

I confirm that the researcher has answered any queries to my satisfaction.

I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.

I understand that I can withdraw my data from the research database at any time.

I understand that any of my information recorded in the investigation may be looked at by representatives of the study Sponsor (University of Glasgow) for audit purposes but it will remain confidential and no information that identifies me will be made publicly available.

I consent to being a participant in the project.

1 copy to staff member, 1 copy to researcher

Information sheet for inpatient participants



Study title:

Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI).

Information sheet

My name is Janie Hunter. I am a trainee clinical psychologist conducting a research project as part of my course. You are being invited to take part in this project as part of my research study. Please take time to read this information about the study carefully. Please ask if there is anything that is not clear or if you would like more information. You do not have to make an immediate decision about taking part in the study.

What is the purpose of the study?

We would like to find out about the effects of a short video about rehabilitation for acquired brain injury (ABI) in an inpatient setting. The study will be submitted as part of a research portfolio for a Doctorate in Clinical Psychology at the University of Glasgow.

What does taking part involve?

Taking part first involves a face-to-face appointment with a researcher where you will be asked to complete two questionnaires. This will take place at Graham Anderson House and should take around 20 minutes. You will then be randomly allocated to one of two groups, both of which consist of watching a short video about ABI rehabilitation. You will be supported by Graham Anderson House staff to watch a five-minute long video every 2-3 days. There may be a delay of two weeks before you begin watching the video. You will be asked to come along for more sessions with a researcher after two weeks and four weeks, where you will complete another two questionnaires, again taking around 20 minutes. If you had a delay before watching the video, you will also meet with the researcher after six weeks. Over the six weeks you will watch the video approximately 12 times, and complete six to eight questionnaires. We will also need to obtain some information from your Graham Anderson House records, for example about the brain injury. Throughout the study you will continue to receive your normal care from Graham Anderson House.

Why have I been invited?

We have asked the staff at Graham Anderson House to identify people who might take part in the study. This means they will ask you if you want to take part, before contacting the researcher with your permission. After this we will gather some information about you, but this will not be stored if you do not go ahead with completing the questionnaire and viewing the videos. If you are invited to take part, it will be because you experienced a moderate-severe acquired brain injury (ABI).

Who is conducting the research?

Janie Hunter, a Trainee Clinical Psychologist from the University of Glasgow, is carrying out this study. Dr. Hamish McLeod and Professor Tom McMillan, also from the University of Glasgow, are supervising the study.

Do I have to take part?

No; participation is voluntary and it is up to you to decide. If you want to take part, you will be asked to sign a consent form to show you have agreed. If you would like to take a break during any part of the study, you would be free to do this. You would also be free to withdraw from the study at any time, and you would not have to give a reason for this. Withdrawing from the study would not affect the standard of care you receive or your future treatment.

What happens to the information gathered?

Your identity and personal information will be kept completely confidential and known only to the researchers. The study Sponsor (University of Glasgow) may audit the conduct of the study so would also have access to participant information.The information will be stored securely; paper files will be kept within a locked filing cabinet in Graham Anderson House, and electronic information will be anonymised and stored on an encrypted laptop. Data collected will be anonymised and unique numerical codes will be used as identifiers. The data will be held in accordance with the Data Protection Act, which means that we will keep it safely and will not reveal it to other people without your permission or unless we are obliged to for legal reasons.

Will you contact my GP?

With your consent, we will send your GP a short letter to let them know that you are taking part in the study. If you would like to see an example of the letter, please just ask the researcher. This information will help your GP understand what care and treatment you have received.

What are the possible effects on me?

Watching the video might make you feel some different emotions, which might be positive or negative. If you feel negative emotions you will be offered the opportunity to discuss this with the researcher or a member of your clinical support staff. Although the questionnaire sessions are short you might feel tired from concentrating and providing answers. To manage this you will be offered the opportunity for breaks if you need them, and the researcher or a member of Graham Anderson House staff can also support you if you need help.

What are the possible benefits of taking part?

By taking part in this research you will be providing valuable information on how we can best support people who have experienced a head injury to take part in rehabilitation programmes.

Who has reviewed the study?

The NHS West of Scotland Research Ethics Committee and the Brain Injury Rehabilitation Trust (BIRT) Ethics Committee have reviewed this study.

What do I do now?

If you are interested in taking part in the study, please let a member of staff within Graham Anderson House know. They will pass your details to the Research Team who will then contact you by telephone to answer any other questions that you may have about the study. If you are still interested in taking part following this, we will arrange a time for you to begin the study. When we meet you will be asked to sign a consent form to show that you have read and understood the information provided to you and that you agree to take part in the study.

What will happen to the results of the study?

The results of the study will be written into a report and submitted to the University of Glasgow as part of the requirements for the Doctorate in Clinical Psychology. It is possible that this report will also be published in an academic journal. A summary of this report will be distributed toGraham Anderson House; the researcher and Graham Anderson House clinical team can make sure you have access to this report if you are interested in the results.

If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact **Dr Sue Turnbull**, Research Tutor, University of Glasgow, Institute of Health and Wellbeing, email: <u>s.turnbull@clinmed.gla.ac.uk</u>, tel no: 0141 211 3927.

If you have a complaint about any aspect of the study?

We value the time you will take to participate in the study and will try to ensure you are comfortable with all aspects of your participation. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Glasgow who are acting as the research sponsor. Please contact the Chief Investigator, Dr Hamish McLeod, in the first instance, on the contact details below.

Contact Details:

Main Researcher (Trainee Clinical Psychologist): Janie Hunter University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow G12 0XH <u>j.hunter.1@research.gla.ac.uk</u> 0141 211 3920 Research Supervisors: Dr. Hamish McLeod University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow G12 0XH Hamish.McLeod@glasgow.ac.uk 0141 211 3922

Professor Tom McMillan University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow G12 0XH <u>Thomas.McMillan@glasgow.ac.uk</u> 0141 211 0354

Thank you for taking the time to read this Information Sheet and forconsidering taking part in this study.

Appendix 2.12

Consent form for inpatient participants



Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI)

Contact details: Janie Hunter (Trainee Clinical Psychologist) University of Glasgow, Section of Psychological Medicine, 1055 Great Western Road, Glasgow, G12 0XH Email: <u>i.hunter.1@research.gla.ac.uk</u> 0141 211 3920

Please initial the BOX

I confirm that I have read and understand the information sheet (version 8, dated 25thJanuary 2017) for the above study.

I confirm that the researcher has answered any queries to my satisfaction.

I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.

I consent to medical records in relation to head injury being accessed for the purposes of the study.

I understand that I can withdraw my data from the research database at any time.

I understand that any of my information recorded in the investigation may be looked at by representatives of the study Sponsor (University of Glasgow) for audit purposes but it will remain confidential and no information that identifies me will be made publicly available.

I give permission for my care team to be informed that I am taking part in the study.

I give permission for my G.P. to be informed that I am taking part in the study.



| | | _ |
|--|--|---|
| | | ٦ |
| | | |





I consent to being a participant in the project.

| Name of Participant | Date | | Signature | | | |
|---------------------|------|-----|-----------|--|--|--|
| | | | | | | |
| Name of Researcher | D | ate | Signature | | | |
| | | | | | | |

1 copy to patient, 1 copy to researcher, 1 original for the patient's notes

GP letter

118



Improving treatment motivation and self-awareness in people with moderate to severe acquired brain injury (ABI)

Dear Doctor Name

RE: Participant Name, DOB, CHI

I am writing to inform you that your patient has agreed to participate in the above research study at Graham Anderson House, Brain Injury Rehabilitation Trust. The purpose of this study is to determine whether providing preparatory information is feasible as a general protocol for acquired brain injury (ABI) inpatient services, and to investigate the use of this preparatory material in increasing insight, motivation, and engagement in rehabilitation.

The study is investigating the use of a short DVD as a preparatory protocol for rehabilitation; the DVD is aimed at improving insight into ABI sequalae and increasing motivation for rehabilitation. Participants will be asked to complete pre- and post-trial measures of insight and motivation for rehabilitation, before being randomised to watch the video immediately (intervention group A) or delayed viewing of the video in 2 weeks time (waitlist control group B). Additionally, staff will evaluate of the feasibility of delivering the protocol.

The main effects to be aware of are detailed in the Patient Information Sheet.

I have enclosed a copy of the Participant Information Sheet for your reference; however if you have any queries or require further information please contact me using the details below.

Yours Sincerely,

Janie Hunter (Trainee Clinical Psychologist) University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow G12 0XH j.hunter.1@research.gla.ac.uk 0141 211 3920

Research Supervisors: Professor Tom McMillan Dr. Hamish McLeod University of Glasgow University of Glasgow Institute of Health and Wellbeing Institute of Health and Wellbeing 1055 Great Western Road 1055 Great Western Road Glasgow G12 0XH Glasgow G12 0XH Hamish.McLeod@glasgow.ac.uk Thomas.McMillan@glasgow.ac.uk 0141 211 0354 0141 211 3922 Encs: Participant Information Sheet, version 8 dated 25/01/17.

Rehabilitation preparatory video script

(Italics provided in written form on video, as summaries and headings)

Hello. My name is Janie, and I'm a psychologist who works with people who have suffered a brain injury. You are here in this unit because your brain has been injured. We are working to help you get better.

This video will explain a bit about what that might mean for you.

What is brain injury?

(Insert simple visual image of brain)

Our brain is an amazing organ; it is responsible for all our thoughts, memories, feelings, dreams and actions. All of these functions of your brain are what makes you 'you'.

People can suffer a brain injury from a blow to the head, like in a road traffic accident, a fall, or an assault. Brain injury can also happen in illnesses like stroke, heart attack, or swelling of the brain due to an infection. These injuries can cause actual damage to the brain, or disrupt connections between different areas.

Common difficulties following brain injury

So what are some of the difficulties faced by people with a brain injury? Well, because different areas of the brain control different functions, the area that is damaged can influence the problems you might have. The clinical team here can tell you more about the kind of injury you had, but you might recognise some of these yourself. Lots of people who have had brain injury have the same worries and concerns, like wanting to get out of hospital or get 'back to normal'. It can be hard, but the reason you are not feeling 'yourself' is not because you are in hospital; going home will not get everything back to normal. This unit is here to help you normalise things again.

Physical problems (insert cartoon image of body)

Some common physical problems people have include trouble moving parts of their body the way they used to, weaknesses, problems with balance or feeling tired more easily.

The Senses

Sensations like sight, hearing, smell and touch can all be affected by brain injuries, You might find bright lights painful, or that sudden noises make you jump more than before.

Sleep

Sleep is affected in most people after a brain injury. You may find that it is hard to fall asleep, or that you can't stay asleep for as long as you used to.

Thinking (insert cartoon image conveying thinking)

Sometimes the way people think is changed. For example, people have difficulties paying attention, feel confused more easily, have difficulty finding the right words or making sentences, or struggle with solving problems. Sometimes people find it more difficult to have conversations, or communicate with other people.

Memory

People might have difficulty remembering things. This may be events that happened in the past, peoples' names or faces, things people have said to them, or how to do things that they did before.

Emotions (insert cartoon image of happy/sad faces conveying emotion)

Brain injury can also affect emotions or feelings. Some people find they feel more nervous or scared than they used to, feel sad, or have 'mood swings'. It might be more difficult to enjoy things you used to, especially if things that used to be easy are now more difficult. It can also be hard to get motivated and keep working towards goals. Emotions cannot be easily seen, so people will ask you about them. If you are having very strong feelings just now, **tell** others how you are feeling.

Awareness

It might sound strange, but another common problem after brain injury is not being fully aware of the effects of the brain injury. Sometimes loved ones might notice changes that you don't, and this can cause problems such as arguments or disagreements about the need for being in hospital

Fortunately, many people experience improved recovery with hospital treatment and rehabilitation.

What is rehabilitation?

Brain injury rehabilitation is a bit like having 'physiotherapy for your brain'; imagine your brain is a muscle you need to exercise and practise using to help it get stronger. The type of rehabilitation you need will depend on your brain injury. But, one of the most important things in the success of your rehabilitation is your active involvement. So, part of your rehabilitation will involve asking you to think about what goals you have in your time here. These will become part of your care plan.

Working towards your goals can be hard after a brain injury so we need to start by helping you understand the difficulties you have and then learn ways to solve or work around the problems they cause. This might mean *re-learning* some things that you used to do easily like cooking a meal or managing your money. Although this might be frustrating, it is possible with practice to *learn new ways* of doing daily tasks in order to become more independent. This will involve some hard work and practice but it is worth it, so that you can be more independent in

preparation for when the time comes to leave the unit. Everyone here is faced with the same challenge – they need to learn to:

- 1. Identify their strengths and weaknesses since their brain injury
- 2. Work out their goals
- 3. Make the changes needed to reach goals
- 4. Practice new skills with the support of the unit staff

So, what will rehabilitation be like day to day? You will have a timetable of sessions that are mapped out across every day. *(Insert visual image of timetable)* This will help you stay organised and focused on the activities. Some days you might feel less motivated to go to your sessions. But, that is exactly the time when you should follow your timetable, as doing things that are challenging is one of the ways that you will become stronger and more independent. The staff are here to support you when you are finding it hard to get motivated or the rehabilitation activities are challenging.

There are lots of different professionals in the unit, who specialise in different aspects of brain injury rehabilitation. *Nurses, psychologists, occupational therapists, physiotherapists, speech & language therapists and support workers.* Who you work with will depend on your personal needs and goals. Some sessions will be on your own with one of the team, and others will be in groups with other people. You might take a few sessions to get used to the activities but it is important that you keep attending and trying hard so that you have the best chance of learning ways of becoming more independent. You might also be asked to practise things in between sessions. This is like 'exercise' for your brain and the more you do, the more independent and capable you will become.

If there is something you really love doing, and it is not on your timetable, ask if you can do this. Rehabilitation works best when it is meaningful, and setting your own goals for activities is the best way to make things meaningful.

If you have questions about the roles of people in the team, you can ask them to explain more about their own special skills, and what their work with you will involve. We know from treating many people that the more you work together with the staff, the better the chance that you will recover more. Everybody here really wants to help and you can ask questions to help you understand your rehabilitation at any time.

Thanks for listening, and good luck with your rehabilitation.

[https://vimeo.com/214526226_(password: rehabvideo)]

Reliable Change Index calculation methods

$$\mathrm{RCI} = \frac{X_2 - X_1}{S_1 \sqrt{1} - r_{xx}}$$

Where X_1 = baseline scores; X_2 = post-baseline score; S_1 = the standard deviation at baseline; \mathbf{r}_{xx} = the internal reliability.