Thesis title: Neuropsychological rehabilitation for memory impairment following stroke

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CHAPTER 1: Systematic Review

Title: Comparing apples and oranges: A systematic review of measures used to assess the efficacy of neuropsychological rehabilitation interventions for memory difficulties following stroke.

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ABSTRACT

Memory difficulties are common post-stroke. Previous reviews have examined the efficacy of neuropsychological rehabilitation but reported methodological issues, including inconsistency regarding outcome measures. This systematic review aimed to identify and characterise outcome measures used to assess efficacy of memory rehabilitation interventions in stroke and identify which measures capture changes post-intervention. We used a comprehensive search strategy to identify randomised control trials (RCTs) and single-case experimental design (SCED) studies indexed in Ovid Medline, Embase, EBSCOhost PsycINFO, CINAHL, and relevant trial registries. We hand-searched references of included studies and published systematic reviews. Methodological quality of included studies was assessed by two independent reviewers using the PEDro-P and RoBiNT scales. Fifteen papers (11 RCTs, 4 SCEDs) met inclusion criteria. Of these, 11 studies (8 RCTs, 3 SCED) involved compensatory interventions and five (4 RCTs, 1 SCED) involved restorative interventions. Diverse measures of memory function were used to assess efficacy across studies. There was a lack of consistency in how outcomes are measured, and as yet there is no clear evidence regarding which measures are most sensitive to change following intervention. Issues relevant to the use of different measurement types are discussed regarding methodological considerations and goals of neurorehabilitation interventions.

Keywords: Stroke, Memory, Measurement, Neurorehabilitation, RCT, SCED

INTRODUCTION

Description of the condition(s)

Stroke is the fourth single leading cause of death and single largest cause of complex disability in the UK (Stroke Association, 2018). Stroke often results in impairment of cognitive functions including attention, memory and executive functions. A recent meta-analysis indicated that 38% of stroke survivors are affected by cognitive impairment one year post-stroke (Sexton et al., 2019). Stroke survivors and their caregivers consistently rate problems with memory and thinking as one of their greatest concerns (Pollock et al., 2012). Memory impairment can involve various memory processes (e.g., encoding, storage, retrieval) and subtypes, including working memory (a cognitive system that facilitates temporary storage, processing and manipulation of information), semantic memory (recalling information such as facts, concepts, and words), episodic memory (recalling specific personal past events and experiences), procedural or implicit memory (involved in perceptual and motor skills and procedures) and prospective memory (remembering to do something in the future). These impairments can significantly impact daily functioning, independence, and quality of life (Evans, 2013; 2014).

Description of the intervention(s)

The Stroke Association (2021) have highlighted cognitive and memory difficulties as a top priority for stroke rehabilitation research. Cognitive rehabilitation uses restorative and/or compensatory interventions to support individuals with cognitive impairments and memory dysfunction to maintain or improve functioning, promote independence, and enhance quality of life (Wilson et al., 2009). Restorative interventions aim to restore or improve cognitive functioning and can include pharmacological interventions or cognitive retraining. Compensatory approaches involve teaching people to adapt to or circumvent their cognitive impairment by using enhanced learning (e.g., errorless learning, repetition), internal

(e.g., mnemonics, method of loci), environmental (e.g., signs, sensors), and external strategies, including passive and active reminder tools (e.g., diaries, smartphone applications).

To date, several systematic reviews and meta-analyses have examined the efficacy of memory rehabilitation interventions for diverse acquired brain injury (ABI) populations, including stroke (das Nair et al., 2016; O'Donoghue et al., 2022), and combined stroke and Traumatic Brain Injury (TBI) populations (Cicerone et al., 2019). Cicerone and colleagues (2019) concluded that there is evidence to support interventions for memory difficulties, including memory strategies for mild memory deficits and external aids for people with severe memory impairment. Das Nair and colleagues (2016) found that participants who received cognitive rehabilitation for memory problems following stroke indicated short-term subjective improvement on self-report measures of memory function. However, this effect was not observed at 3-months follow-up. The authors reported inconsistencies regarding outcome measures across studies and small sample sizes, and a need for common standardised outcome measures.

Why is it important to do this review?

Issues regarding measurement have been highlighted regarding assessing the efficacy of neurorehabilitation interventions for memory difficulties. Outcome measures vary across studies and may include validated and non-validated neuropsychological assessment tools and tests, self-report measures, observer-reported measures completed by carers and/or professionals, and behavioural data (e.g., everyday memory task performance). It is crucial that we can accurately detect intervention effects using meaningful outcome measures as this has implications for guiding clinical decision-making regarding which interventions to use for which difficulties and which clinical populations.

Strengths and limitations of different measurement tools may impact data accuracy (e.g., self-report data may be impacted by cognitive impairment and limited insight), performance on behavioural measures (e.g., individuals may alter their behaviour due to participating in research), and sensitivity to detecting effects of intervention (e.g., ceiling effects may make it difficult to capture improvements in memory functioning). Also, due to the complexity of cognitive rehabilitation interventions (e.g., multiple intervention components introduced at different times in a range of settings, involving diverse professionals), cause-effect relationships may be difficult to establish (Wade, 2020).

Aims

The aims of this systematic review were to identify and characterise outcome measures used to assess the efficacy of neuropsychological rehabilitation interventions targeting post-stroke memory difficulties in adults[1], and to identify which (if any) of these measures captured changes in memory functioning following these interventions. We anticipated that the type of intervention ('restorative', 'compensatory') might influence the types of outcome measures used within included studies. For instance, as restorative interventions aim to restore or improve memory functioning, these studies may primarily use neuropsychological assessments tests to capture these changes, in addition to other measures of memory functioning. Whereas compensatory interventions teach strategies, or modify the environment to help manage memory impairment, and so studies involving these interventions may use diverse measures of memory functioning, such as self- and other-reported memory-related functioning and/or observable behavioural data (e.g., completion of to-be-remembered tasks). We wondered whether there might be a relationship between type of intervention, and the outcome measures that demonstrate effects regarding changes in

[1] Originally, this systematic review included diverse ABI populations (e.g., stroke, TBI). However, we subsequently decided to focus on stroke specifically.

memory functioning following intervention. We also considered the methodological quality of included studies as this might impact estimates of intervention effects captured via measures of memory functioning, as well as the conclusions that might be drawn regarding the overall review findings. Hence, we aimed to assess the internal validity (the degree to which included studies' design, conduct, and analysis have minimised bias) and external validity (regarding generalisability of results), as well as statistical analysis of included studies.

Objectives

- To identify and characterise outcome measures used to assess the efficacy of neurorehabilitation interventions targeting memory difficulties following stroke in adults.
- To report on the specific memory interventions or techniques used within these studies, and categorise these as 'restorative', 'compensatory', or 'mixed'.
- To identify which measure(s) capture changes in memory function following intervention, including effect sizes.
- To assess the methodological quality of the included studies.

METHODS

This review was registered on PROSPERO (registration and protocol number: CRD42023413288) on 18th April 2023 and subsequently updated on 22nd May 2023 following the decision to focus exclusively on stroke.

Types of participants

We included adult human participants (aged ≥18yrs) who experienced stroke and clinician, observer and/or self-reported memory difficulties. We only included studies where memory difficulties were specified within inclusion criteria, with no restrictions regarding

type(s) of memory difficulties. We excluded studies that included participants whose memory deficits were the result of other ABI, unless ≥75% of the sample within each study condition had a stroke, or a stroke sub-group could be identified for which there were separate data.

Types of interventions

We considered neurorehabilitation interventions to involve psychosocial interventions that aimed to improve memory functioning for participants indicating memory difficulties post-stroke. We included both individual and group interventions involving 'restorative', 'compensatory', and 'mixed' approaches. We excluded drug trials, and studies investigating alternative medical interventions (e.g., acupuncture), supplements, or other dietary interventions, brain stimulation (e.g., transcranial Direct Current Stimulation), and exclusively physical exercise interventions.

Types of comparisons

We included randomised controlled trials (RCTs) and clinical controlled trials (CCTs) in which there was a comparison between a treatment group that received one of various memory rehabilitation interventions, and a control group that received either an alternative form of treatment or no memory intervention. We included single case experimental design (SCED), or N-of-1 trials, where participants served as their own control.

Types of outcome measures

We considered the following outcome measures of memory function:

- Validated and non-validated neuropsychological tests/subtests
- Validated and non-validated self-report measures
- Validated and non-validated professional/carer-reported measures
- Objective measures (e.g., everyday memory task performance)
- Other outcome measures not listed above

Search strategy

We searched peer-reviewed published studies written in English with no restrictions in the date of publication.

Electronic searches

- Ovid Medline (1946 to 3rd April 2023)
- Ovid Embase (1947 to 3rd April 2023)
- EBSCOhost PsycINFO (1806 to 3rd April 2023)
- EBSCOhost CINAHL (1981 to 3rd April 2023)
- ClinicalTrials.gov (https://clinicaltrials.gov) (28th May 2023)
- WHO International Clinical Trials Registry Platform (https://trialsearch.who.int) (3rd April 2023)
- Clinical Trials in Stroke (https://www.ucl.ac.uk/stroke/clinical-trials-stroke) (3rd April 2023)

Details of search strategies for each database are reported in Appendix 1.2. Screening of reference lists was conducted for all included studies. Published systematic and Cochrane reviews of cognitive neurorehabilitation interventions involving stroke populations were also screened for additional references (das Nair et al., 2016; O'Donoghue et al., 2022).

Assessment of Risk of Bias in included studies

Two reviewers (CS, MJ) independently assessed the methodological quality and completed 'Risk of Bias' tables of each included study. The Physiotherapy Evidence Database (PEDro-P) scale (Maher et al., 2003) was used for critical appraisal of RCTs (Appendix 1.3). This scale consists of 11 items encompassing external validity (item 1), internal validity (items 2-9), and statistical reporting (items 10 and 11). Items are rated 'yes' (1) or 'no' (0) according to whether each criterion is clearly satisfied. A total PEDro-P score is calculated by adding ratings of items 2 to 11 for a combined total score between 0-10; with

higher scores indicating superior methodological quality. Total PEDro-P scores of 0-3 are considered ‘poor’, 4-5 ‘fair’, 6-8 ‘good’, and 9-10 ‘excellent’ (Maher et al., 2003), although these classifications have not been validated. Cashin and McAuley (2020) suggest that for trials evaluating complex interventions, a score of 8/10 is optimal.

The Risk-of-Bias in N-of-1 Trials (RoBiNT) Scale (Tate et al., 2013) was used for SCED studies (Appendix 1.4). The RoBiNT Scale consists of 15 items comprised of two subscales, including internal validity (7 items) and external validity and interpretation (8 items). Items are rated from 0-2, with a maximum possible score of 30, with higher scores indicating superior methodological quality.

Data collection, management and synthesis

The electronic search strategy was developed in consultation with University of Glasgow and NHS GG&C senior librarians. Following title and abstract screening by CS, a second reviewer (MJ) cross-checked 25% of abstracts, and 100% of full texts obtained by this search strategy for inclusion using the PICO inclusion criteria. There was 87.12% agreement for abstracts (k=.6; moderate-substantial agreement), and 95.4% agreement for full texts (k=.78; substantial agreement). None of the papers included by MJ but rejected by CS during abstract review were included by MJ during full text review. Disagreements regarding full text inclusion/exclusion were resolved via discussion. Five papers included by MJ but rejected by CS were subsequently excluded for the following reasons: <75% stroke aetiology within study conditions (Hildebrandt et al., 2006; 2011); study inclusion criteria were impaired attention, not memory impairment (Westerberg et al., 2007); general cognitive rehabilitation intervention (i.e., not memory-specific; Sihoven et al., 2020); and participants were not randomised to study conditions (Lawson et al., 2020). One paper excluded by MJ but included by CS was included after confirmation that it met PICO inclusion criteria (Gamito et al., 2012).

Data were extracted by CS using a customised form (based on PICO items), piloted prior to use. Accuracy of completed data extraction forms was not checked by a second reviewer. This was used to extract relevant data on eligibility criteria; participants (sample size, characteristics); study design (SCED, RCT); type of intervention (e.g., restorative, compensatory); intervention details; comparison(s); outcome measure(s); follow-up time-points; and results, including effect sizes where reported or where these could be calculated using G*Power (Faul et al., 2007). Where data were missing from a study, this was reported as such. All outcome measures of memory function for each included study were detailed, and the number of follow-up time points for each individual measure. For each included SCED, effect sizes (*Tau-U*) and Reliable Change Indices (RCI; as defined and calculated by study authors) were reported for non-overlap between baseline and intervention phases for each participant. Data were summarised via narrative synthesis.

RESULTS

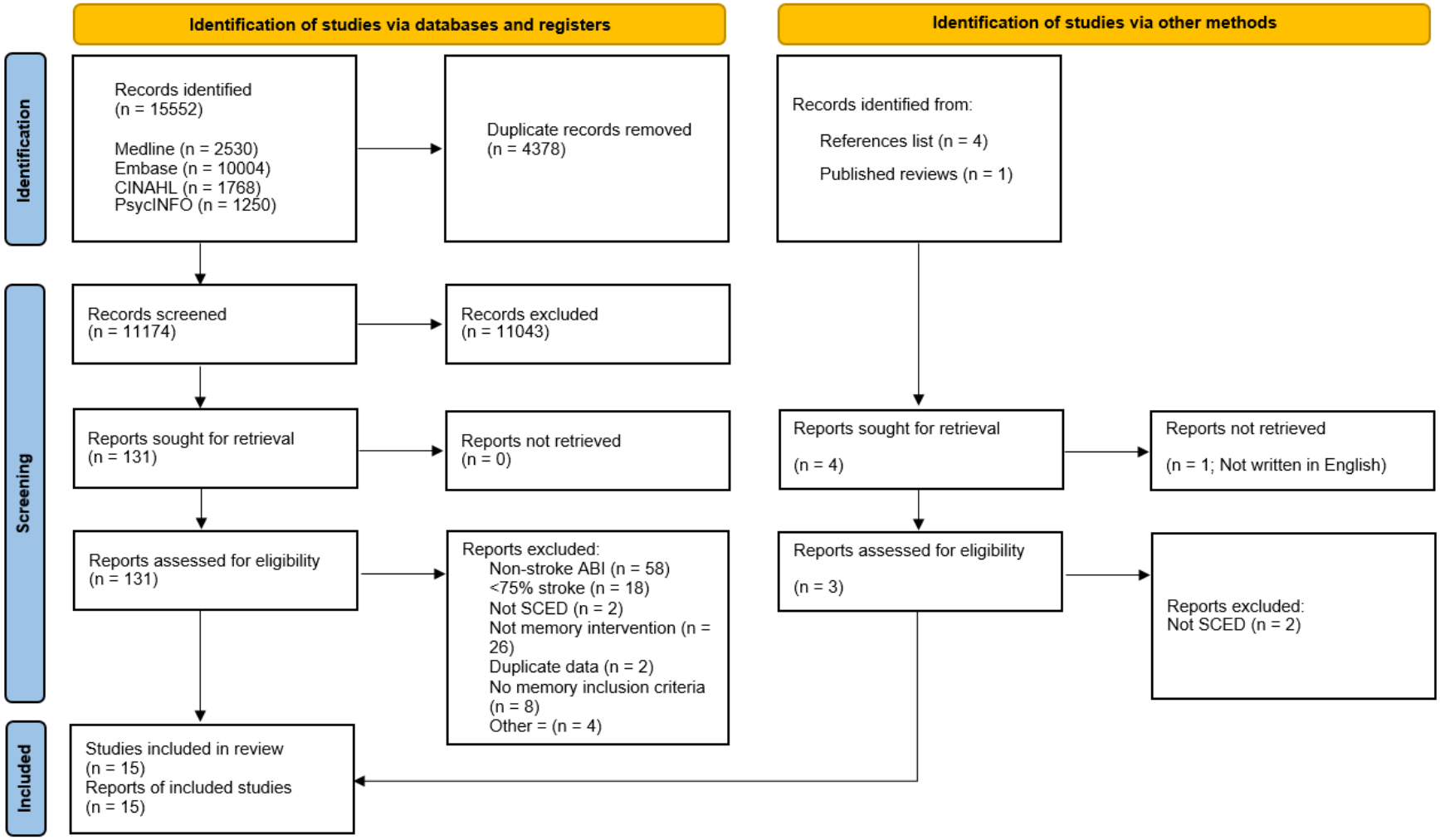
The PRISMA flow chart detailing search processes and results is presented in Figure 1.1. Fifteen papers were identified, including eleven RCTs and four SCED studies. Characteristics of included studies are presented in Tables 1.1. and 1.2 respectively. Fourteen studies were conducted in High Income Countries, including Australia (Miller & Radford, 2014; Withiel et al., 2019; 2020a; 2020b), Germany (Richter et al., 2018; Studer et al., 2021), the Netherlands (Aben et al., 2014; Doornhein & De Haan, 1998), Portugal (Gamito et al., 2012), UK (Fish et al., 2008; Wilson, 1982), and USA (Chen et al., 2012; Lemoncello et al., 2011; Mount et al., 2007), and one upper-middle income country (China; Lin et al., 2014). Of the included RCTs *(N*=556), six were conducted in inpatient settings, three in outpatient settings, and two in community settings. Three SCED studies (*N*=13) were conducted in community settings, and one in an inpatient setting.

Quality Appraisal

Inter-rater agreement was 91.6% (*k*=.90; almost perfect agreement) for PEDro-P and 90% (*k*=.83; almost perfect agreement) for RoBiNT scales. All RCTs were externally valid (PEDro-P item 1). Based on PEDro-P classifications, two studies were considered 'excellent' (Aben et al., 2014; Chen et al., 2012), five were considered 'good' (Doornhein & De Haan, 1998; Fish et al., 2008; Richter et al., 2018; Studer et al., 2021; Withiel et al., 2019), three were 'fair' (Gamito et al., 2012; Lin et al., 2014; Mount et al., 2007), and one was 'poor' (Miller & Radford, 2014). Table 1.3 shows RCT study characteristics ranked according to their PEDro-P methodological quality ratings. On the RoBiNT, Lemoncello et al. (2011) scored 20/30, Wilson (1982) scored 13/30, Withiel et al. (2020a) 18/30, and Withiel et al. (2020b) 19/30. Blinding of therapists was generally not possible across studies, unless interventions were delivered by technology.

Figure 1.1.

PRISMA flow chart of study selection



Intervention types and targets

Eight RCTs and three SCED studies involved compensatory interventions, including assistive technology, such as pagers (Fish et al., 2008) and Television Assisted Prompting (TAP; Lemoncello et al., 2011); Virtual Reality (Gamito et al., 2012); teaching internal and external memory strategies (Aben et al., 2014; Doornhein & De Haan, 1998; Miller & Radford, 2014; Wilson, 1982; Withiel et al., 2019; 2020a), four of which were delivered in a group format; and different learning strategies, such as trial-and-error versus errorless learning (Mount et al., 2007), and global processing versus rote repetition training (Chen et al., 2012). Four RCTs and one SCED study involved restorative interventions. These involved individual computer-assisted training, including *Lumosity*™ (Withiel et al., 2019[2]; 2020b[3]), *Wizard* (Studer et al., 2021), and *RehaCom* Cognitive Training (Lin et al. 2014, Richter et al., 2018). Richter and colleagues also used computerised Recollection Training. These interventions were categorised as restorative based on claims that these computer-based training packages "restore" cognitive function by their respective developers or study authors.

Five studies targeted diverse memory functions (Gamito et al., 2012; Miller & Radford, 2014; Withiel et al., 2019; 2020a; 2020b). One study targeted memory self-efficacy (Aben et al., 2014). Two targeted specific memory skills, such as remembering routes and people's names (Doornhein & De Haan, 1998; Wilson, 1982). One targeted prospective memory tasks (Fish et al., 2008). One targeted visual memory (Chen et al., 2012). Three targeted working memory and its subtypes (Lin et al., 2014; Richter et al., 2018; Studer et al., 2012). Two studies aimed to augment rehabilitation in relation to specific skills training,

[2] Withiel et al. (2019) compared compensatory (*Memory* group) and restorative interventions (*Lumosity*™).

[3] Following correspondence, the authors of the Withiel et al. papers confirmed overlap regarding participants who took part in the RCT (Withiel et al., 2019) and participants included in the SCED studies (Withiel et al., 2020a; 2020b).

including swallowing exercises (Lemoncello et al., 2011), and sock-donning and wheelchair use (Mount et al., 2007).

Memory measures

Validated and adapted neuropsychological tests and subtests[4] included (i) general memory assessment batteries, including the Rivermead Behavioural Memory Test (RBMT), Weschler Memory Test (WMS), and Everyday Memory Test (EMT; adapted from the RBMT by Richter et al., 2018); (ii) complex figure tests, including Rey Complex Figure Test (RCFT), Rey-Osterrieth Complex Figure (ROCF), Modified Taylor Complex Figure (MTCF), and Medical College of Georgia Complex (MCGCF); and Name-Face Paired Associated Memory Test, Stylus Maze Test, Oxford Recurring Faces Test, Brief Visuospatial Memory Test-Revised (BVMT-R), Benton Visual Retention Test, and Rey-Davis Non-verbal Learning Test for visual memory function; (iii) auditory verbal learning tests including Rey Auditory Verbal Learning Test (RVLT), Verbal Memory and Learning Test (VMLT), California Verbal Learning Test (CVLT), and the 15 Words Test; (iv) subtests of the WMS and Weschler Adult Intelligence Scales (WAIS-IV) for working memory, and (v) Royal Prince Alfred Prospective Memory Test (RPA-ProMem) for prospective memory function.

Validated and adapted self- and others-reported measures of memory function and everyday memory failures included Meta-memory in Adulthood Questionnaire, Memory Questionnaire, Everyday Memory Questionnaire (EMQ-R), Comprehensive Assessment of Prospective Memory (CAPM-Self & CAPM-Other scales), and Goal Attainment Scaling (GAS). Objective measures included percentages of completed to-be-remembered tasks, task retention and carry-over, and exercise adherence and percentage of sessions completed. fMRI data were used in one study.

[4] References for all memory outcome measures are included in Appendix 1.5.

Validated and adapted neuropsychological tests/subtests were used in 11 studies (7 compensatory: Chen et al., 2012; Doornhein & De Haan, 1998; Gamito et al., 2012; Miller & Radford, 2014; Wilson, 1982; Withiel et al., 2019; 2020a; 5 restorative: Lin et al., 2014; Richter et al., 2018; Studer et al., 2021; Withiel et al., 2019; 2020b). Validated and adapted self-report measures were used in six studies (5 compensatory; Aben et al., 2014; Doornhein & De Haan, 1998; Miller & Radford, 2014; Withiel et al., 2019; 2020a; 2 restorative: Withiel et al., 2019; 2020b). The CAPM-Other was used in two (compensatory) studies (Miller & Radford, 2014; Withiel et al., 2019). Memory diaries (Fish et al., 2008), performance-related outcomes (e.g., task retention and carry-over; Mount et al., 2007), and intervention adherence (Lemoncello et al., 2011) were used as the sole memory outcome measures for three compensatory studies. These were completed by participants, clinicians, and/or carers, with some data automatically recorded by assistive technology software (e.g., TAP; Lemoncello et al., 2011). Recall accuracy across specific memory tasks (e.g., timetables, names, etc.) were recorded weekly across study phases by Wilson (1982). One study used fMRI (Lin et al., 2014).

Changes on memory measures

Efficacy of compensatory and restorative memory interventions are summarised in relation to each category of memory measures.

Validated and adapted neuropsychological tests

Compensatory interventions

Global Processing Training was associated with significant improvements in visual memory immediately post-training and at 24hrs follow-up relative to Rote Rehearsal training (*Cohen's d*=.51). Non-significant small effects for Immediate Recall (*Cohen's d*=.42 & .37) and moderate effects for Delayed Recall (*Cohen's d*=.55 & .61) were observed at 2- and 4-weeks follow-up respectively (Chen et al., 2012). Memory strategy training was associated

with significant improvements post-training on the Name-Face Memory Test (intervention group: *Cohen's d*=.76 for; controls: *Cohen's d*=.10s) but not on the Stylus Maze test or "control" memory tasks (Doornhein & De Haan, 1998). No significant between-groups differences were observed for the memory rehabilitation group relative to controls at 12-weeks post-baseline (Miller & Radford, 2014), although non-significant small to moderate effects were observed on RAVLT Total Learning and Delayed Recall, and RPA-ProMem (*Cohen's d*=.30-.54). Significant large effects were observed across all participants on the WMS (*Cohen's d*=1.83) and RCF (*Cohen's d*=1.52) following the VR memory intervention, but no significant between-groups differences regarding delivery method (desktop vs. head-mounted display; Gamito et al., 2012). Significant between-groups differences were observed on the RPA-ProMem for Memory group intervention (*Cohen's d*=.84) relative to *Lumosity*™ (*Cohen's d*=.35) at post-intervention (Withiel et al., 2019).

Withiel et al. (2020a; 2020b) calculated Reliable Change Indices (RCI), with *z-scores* ±1.96 and within normal range (*z-scores* ±1.5) considered clinically significant. One participant indicated significant RCI on WAIS-IV Symbol Span and RAVLT, and two participants indicated significant RCI on BVMT-R Delayed Recall from baseline to post-memory group intervention. Wilson (1982) reported that the participant repeated the same versions of the Benton Visual Retention Test and ROCF daily and the Rey-Davis pegboard three times per week for six weeks, but showed no improvements.

Restorative interventions

RehaCom Cognitive Training and computerised Recollection Training was associated with significant medium-large effects on the Everyday Memory Test (*Cohen's d*=.95) and Working Memory composite score (*Cohen's d*=.77; Richter et al., 2018). *Wizard* was associated with significant improvements in WMS Backwards Spatial Span (*Cohen's d*=.72), VLMT Total Learning (*Cohen's d*=.62), and non-significant improvements in Forward

Spatial Span (*Cohen's d*=.43) relative to controls (Studer et al., 2021). No significant between-groups differences were reported for *RehaCom* on neuropsychological tests (or fMRI) by Lin et al. (2014). Withiel et al. (2019) did not observe any significant between-groups differences for *Lumosity*™ relative to the Memory group or controls. Withiel et al. (2020b) reported that three participants indicated significant RCI on BVMT-R Delayed Recall, one participant indicated significant RCI on BVMT-R Total Learning, and one on RAVLT Delayed Recall post-*Lumosity*™ training.

Validated and adapted self- and other-report measures of memory function

Compensatory interventions

Group memory self-efficacy (MSE) training was associated with increased MSE on the Meta-memory in Adulthood questionnaire relative to controls, with effects maintained at 6- and 12-months follow-up (*Cohen's d*=.37; Aben et al., 2014). Miller and Radford (2014) did not observe significant between-group differences for CAPM-Self scores, but reported non-significant differences in CAPM-Other scores following group memory training (*Cohen's d*=.47). No significant between-groups differences were observed on the Memory Questionnaire by Doornhein and De Haan (1998). On the EMQ-R, one participant demonstrated significant improvements from baseline to Memory group intervention phases (*Tau-U*=-.89), and three participants demonstrated significant improvements from intervention to follow-up phases (*Tau-U*=-.86, -.91, -1.00). One participant demonstrated significant improvement On the CAPM-Self from intervention to follow-up phases (*Tau-U*=-.86; Withiel et al., 2020a).

On Goal Attainment Scaling, Withiel et al. (2019) reported that the Memory group showed significantly greater attainment of personal memory goals from baseline to post-intervention relative to controls, with gains maintained at follow-up and significantly greater relative to *Lumosity*™ and controls (Memory group: *Cohen's d*=1.54; *Lumosity*™: *Cohen's*

d=.90). Withiel et al. (2020a) reported that all participants reported improvements on at least one goal at post-intervention, with effects maintained for two and improved for two participants at follow-up.

Restorative interventions

Withiel et al. (2019) did not observe significant between-group differences for CAPM-Self scores. They reported significant differences in CAPM-Other scores, with *Lumosity*™ group indicating fewer observed memory failures at post-intervention (*Cohen's d*=.64), which was not maintained at follow-up. Withiel et al. (2020b) reported that one participant demonstrated a significant decline in EMQ-R scores from baseline to *Lumosity*™ phases (*Tau-U*=1.00), and another demonstrated significant improvement from *Lumosity*™ to follow-up phases (*Tau-U*=-.86). On the CAPM-Self, one participant demonstrated a significant decline (*Tau-U*=.89) and another a significant improvement (*Tau-U*=-.94) from baseline to *Lumosity*™ phases, and one participant demonstrated significant improvement (*Tau-U*=-.94) from *Lumosity*™ to follow-up phases (Withiel et al., 2020b). On the GAS, four participants reported improvement on at least one goal post-*Lumosity*™ training, which was maintained at follow-up for three and deteriorated for one.

Objective measures of memory function

Fish et al. (2008) observed significant between-groups differences in percentages of completed to-be-remembered tasks between Group A Neuropage intervention versus Group B baseline phases, and between Group A return-to-baseline versus Group B intervention phases. Mount et al. (2007) did not observe between-group differences in method of instruction (Trial-and-error vs. Errorless Learning) for retention on either task. Trial-and-error significantly improved the odds of carry-over for sock-donning (no differences observed for wheelchair). Lemoncello et al. (2011) observed significantly more completed

sessions and mean number of exercises completed per session during Television Assisted Prompted compared with typical practice for two participants (*Cohen's d*=1.49 & 1.59).

Wilson's (1982) study preceded recent standardised guidelines for visual and non-overlap data analyses, and raw data were not included. Wilson reported that (i) the participant was supported to learn timetables (but never reached 100% accuracy), which was maintained at 3-months follow-up; (ii) visual imagery helped him to gradually reach 100% accuracy for name recall, which was maintained at follow-up; (iii) he rapidly reached 100% accuracy for shopping list learning following first-letter mnemonic procedure, which was maintained throughout intervention and follow-up phases; and (iv) he was unable to learn routes regardless of intervention type.

Table 1.1.

Characteristics of included RCT studies

Author(s); Year; Country	**Participants; Setting; Dropout/Withdrawal; Stroke details (type, location, time since onset)**	**Design; Randomisation**	**Intervention details (type, duration, frequency)**	**Control condition**	**Memory outcome measure(s); Assessment time points**	**Results (between-groups comparisons); Effect size(s)**	**PEDro-P total score, Internal Validity (IV), Statistical Reporting (SR)**
Aben et al. (2014) The Netherlands	*Outpatient* 153 randomised (77 IG; 76 CG); 139 completed T3 (67 IG; 72 CG) *Mean time post-stroke*= 54 months (*SD*=37) Ischemic=105 Left-hemisphere=87	Double-blinded, multi-centred RCT Block randomisation via randomisation program	*Compensatory* Adapted Memory Self-efficacy group training program x2 weekly 1hr sessions across 9 weeks	Peer support group x2 weekly 1hr sessions across 9 weeks	MIA questionnaire: Change, Capacity & Anxiety subscales T0=Baseline T1=10days post-intervention T2=6 months T3=12 months	IG>CG T0-T3; *p*=.010; *Cohen's d*=.37	Total=9/10 IV=7 SR=2
Chen et al. (2012) USA	*Inpatient* 11 randomised (6 IG, 5 CG); 9 completed T4 (IG 5; 4 CG) First stroke ≤6months Lesions in right cerebral sub/cortical regions	Single-blinded randomised control study Randomisation via card draw by independent investigator Pts blinded to condition	*Compensatory* Global Processing Training using ROCF Single ~90mins session	Rote Repetition Training using ROCF Single ~90mins session	T0(Baseline): MTCF1 T1(During training): ROCF T2(24hrs post-training): MTCF2 T3(2 weeks post-training): MCGCF1 T4(4 weeks post-	T1: IPTR1-5 Accuracy: IG>CG, *p*=.024, IPTR5: Proportion improved IG>CG, *Cohen's d*=1.69 Recog: IG>CG, *p*=.041, *Cohen's d*=1.26 T2: IR: IG>CG; *p*=.017, *Cohen's d*=.50	Total=9/10 IV=7 SR=2

					training): MCGCF2	Retention: NS, *Cohen's d*=.51 T3: IR: NS, *Cohen's d*=.42 Retention: NS, *Cohen's d*=.55 T4: IR: NS, *Cohen's d*=.37 Retention: NS, *Cohen's d*=.61	
Doornhein & De Haan (1998) The Netherlands	*Inpatient* 12 randomised (6 IG; 6 CG) First-time, cerebral stroke	RCT Random group allocation (Method not reported)	*Compensatory* x2 weekly individual Memory Strategy Training sessions across 4 weeks	x2 weekly pseudo-treatment ("drill-and-practice") sessions across 4 weeks	N-FPAMT SMT RAVLT: 15 Words Test ORFT MQ T0= Baseline T1=Post-training	N-FPAMT: IG>CG; *p*<.05 IG: *Cohen's d*=.76 CG: *Cohen's d*=.10 SMT: NS IG: *Cohen's d*=.10 CG: *Cohen's d*=.04 RAVLT: NS IG: *Cohen's d*=.27 CG: *Cohen's d*=.08 ORFT: NS IG: *Cohen's d*=.11 CG: *Cohen's d*=.05 MQ: NS IG: *Cohen's d*=.40 CG: *Cohen's d*=.24	Total=6/10 IV=4 SR=2

Fish et al. (2008) UK	*Community* (primarily) Sub-group analysis from Wilson et al. (2001) 36 randomised (24 Group A; 12 Group B) Subarachnoid haemorrhage=18 Ischaemic=14 Intracerebral haemorrhage=2 Other=1	Randomised crossover study Waitlist crossover design	*Compensatory* Neuropage Group A: A:Baseline B:Neuropage A:Return-to-baseline	Group B: A:Baseline A:Baseline B:Neuropage	Memory diaries: % completed tasks T0=2weeks T1=7weeks T2=7weeks	T1: Group A>Group B, *p*=.003 T2: Group B>Group A, *p*=.01	Total=6/10 IV=4 SR=2
Gamito et al. (2012) Portugal	*Outpatient* 17 randomised (9 desktop VR; 8 Head-mounted display, HMD, VR) ≤6months post-stroke	Randomised control study Randomisation method not reported	*Compensatory* HMD delivery format Weekly sessions across 12 weeks	Desktop delivery format	WMS-III RCFT T0=Session 1 T1=Post-training	RCF: NS WMS-III: NS	Total=5/10 IV=3 SR=2
Lin et al. (2014) China	*Inpatient* 34 randomised (16 IG; 18 CG) *Mean time post-first stroke*= 228days Left-hemisphere=15; Right =19	RCT Randomisation via random number table	*Restorative* Computer-assisted training x6 1hr weekly sessions across 10 weeks	No intervention	WMS fMRI T0=Baseline T1=Post-training	WMS & fMRI: No between-groups comparisons reported	Total=5/10 IV=3 SR=2

Miller & Radford (2014) Australia	*Outpatient* 40 randomised (20 Group A; 20 Group B); 32 completed T1 (15 Group A; 17 Group B); 24 completed T2 (12 Group A; 12 Group B) *Mean time post-stroke*=76.6 months (*SD*=134.8) Group A; 38 months (*SD*=31.5) Group B Infarction=24 Haemorrhage=16 Left-hemisphere=23 Right-hemisphere=10 Bilateral=7	Randomised crossover study Pseudo-random allocation; Matched for age, sex, estimated IQ, memory performance Non-random assignment of final 16pts	*Compensatory* Memory rehabilitation group Group A: A:Baseline B:Group intervention A:Return-to-baseline Weekly 2hrs group sessions across 6 weeks	Group B: A:Baseline A:Baseline B:Group intervention	RAVLT CFT RPA-ProMem CAPM-Self & CAPM-Other T0=Baseline T1=12 weeks post-baseline T2=12 weeks post-T1	T1: RAVLT TL: NS, *Cohen's d*=.53 DR: NS, *Cohen's d*=.54 CFT: DR: NS, *Cohen's d*=.11 RPA-ProMem: NS, *Cohen's d*=.30 CAPM-Self: NS, *Cohen's d*=.04 CAPM-Other: NS, *Cohen's d*=.47	Total=3/10 IV=2 SR=1
Mount et al. (2007) USA	*Inpatient* 47 randomised (22 Group A; 25 Group B); 33 completed (16 Group A; 17 Group B) *Mean time post-stroke*= 21 days (*SD*=10) Right-hemisphere=21 Left-hemisphere=12	Randomised crossover study Randomisation method not reported	*Compensatory* Group A: Wheelchair Trial-&-error (TEL), Sock Errorless Learning (EL) Training≤7days	Group B: Wheelchair EL, Sock TEL Training≤7days	Retention: Correct task completion on 2 consecutive trials Incidence Rates (IR): No. of pts who succeeded in learning task expressed as proportion of number of pt-days Carry-over: To similar task (following retention achievement); Odds Ratio (OR)	Retention: NS Wheelchair: EL: IR=.462; TEL: IR=.207 Sock-donning: EL: IR=.259; TEL: IR=.333 Carry-over: TEL sig. >odds for sock task, *OR*=19.92, *p*=0.03 NS TEL vs. EL wheelchair, *OR*=.86, *p*=.89	Total=4/10 IV=2 SR=2

Richter et al. (2018) Germany	*Inpatient* 46 randomised (24 IG; 22 CG); 36 completed study (18 IG; 18 CG) 77.77% Stroke (IG & CG)	Double-blind RCT Traditional lottery procedure	*Restorative* x4-6 weekly 30mins sessions (18 sessions total) across 3 weeks Computer-based WM training + Recollection Training (RLT)	x3 weekly 1hr group sessions of standard memory therapy across 3 weeks	EMT CVLT RBMT RWT: Verbal fluency WMS: Digit-span TAP: 2-back WM task, Alertness task Composite scores calculated for WM, Verbal learning, & Word fluency T0=Baseline T1=Post-intervention	EMT: IG>CG; *p*=.005, *Cohen's d*=.95 WM: T1 scores IG>CG, *p*<.05; *Cohen's d*=.77 Verbal learning: NS, *Cohen's d*=.20 Word fluency: NS, *Cohen's d*=.25	Total=7/10 IV=5 SR=2
Studer et al. (2021) Germany	*Inpatient* 95 randomised (33 IG; 31 CG; 31 ST); 83 completed (25 IG; 30 CG; 28 ST) *Wizard* training, *n*=36; No *Wizard*, *n*=47 *Mean time post-stroke*=39.6days (*SE*=2.8) Ischaemic=68 Haemorrhagic=15	RCT Minimization-based randomization algorithm (accounting for memory scores, age, education)	*Restorative* Daily 30mins *Wizard* training + multi-disciplinary standard therapy across 2 weeks Choice to add 0-2 pre-commitment schemes	CG: Daily 30mins *Wizard* training + multi-disciplinary standard therapy across 2 weeks ST: Multi-disciplinary standard therapy across 2 weeks	WMS; Spatial Span Forward, Backward VLMT T0=Baseline T1=Post-intervention	*Wizard*>No *Wizard* WMS: Forward: NS, *Cohen's d*=.43 Backward: *p*=.002, *Cohen's d*=.72 VLMT: TL: *p*=.036, *Cohen's d*=.62 DR: NS, *Cohen's d*=.02 Recog: NS, *Cohen's d*=.16	Total=6/10 IV=4 SR=2

Withiel et al. (2019) Australia	*Community* 65 randomised (24 IG1; 22 IG2; 19 CG); 51 completed study (18 IG1; 16 IG2; 17 CG) *Mean time post-stroke*=41.77 months (*SD*=44.8) Ischaemic=45 Left-hemisphere=36 Bilateral=6	Single-blinded RCT Randomisation via online random sequence generator by independent researcher	*Compensatory* IG1: Manualised *Memory* skills group (3-8pts per group) 2hrs weekly sessions across 6 weeks	*Restorative* IG2: *Lumosity*™: 30mins per day, 5 days per week, across 6 weeks (30 sessions) + weekly telephone contact with researcher CG: *Waitlist control*	GAS RAVLT BVMT-R WMS-IV: Symbol Span WAIS-IV: Digit Span, backward RPA-ProMem EMQ-R CAPM-Self & -Other T0=Baseline T1=Post-intervention T2=6 weeks follow-up	GAS: T1: TG1>TG2 & CG, $p<.01$ TG2>CG, $p<.01$ T2: TG1>TG2 & CG, $p<.01$ TG1: *Cohen's d*=1.54 TG2: *Cohen's d*=.90 CG: *Cohen's d*=.39 RAVLT TL: NS TG1: *Cohen's d*=.10 TG2: *Cohen's d*=.35 CG: *Cohen's d*=.11 DR: TG1: *Cohen's d*=.04 TG2: *Cohen's d*=.02 CG: *Cohen's d*=.00 BVMT-R TL: NS TG1: *Cohen's d*=.65 TG2: *Cohen's d*=.34 CG: *Cohen's d*=.26 DR: TG1: *Cohen's d*=.54 TG2: *Cohen's d*=.50 CG: *Cohen's d*=.12 WMS-IV: NS TG1: *Cohen's d*=.47 TG2: *Cohen's d*=.10 CG: *Cohen's d*=.24 WAIS-IV:	Total=7/10 IV=5 SR=2

						T1: NS T2: IG1>IG2 & CG, $p \leq .05$ TG1: *Cohen's d*=.26 TG2: *Cohen's d*=.22 CG: *Cohen's d*=.11 RPA-ProMem: T1: IG1>IG2 &CG, $p < .01$ T2: NS TG1: *Cohen's d*=.84 TG2: *Cohen's d*=.35 CG: *Cohen's d*=.30 EMQ-R: T1: IG1>CG; $p < .05$ TG1: *Cohen's d*=.36 TG2: *Cohen's d*=.28 CG: *Cohen's d*=.22 CAPM-Self: NS TG1: *Cohen's d*=.26 TG2: *Cohen's d*=.22 CG: *Cohen's d*=.25 CAPM-Other: T1: IG2>CG; $p < .05$; TG1: *Cohen's d*=.18 TG2: *Cohen's d*=.64 CG[5]: *Cohen's d*=.13	

[5] Withiel et al. (2019) reported treatment effect size, defined as the magnitude of change from baseline within conditions, using *Cohen's d*

BVMT-R=Brief Visuospatial Memory Test-Revised; CAPM=Comprehensive Assessment of Prospective Memory; CFT=Complex Figure Tests; CG=Control group; CVLT=California Verbal Learning Test; DR=Delayed recall; EMQ-R=Everyday Memory Questionnaire-Revised; EMT=Everyday Memory Test; GAS=Goal Attainment Scaling; IG=Intervention group; IPTR=Immediate post-training recall; IR=Immediate recall; MCGC=Medical College of Georgia Complex; MIA=Metamemory-In-Adulthood Questionnaire; MQ=Memory Questionnaire; MTCF=Modified Taylor Complex Figure; N-FPAMT=Name–Face Paired Association Memory Test; NS=non-significant; ORFT=Oxford Recurring Faces Test; RAVLT=Rey Auditory Verbal Learning Test; RBMT=Rivermead Behavioural Memory Test; RCFT=Rey Complex Figure Test; Recog=Recognition; RPA-ProMem=Royal Prince Alfred Prospective Memory Test; RWT=Regensburger Wortflüssigkeits Test; SMT=Stylus Maze Test; TAP=Testbatterie für Aufmerksamkeit; TL=Total Learning; VLMT= Verbal Learning & Memory Test; WAIS=Weschler Adult Intelligence Scales; WMS=Weschler Memory Scales

Table 1.2.

Characteristics of included SCED studies

Author(s); Year; Country	**Participants; Setting; Dropout/Withdrawal; Stroke details (type, location of damage, time since onset)**	**Design; Randomisation**	**Intervention details (type, duration, frequency)**	**Memory outcome measure(s); Assessment time points**	**Results; Effect size(s)**	**RoBiNT Scale total score, Internal Validity (IV), External Validity (EV)**
Lemoncello et al. (2011) USA	*Community* *N*=3 *Time post-stroke*=1 month, 2 months, & 4yrs Left-hemisphere=2 Right hemisphere=1	Within-pt alternating treatment design TAP vs TYP order randomly assigned (<3 consecutive days)	*Compensatory* Television Assisted Prompting (TAP) Typical practice (TYP) delivery Daily, across 4 weeks	Adherence: Mean exercises completed per session; % completed sessions TAP log TYP log completed by carers (*n*=2)/pt interview (*n*=1)	Pt 1: TAP>TYP; *Cohen's d*=1.49 Pt 2: TAP>TYP; *Cohen's d*=1.59 Pt 3: TAP≠TYP; *Cohen's d*=0.13	Total=20/30 IV=8 EV=12

Wilson (1982) UK	*Inpatient* *N*=1 *Time post-stroke*=5 months Bilateral	Multiple baseline across 4 memory problems	*Compensatory* Individualised memory neurorehabilitation x4 per week, across 6 weeks	Problem tasks: % recalled (i) timetable, (ii) names, (iii) shopping list & (iv) routes Recall assessed x1 per day across 24+4 days A: (i) baseline + rehearsal only; (ii) 8 days; (iii) 12 days; (iv) 16 days B: (i) 24 days; (ii) 16 days; (iii) 12 days; (iv) 7 days A*: 3-months follow-up (4 days) ROCF (daily for 6 weeks) Benton Visual Retention Test (daily for 6 weeks) Rey-Davis peg board (x3 per week for 6 weeks) T0=Baseline T1=6 weeks post-baseline	Unable to calculate *Tau-U* No statistical analyses for neuropsychological tests	Total=13/30 IV=2 EV=11
Withiel et al. (2020a) Australia	*Community* *N*=4 *Time post-stroke*=4, 10, 13 & 41months Ischaemic=2 Haemorrhagic=1 Mixed=1	Single-case AB with follow-up (A*) No randomisation	*Compensatory* Manualised *Memory* group Weekly 2hrs sessions across 6 weeks	EMQ-R CAPM-Self Completed weekly during all phases A:3 weeks B:6 weeks A*:6 weeks	*Tau-U* EMQ-R: AB: .72, .44, -.89, -.088 BA*: -.86, -.91, -.61, -1 CAPM-Self: AB: .33, .17, -.61, -.36 BA*: -.86, -.64, -.50, -.70 GAS: AB: All pts improved ≥1	Total=18/30 IV=3 EV=15

	Left-hemisphere=3 Bilateral=1			GAS RAVLT BVMT-R WMS-IV: Symbol Span WAIS-IV: Digit Span, backward T0=Baseline T1=Post-intervention T2=6 weeks follow-up	goal; BA: Maintained or improved *Reliable Change Indices (RCI)* RAVLT: TL: T1: 1pt –1.2; other pts NS DR: NS BVMT-R: TL: T1: 1pt -.7; other pts NS DR: T1: 2pts .1 & .0 WMS-IV: T1: 1pt 1.0; other pts NS WAIS-IV: NS	
Withiel et al. (2020b) Australia	*Community* *N*=5 *Time post-stroke*= 8, 10, 26, 71, 78 months Ischaemic=2 Haemorrhagic=3 Left-hemisphere=4 Bilateral=1	Single-subject AB with follow up (A*) design No randomisation	*Restorative* *Lumosity*™: 7 games (Total: 30mins) per day, 5 days per week, across 6 weeks (30 sessions) + weekly telephone contact with researcher	EMQ-R CAPM-Self Completed weekly during all phases A:3 weeks B:6 weeks A*:6 weeks GAS RAVLT BVMT-R	*Tau-U* EMQ-R: AB: .33, 1.0, .27, -.48, -.50 BA*: -.06, -.11, -.86, -.57, -.44 CAPM-Self: AB: .67, .89, .22, -.67, -.94 BA*: .06, .22, -.94, .60, -.36 GAS: T1: 4 improved; 1 declined T2: 3 maintained T1 scores; 1 declined; 1 improved	Total=17/30 IV=4 EV=13

				WMS-IV: Symbol Span WAIS-IV: Digit Span, backward T0=Baseline T1=Post-intervention T2=6 weeks follow-up	*RCI* RAVLT: TL: NS DR: T1: 1pt -.50; all other pts NS BVMT-R: TL: T1: 1pt 1.51; all other pts NS DR: T1 3pts –1.69, -3.82, -1.29; other 2pts NS WMS-IV: NS WAIS-IV: NS	

BVMT-R=Brief Visuospatial Memory Test-Revised; CAPM=Comprehensive Assessment of Prospective Memory; DR=Delayed recall; EMQ-R=Everyday Memory Questionnaire-Revised; GAS=Goal Attainment Scaling; NS=non-significant; RAVLT=Rey Auditory Verbal Learning Test; RCI=Reliable Change Indices; ROCF= Rey-Osterreith Complex Figure; TAP=Television Assisted Prompting; TYP=Typical practice delivery conditions; TL=Total Learning; WAIS=Weschler Adult Intelligence Scales; WMS=Weschler Memory Scales

Table 1.3.

Summary of included RCTs and CCTs ranked according to methodological quality ratings.

PEDro-P Quality	**Authors; *N* (analyses)**	**Intervention type**	**Measure type**	**Measure(s); Time point(s)**	**Sig effects; time point(s)**	**Effect size(s)**
Excellent	Aben et al. (2014) *N*=139	Compensatory	Adapted self-report	**MIA** (T0, T1, T2, T3)	T1, T2, T3	Small
	Chen et al. (2012) *N*=11	Compensatory	Validated neuro tests	**MTCF1** (T1); **MTCF2** (T2); MCGC1 (T3), MCGC2(T4)	T1 & T2	Small-Medium
Good	Doornhein & De Haan (1998) *N*=12	Compensatory	Validated neuro tests	**Name–Face Test**, Stylus Maze Test, 15 Words Test; ORFT (T0, T1)	T1	Large
			Validated self-report	MQ (T0, T1)	None	
	Fish et al. (2008) *N*=36	Compensatory	Behavioural data	**Memory diary: % of completed PM tasks** (T0, T1, T2)	T1 & T2	Unable to calculate
	Richter et al. (2018) *N*=46	Restorative	Adapted neuro (sub)tests	**EMT**, CVLT, RBMT, RWT, WMS, TAP (T0, T1) *Note:* **WM composite score*** calculated using CVLT, WMS & TAP	T1 T1*	Large Large*
	Studer et al. (2021) *N*=83	Restorative	Validated neuro (sub)tests	**WMS** (forward, **backward**)**, VLMT** (**TL***, DR) (T0, T1)	T1 T1*	Medium Medium*
	Withiel et al. (2019)	Compensatory vs. Restorative	Validated neuro (sub)tests	RAVLT, BVMT-R, WMS, **WAIS-IV**, **RPA-ProMem*** (T0, T1, T2)	T2 T1*	Small Large*

	N=51		Validated self-report	**GAS, EMQ-R*,** CAPM (T0, T1, T2)	T1, T2 T1*	Large Small*
			Validated other-report	**CAPM** (T0, T1, T2)	T1	Medium
Fair	Lin et al. (2014) *N*=34	Restorative	Validated neuro test	WMS (T0, T1)	None	
	Gamito et al. (2012) *N*=17	Compensatory	Validated neuro test(s)	WMS, RCFT (T0, T1)	None	
	Mount et al. (2007) *N*=33	Compensatory	Behavioural data	Task retention; **Task carry-over**	TEL superior for 1 (of 2) tasks	Unable to calculate
Poor	Miller & Radford (2012) *N*=32	Compensatory	Validated neuro test(s)	RAVLT, RCFT, RPA-ProMem (T0, T1, T2)	None	
			Validated self-report	CAPM-Self (T0, T1, T2)	None	
			Validated other-report	CAPM-Other (T0, T1, T2)	None	

BVMT-R=Brief Visuospatial Memory Test-Revised; CAPM=Comprehensive Assessment of Prospective Memory; CVLT=California Verbal Learning Test; EMQ-R=Everyday Memory Questionnaire-Revised; EMT=Everyday Memory Test; GAS=Goal Attainment ScalingMCGC=Medical College of Georgia Complex; MIA=Metamemory-In-Adulthood Questionnaire; MQ=Memory Questionnaire; MTCF=Modified Taylor Complex Figure; N-FPAMT=Name–Face Paired Association Memory Test; ORFT=Oxford Recurring Faces Test; RAVLT=Rey Auditory Verbal Learning Test; RBMT=Rivermead Behavioural Memory Test; RCFT=Rey Complex Figure Test; Recog=Recognition; RPA-ProMem=Royal Prince Alfred Prospective Memory Test; RWT=Regensburger Wortflüssigkeits Test; SMT=Stylus Maze Test; TAP=Testbatterie für Aufmerksamkeit; TL=Total Learning; VLMT= Verbal Learning & Memory Test; WAIS=Weschler Adult Intelligence Scales; WMS=Weschler Memory Scales

DISCUSSION

The inter-related aims of this review were to (i) identify and characterise outcome measures used to assess the efficacy of neuropsychological rehabilitation interventions targeting post-stroke memory difficulties; (ii) categorise interventions as 'restorative', 'compensatory', or 'mixed'; (iii) identify which measures capture changes in memory function post-intervention; and (iv) assess the methodological quality of these studies. Fifteen papers, including 11 RCTs and four SCED studies, met inclusion criteria. Of these, 11 studies (8 RCTs, 3 SCED) involved compensatory interventions and five studies (4 RCTs, 1 SCED) involved restorative interventions. There was a lack of consistency in how memory function outcomes were measured across included studies, limiting conclusions that can be drawn regarding which measures are most sensitive to change following intervention.

Methodological considerations

For RCTs, studies rated 'excellent' and 'good' regarding methodological quality included four compensatory (Aben et al., 2014; Chen et al., 2012; Doornhein & De Haan, 1998; Fish et al., 2008), two restorative (Richter et al., 2018; Studer et al., 2021), and one comparing compensatory and restorative interventions (Withiel et al., 2019). Studies rated 'fair' (Gamito et al., 2012; Lin et al., 2014; Mount et al., 2007), and 'poor' (Miller & Radford, 2014) were generally less internally valid, with no stated concealed allocation, or blinding of participants or assessors. These studies were therefore at greater risk of bias, impacting the reliability of results. SCED studies also varied in methodological quality, with all studies scoring higher on external than internal validity items. Lemoncello et al.'s (2011) study involved an alternating treatment design, and scored highest for internal validity and overall on the RoBiNT. Withiel et al. (2020a; 2020b) and Wilson (1982) scored relatively high for external validity but low for internal validity.

Sample sizes varied across studies, with some involving small numbers of participants within each condition, including RCTs rated as "excellent" (e.g., Chen et al., 2012; *N*=11) and "good" (e.g., "Doornhein & De Haan, 1998; *N*=12), limiting the generalisability of these findings. Richer et al. (2018) reported effects on an adapted and non-validated neuropsychological test (EMT) and WM composite scores, which were calculated from a number of measures. This affects the validity and reliability of these measures, scores, and conclusions that can be drawn regarding the efficacy of their intervention. Withiel et al. (2019) used a large range of outcome measures in their study. Although a power calculation was used to determine sample size and Bonferroni correction was used in analyses, the sample was relatively small (*N*=51) given the volume of measures used, increasing the risk of Type 1 error. The PEDro-P does not evaluate these factors; these have important implications regarding the inferences that can be made about study findings.

Measurement considerations

Results varied both within and across included studies regarding the treatment effects observed on the various included outcome measures. Studies that involved diverse measures indicated treatment effects on some measures but not others (e.g., Doornheim & De Haan, 1998; Richter et al., 2018; Withiel et al., 2019). Some studies did not evidence any effects (e.g., Miller & Radford, 2012). There are several reasons why changes might not be observed on a particular measure. First, the measure may not be sensitive (or responsive) to detect changes in the relevant memory-related outcome when this did in fact occur following intervention. Second and conversely, the measure does target the relevant aspect of memory but no real change has occurred in that aspect of memory (i.e., the intervention was not effective). In this instance, the absence of a treatment effect is appropriate, and therefore not a failure of sensitivity of the measure. Finally, the measure targets an aspect of memory that was not intended to be affected by the intervention. For instance, Doornheim and De Haan

(1998) included ‘target’ and ‘control’ neuropsychological assessments of memory functioning, with the latter considered to assess memory skills that were not specifically practised within the intervention. They stated that these provided a measure of generalisation of their memory training intervention. The observed lack of effects on these measures might be considered appropriate and expected.

In their review of outcome measures used in ABI neuropsychological rehabilitation research, Van Heugten (2020) highlighted the different factors that might influence selection of outcome measures, such as selecting currently or commonly used measures, and considering quality regarding their psychometric properties. However, they argued that “the instrument should at least have adequate responsiveness, the ability of the instrument to detect clinically relevant changes over time” (p.1616). We did not conduct quality appraisal regarding the psychometric properties (e.g., reliability, validity, responsiveness) of the measures that were used in the included studies, which could be considered a limitation of this review. However, the focus of our review extended beyond this, to identifying which of these measures showed treatment effects following intervention. Hence, we considered risk of bias to inform interpretation of study results regarding treatment effects, and the conclusions that could be drawn regarding overall findings.

Intervention type and measurement considerations

The use of and rationale for including validated and non-validated neuropsychological tests varied within and across studies. These measures were included in all five restorative intervention studies, and were primary outcomes in three (Lin et al., 2014; Richter et al., 2018; Studer et al., 2021). Seven of 11 compensatory intervention studies included neuropsychological tests, and these were primary outcomes in four (Chen et al., 2012; Doornhein & De Haan, 1998; Gamito et al., 2012; Miller & Radford, 2014). In their recent

review of outcome measures used in neurorehabilitation research in adults with acquired brain injury (ABI), van Heugten and colleagues (2020) observed that neuropsychological tests were most commonly used for measuring outcomes, with a large range of tests observed across studies.

While neuropsychological tests typically demonstrate excellent psychometric properties, their utility and appropriateness as outcome measures for intervention trials remains unclear, and there is debate regarding whether or not these tests should ever be used as outcome measures (Wilson, 2003). Traditionally, the primary purpose of neuropsychological assessment has been to (i) detect neurological dysfunction and guide differential diagnosis, (2) characterise changes in cognitive strengths and difficulties over time, and (3) guide treatment recommendations (Casaletto & Heaton, 2017; Schaefer et al., 2023). More research is needed to examine their use as outcome measures in intervention research, particularly where this involves repeated testing. Time intervals between testing in included studies were generally brief, ranging from as little as 24hrs (Chen et al., 2012) to 12 weeks (e.g., Miller & Radford, 2014), with an average of approximately six weeks across studies, increasing the risk of practice effects. Some studies reported using alternate test versions (Chen et al., 2012; Miller & Radford, 2014; Richter et al., 0218; Withiel et al., 2019; 2020a; 2020b), whereas others did not (Gamito et al., 2012; Lin et al., 2014; Studer et al., 2021). Previous research has shown that performance may be enhanced on retest even when the test items are different (e.g., on alternate versions), as participants can benefit from knowing *how to* approach the task more effectively (e.g., acquiring a test-taking strategy) and with increased familiarity with testing procedures (see Heilbronner et al. 2010).

Previous reviews (Cicerone et al., 2019; das Nair et al., 2016) and neurorehabilitation guidelines (National Institute for Health and Care Excellence, 2021) have highlighted the evidence-base supporting the use of compensatory strategies to manage cognitive difficulties

post-stroke, including learning strategies (e.g., mnemonics), external aids (e.g., alarms, diaries), and environmental strategies (e.g., routines, prompts). There has been no substantial evidence to date that post-stroke memory impairment can be improved through restorative interventions, although this is primarily due to "absence of evidence rather than evidence of absence of an effect" (Evans, 2006, p.520). Given the heterogeneity in measures and interventions across included studies, it is not appropriate to directly compare neuropsychological test outcomes between compensatory and restorative interventions. It is interesting that these tests were used in some compensatory studies, including as primary outcomes, as compensatory strategies involve teaching people to adapt to or circumvent their cognitive impairment where restoration is not possible. As performance on neuropsychological tests are considered to reflect cognitive function, improved scores could be interpreted as evidence of 'restoration'. Of note, where effects were observed on neuropsychological tests for both intervention types, these tests were typically close in form to training tasks. For instance, Studer et al. (2021) predicted and subsequently observed significant medium effects on the WMS Spatial Span Test as their intervention primarily targeted visuospatial WM. Chen et al. (2012) used complex figure tests to train global processing and observed significant large effects on these tests post-intervention and 24hrs later, but not at subsequent follow-up. Studer did not include further follow-up so it is unclear if these effects were maintained. In their meta-analysis of studies that examined transfer effects following WM training, Melby-Lervåg et al. (2016) observed 'near transfer' to untrained but similar tasks, but not 'far transfer' to different cognitive tasks. Taken together, the findings from the current review and Melby-Lervåg et al.'s review suggest that some memory interventions may produce short-term, specific training effects but question remain as to whether these generalise to measures of "real-world" cognitive skills.

Applications to everyday memory function

The aims of neuropsychological rehabilitation extend beyond reducing cognitive deficits, but rather to supporting people to manage, circumvent, or adjust to their difficulties, and promote independence, participation, and quality of life (Wilson et al., 2009). A common complaint regarding neuropsychological evaluations is their apparent lack of relevance to real-life problems that patients may experience (Casaletto & Heaton, 2017). Several included studies did not include measures of generalisation to everyday memory function or related activities. Recently, an international standard set of Patient Centred Outcome Measures was proposed to help define a set of global standards for measuring outcomes that matter most to stroke patients (Salinas et al., 2016). These include cognitive and physical functioning (e.g., feeding, self-care), as well as social participation, return to usual activities, and health-related quality of life. Validated and adapted self- and other-report measures of everyday memory function were used in six (five compensatory), with self-reported memory self-efficacy (MSE), everyday memory function (e.g., EMQ-R), and goal attainment as primary outcomes in five (Aben et al., 2014; Miller & Radford, 2014; Withiel et al., 2019; 2020a; 2020b). Behavioural data regarding tasks relevant to other rehabilitation goals (Lemoncello et al., 2011; Mount et al., 2007) and personally meaningful prospective memory tasks (Fish et al., 2008) were the sole outcome measures for three studies. These measures could be considered to have greater ecological validity and relevance to patients' rehabilitation goals.

Self-report and behavioural measures demonstrated sensitivity to interventions within some studies. Regarding self-report measures, Aben et al. reported small improvements in MSE at 6 and 12-months follow-up following MSE training. Withiel et al. (2020a) observed that four participants showed large reductions in self-reported everyday memory failures from post-Memory group to 6-weeks follow-up, and one participant from baseline to post-intervention. Only one participant showed significant reductions in everyday memory failure

following *Lumosity*™ in Withiel et al. (2020b). Participants in Withiel et al.'s (2019; 2020a) studies received the same Memory group intervention; 83% of participants in the former and all four in the latter achieved at least one memory-related goal post-intervention, with effects maintained at 6-weeks follow-up. Regarding behavioural data, Lemoncello et al. reported significant and large effects for session completion for two (out of 3) participants following Television Assisted Prompting, suggesting that this approach improved adherence to swallowing exercises. Fish et al. reported that Neuropage was associated with significant improvements in everyday memory function compared with an equivalent but as yet untreated group.

Limitations

Participants included in the SCED studies by Withiel et al. (2020a; 2020b) also participated in their RCT comparing the Memory group and *Lumosity*™ interventions with a control group (2019). This was not reported within these papers but was confirmed via correspondence with the study authors. This potentially introduces a risk of bias regarding participant selection and inclusion. For example, participants who were most responsive to the interventions included in the RCT might have been selected for inclusion within the SCED studies.

Conclusions

Outcome measurement is the cornerstone of evidence-based health care, including neuropsychological rehabilitation (van Heugten et al., 2020). Standardised outcome measures are needed to improve research quality and facilitate comparison and meta-analyses across studies (das Nair et al., 2016; van Heugten et al., 2017). Based on the goals and assumptions underpinning restorative interventions, neuropsychological tests may be appropriate for assessing outcomes in these studies. However, it will be important to ensure that training tasks and outcome measures are not close in form, to help reduce potential practice effects.

Similarly, for memory strategy training interventions, memory tests that resemble training strategies will likely offer little value on their own and may be unsuitable primary outcome measures. Where memory interventions are based on enhanced learning strategies (e.g., errorless learning), outcome measures should relate to the specific to-be-learned material. As per Mount et al. (2007), carryover to similar tasks may be appropriate; however, generalisation is not typically expected within these interventions. As compensatory strategies typically focus on supporting everyday memory functioning, then neuropsychological tests could be considered immaterial. Self- and other-reported and/or behavioural measures of everyday memory functioning and related outcomes (e.g., goal attainment) may be more appropriate to assess the efficacy of these interventions. Ideally, generalisation measures, including those that measure impact of everyday memory functioning, should be included in restorative studies also. However, this may depend on various factors, including statistical power regarding sample sizes required to detect change. While outcome measures may therefore understandably vary depending on intervention type and components, it will be important to ensure consistent outcome measures across similar interventions where feasible to allow for comparison across studies. Furthermore, where possible, outcome measures should reflect the priorities of stroke survivors, their family and carers, and clinicians providing these interventions.

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CHAPTER 2: Major Research Project

Title: Investigating the efficacy of ApplTree, a smartphone reminding application, in improving prospective memory performance in individuals who have experienced a stroke using Single Case Experimental Design (SCED).

Declaration of Conflicts of Interest: None

Prepared in accordance with submission requirements for *Neuropsychological Rehabilitation* (https://www.tandfonline.com/journals/pnrh20) and SCRIBE Checklist (Appendix 2.15).

PLAIN LANGUAGE SUMMARY

Title: Investigating the efficacy of ApplTree, a smartphone reminding app, in improving prospective memory performance in individuals who have experienced a stroke.

Background: After a stroke, people can experience memory problems, including finding it hard to remember to do things in the future (called 'prospective memory'). Research has shown smartphone apps, like Google calendar, can help with these difficulties. ApplTree is an app that was designed for people with memory problems. Wilson (2021) investigated whether ApplTree was helpful for people who had a stroke and memory problems. Results showed that ApplTree did not make a significant difference compared to their usual paper calendars. However, there were some problems with this study method.

Aims and Questions: This study repeated, or 'replicated', Wilson's study but improved the measure used to record completion of memory tasks. This study investigated: 1. whether ApplTree helps people complete memory tasks, on time, and without prompting from others; 2. whether participants find ApplTree helpful and easy-to-use; 3. Whether ApplTree helps to reduce effort and worry associated with completing to-be-remembered tasks for participants and their nominated person (i.e., their partners).

Methods: Three people who experienced a stroke and self- or other-reported prospective memory difficulties took part in this study. Each week, participants identified everyday personally-meaningful to-be-remembered tasks. Throughout the study, participants' nominated person recorded these tasks on a Memory Log, and tracked whether these were completed or not, if they were completed on time, and if the participant required prompting.

Participants used their current memory aids for either 5-, 6- or 7-weeks 'baseline' phase (without ApplTree). They then received ApplTree training, and used ApplTree to set task reminders over a 5-week intervention phase. At the end of the study, participants completed a questionnaire and interview about their experiences of ApplTree.

Main Findings and Conclusions: Throughout the baseline and intervention phases, all participants showed a high level of task completion. Variation in prospective memory performance was typically due to 'lateness' and 'prompting'. Two participants showed non-significant small improvements in prospective memory performance following ApplTree, with one demonstrating significant and large reductions in self-reported effort and worry. Their nominated person showed non-significant small reductions in effort and worry also. One participant intended to continue using ApplTree after study completion. A third participant experienced issues with ApplTree, with the app not working as intended.

All participants reported using existing electronic memory aids throughout the study (e.g., Apple calendar). We anticipated that ApplTree might better meet participants' needs due to its specific design features, including its accessible user interface. All participants reported finding ApplTree accessible, and identified useful features to support reminder setting. This study highlights the importance of considering the measures used to record memory performance, and exploring other potential effects of memory interventions, including their impact on effort and worry associated with memory performance for participants and their partners. Study limitations and implications for future research investigating assistive technology to support memory impairment are discussed.

Reference: Wilson, J. (2021). ApplTree: A single case experimental design study of a smartphone reminding application with community-dwelling adults who have sustained a stroke. *Unpublished DClinPsy thesis.*

ABSTRACT

Prospective Memory (PM) impairment is common post-stroke, and a priority for rehabilitation research. External memory aids, including smartphone applications, can compensate for PM difficulties. ApplTree is a reminder application designed to support PM in people with cognitive difficulties. This study investigated the acceptability and efficacy of ApplTree on PM performance in a stroke population using a multiple baseline across participants single-case experimental design (SCED). Three community-dwelling stroke participants with PM difficulties were randomised to a 5-, 6- or 7-week baseline, followed by ApplTree training, and a 5-week intervention phase. Each week, participants identified personally-meaningful everyday PM tasks. Their nominated person recorded weekly PM performance across study phases. We also recorded participants' and nominated persons' weekly ratings of effort and worry regarding participants' PM. Weekly PM performance and effort and worry ratings across both study phases were graphed for all participants. Visual analysis and Tau-U analysis were conducted to examine data non-overlap between study phases and to provide an overall effect size. Results indicated non-significant small-medium improvements in PM performance for two participants during the ApplTree phase, with one demonstrating significant and large reductions in self-reported effort and worry. End-of-study questionnaires and interviews, used to examine the acceptability of ApplTree, indicated that participants found ApplTree accessible, and identified useful features to support reminder setting. Study limitations and implications for future research are discussed.

Keywords: Stroke, memory, prospective memory, assistive technology, external memory aid

INTRODUCTION

Cognitive dysfunction, including memory impairment, is common after stroke (e.g., Sun et al., 2014). Prevalence of post-stroke memory dysfunction varies between 13-50% 3-months post-stroke, and 11-31% 1-year post-stroke (Snaphaan & de Leeuw, 2007). Memory impairment can significantly impact survivors' daily functioning, independence, and quality of life (Hogan et al., 2016; Nys et al., 2005). The Stroke Association (2021) recently highlighted cognitive difficulties, including memory problems, as a top priority for stroke rehabilitation research.

Prospective memory

Stroke can impact various memory subtypes, including prospective memory (PM), defined as the ability to remember to do something in the future. PM has retrospective and prospective components and involves planning, initiating tasks, self-monitoring, and inhibiting distraction (Shum et al., 2002). PM tasks can be *time-based*, requiring an action to be completed at a particular time (e.g., attending appointments); *event-based*, requiring an action to be completed when a specific target event occurs in the person's environment (e.g., buying milk on the way home); and *activity-based*, requiring an action to be completed during or after an activity (e.g., turning off the oven after cooking). Time-based PM appears to be particularly impaired post-stroke (Hogan et al., 2020; Kant et al., 2014). Time-based may be more complex than other PM tasks as this requires active monitoring of the environment and self-initiated retrieval.

Post-stroke neurorehabilitation

Post-stroke neurorehabilitation uses restorative and/or compensatory strategies to treat impairments and maximise participation. The National Institute for Clinical Excellence (NICE, 2021) recommend that interventions for memory function include increasing awareness of memory deficits, using errorless learning, and utilising internal strategies (e.g.,

mnemonics), environmental strategies (e.g., routines), and external memory aids (e.g., calendars, alarms). External memory aids can compensate for memory difficulties and are recommended as a 'practice standard' for improving PM impairment following stroke (Cicerone et al., 2019). Non-technological memory aids (e.g., diaries, calendars) are ubiquitous in everyday life and can be useful for individuals with memory impairments. However, these require the person to remember to check the aid to remind them of PM tasks (i.e., "remember to remember") and so provide 'passive' reminders. Technological memory aids (e.g., smartphone applications, or 'apps'), on the other hand, provide 'active' reminders and typically include a cueing device that attracts the person's attention, thereby reducing the need for them to engage in self-initiated checking of PM tasks. In their systematic review, Ownsworth et al. (2023) found that electronic Assistive Technology (AT) supported memory function after Traumatic Brain Injury (TBI), with most empirical support for the efficacy of AT for facilitating retrieval and execution of pre-determined reminders. In a meta-analysis, Jamieson et al. (2014) found that AT memory aids (including smartphone applications) improved performance on everyday tasks requiring memory for most participants with acquired brain injury or a neurodegenerative disease in these studies. Indeed, smartphone reminding software has been shown to be effective in helping people to compensate for PM difficulties (Svoboda et al., 2012). Most of the research to date has examined their efficacy in TBI and mixed ABI aetiology populations.

ApplTree

ApplTree is a smartphone reminder app which allows users to enter details of future tasks and events and then prompts them to remind them to complete these at a pre-specified time. ApplTree was designed based on feedback from people who experience memory and attention difficulties and has a customisable user interface design to support attention and working memory when entering PM tasks (Jamieson et al., 2020). Wilson (2021) investigated

the efficacy of ApplTree in three community-dwelling stroke participants who reported PM difficulties using a multiple-baseline, across participants, single case experimental design (SCED). Participants were randomised to a 5-, 6- or 7-week baseline, followed by ApplTree training and a 5-week intervention phase. Participants or a nominated person recorded whether participants completed weekly personally-meaningful PM tasks using a Memory Log across both phases. Results indicated that ApplTree did not lead to statistically significant increases in PM task completion. However, baseline PM task completion was high for all participants, and at ceiling for one, making it difficult to statistically determine any positive effect of ApplTree.

All participants reported using paper calendars prior to and during baseline. Wilson suggested that this passive memory aid may have sufficiently supported PM task performance, with an active electronic reminder app offering little added benefit. However, Wilson raised important methodological considerations that may have made it difficult to evaluate any positive effects of ApplTree: 1. The Memory Log may have inadvertently acted as an additional memory aid; 2. Introducing daily PM tasks may have acted as a cue to complete PM tasks, hence reported baseline performance may not have been a true reflection of typical PM performance; and 3. The potential novelty of participating in a study may have impacted performance. There may also have been issues in relation to the main outcome variable; within the Memory Log, PM task completion was recorded as Yes/No, which may not have been nuanced enough to avoid the observed ceiling effects.

ApplTree involves scheduling reminders to complete tasks at a pre-specified time, which should help reduce lateness of task completion, and users can select the sensory modality of the reminder alert, which should negate the need for prompting by another person. It may be that participants demonstrated similar levels of PM task completion using paper calendars and ApplTree, but may have shown reduced lateness and/or required less

prompting with ApplTree. However, it would not have been possible to capture these subtle but important differences between the memory aids using this response format. Also, Memory Log completion was via self-report by participants and nominated persons. As these participants experienced memory difficulties, this may have impacted the accuracy of the data. Another possibility is that using ApplTree enabled participants to complete their PM tasks to the same level as their typical passive memory aids but with less subjective effort and/or worry (e.g., about potentially forgetting PM tasks). This was not investigated in Wilson's study. Research has shown that post-stroke memory difficulties can have both a practical and emotional impact on survivors and their families, which can result in significant burden for all (e.g., Tang et al., 2020).

The current study

The aim of this study examine was to the efficacy of ApplTree on PM performance in individuals who have had a stroke and experience PM difficulties. This study replicated Wilson's (2021) study whilst addressing the aforementioned methodological issues. First, the Memory Log was adapted to include a more nuanced recording system; in addition to recording task completion (Yes/No), it recorded whether tasks were completed "On Time", "Early", or "Late", and whether the participant was "Prompted" to complete tasks by another individual. Second, the Memory Log was stored separately from the participant and completed by the nominated person alone. Third, we recorded participants' and nominated persons' subjective ratings of effort and worry regarding PM task completion across study phases. Finally, we invited participants and nominated persons to provide feedback about their experience of using ApplTree.

Hypotheses

We hypothesised that overall PM Performance would improve and, specifically, PM task completion would increase and "late" and "prompted" task completion would decrease

from baseline to intervention phase. We hypothesised that ApplTree would be acceptable to participants and nominated persons. We also hypothesised that ratings of worry and effort related to participants' PM would decrease from baseline to intervention phases for participants and nominated persons. Reporting follows the Single-Case Reporting Guideline in Behavioural Interventions (SCRIBE) 2016 Checklist (Tate et al. 2016) (Appendix 2.14).

MATERIALS AND METHODS

Design

A multiple-baseline across participants, SCED was used. SCED can be used to test the efficacy of an intervention using a small number of participants, who serve as their own controls. Within SCED studies, the individual behaviour is repeatedly measured during multiple discrete study phases. SCED is considered Level 1 evidence for treatment decision purposes by the Oxford Centre for Evidence-Based Medicine (Howick et al., 2011).

Randomisation

Participants were randomly assigned to either a 5-, 6-, or 7-week baseline using an electronic randomiser programme (http://www.randomizer.org), followed by a 5-week intervention phase. The multiple-baseline design was used to eliminate the need to return to baseline (i.e., withdrawal design), as removing an intervention may be distressing for some participants. It also controls for potential confounding variables related to time (e.g., spontaneous recovery), increasing the internal validity of the study. The Risk of Bias in N of 1 Trials (RoBiN-T) scale (Tate et al., 2013) was used to inform the design of this study and enhance its internal and external validity.

Blinding

Blinding of participants, nominated persons (who recorded weekly PM task performance on the Memory Log), and assessor/researcher was not possible in this study.

Participants

Participants were identified and recruited via the NHS Greater Glasgow & Clyde Stroke Service. Study inclusion/exclusion criteria are listed below.

Inclusion criteria

- Community-dwelling adults aged ≥18 years who have had a medically-confirmed stroke ≥3 months prior to recruitment
- Self- or other-reported PM difficulties
- Capacity to provide informed consent
- Participants must share accommodation with their nominated person
- Participants must own and be competent in use of a smartphone with a reliable internet connection. Nominated persons must also own and be competent in the use of a smartphone and this phone must be separate to that owned by the participants.

Exclusion criteria

- Index stroke <3 months prior to recruitment
- Individuals who do not have capacity to provide informed consent
- Non-fluent English speakers
- Aged <18yrs
- Aphasia that is of a level of severity where it would impact on participants' ability to interact with ApplTree and/or complete study measures
- Diagnosed pre-existing neurological condition, dementia or acquired brain injury
- Psychiatric symptoms (e.g., depression) of sufficient severity to prevent study engagement
- Cognitive impairment of sufficient severity that it would prevent the participant from using ApplTree

- Physical, visual or auditory impairment which, if uncorrected, would prevent the participant from using a smartphone
- Currently participating in other research
- Currently receiving a neuropsychological rehabilitation intervention specifically targeting PM performance

Recruitment

NHS GG&C Stroke Service identified and approached potential participants who met criteria. They provided individuals with Participant and Nominated Person Information Sheets (Appendices 2.3. & 2.4.), and obtained assent for the researcher to contact them. Over the recruitment period, eight people who met criteria were referred. Of these, four consented to participate (see Appendices 2.5. & 2.6. for Consent Forms). These were all men: AB, CD, EF, and GH. However, GH withdrew from the study before any baseline data were collected, therefore planned replication was not possible. Participant characteristics are reported in Table 2.1.

All participants completed baseline phases. AB and CD completed all 5-weeks of the intervention phase. EF experienced difficulties with ApplTree during the intervention (e.g., alarm not sounding at pre-specified times, alarm sounding at unscheduled times). An updated version of ApplTree was provided at the end of Week 9, but the issues persisted. EF ended participation at Week 10. All data up to and including Week 10 were included in the analysis and EF and their nominated person completed the end-of-study interview.

Table 2.1.

Participant characteristics and cognitive profiles. Percentiles and ranges reported for neuropsychological assessments and PRMQ. All test scores are reported as percentile rank.

	AB	**CD**	**EF**
Age in years (gender)	54 (male)	62 (male)	57 (male)
Stroke aetiology	Left cerebellar infarct	Left-hemispheric intracerebral haemorrhage	Left basal ganglia haemorrhage Left lateral medulla & right cerebellar infarct Left occipital infarct
Time since most recent stroke	24 months	58 months	22 months
Years of formal education	19 years	10 years	22 years
Current memory aid(s)	Reliance on partner Apple calendar via smartphone	Apple calendar via smartphone	Reliance on partner Electronic calendar shared with partner (accessed via laptop) Smartwatch
CESD Total	19/60 (Moderate)	16/60 (Moderate)	15/60 (None-Mild)
PRMQ Total	21 (Low average)	66 (Average)	0.13 (Exceptionally low)
Prospective	1.39 (Borderline)	50 (Average)	0.13 (Exceptionally low)
Retrospective	69 (Average)	69 (Average)	1.39 (Low)
TOPF Predicted WAIS-IV Full-scale IQ percentile rank	80 (High average)	45 (Average)	89 (High average)
RBMT Total	95 (Superior)	19 (Low average)	0.3 (Exceptionally low)
PM subtest	63 (Average)	37 (Average)	25 (Low average)
D-KEFS Trails A	84 (High average)	25 (Low average)	0.13 (Exceptionally low)
Trails B	84 (High average)	5 (Borderline)	0.13 (Exceptionally low)
Letter fluency	84 (High average)	2 (Borderline)	50 (Average)
Category fluency	75 (Average)	25 (Low average)	9 (Borderline)
Switching	90 (High average)	5 (Borderline)	37 (Average)
BADS 6-elements	4/4	4/4	4/4

*EF's hemianopia likely impacted his performance on some tests. He was unable to complete the TOPF and so estimated pre-morbid IQ was calculated via regression equation (Crawford et al., 2001): Predicted FSIQ = 87.14 – (5.21 X social class) + (1.78 X years of education) + (0.18 X age).

Description of participants

AB was a 54 year old man who experienced a left cerebellar infarct. He self-reported PM difficulties, including rapid forgetting of to-be-completed tasks (e.g., intentions to tell someone something, recent decisions to do something, leaving items behind). He also reported forgetting appointments and tasks when these are not prompted by others (e.g., his wife) or a reminder (e.g., Apple calendar on his smartphone). He reported that this was a significant source of anxiety and impacted his daily and occupational functioning. Interestingly, his self-reported PM performance on the Prospective and Retrospective Memory Questionnaire (PRMQ) indicated greater impairment on this domain of memory function relative to his performance on the PM sub-test on the Rivermead Behavioural Memory Test (RBMT-3).

CD was a 62 year old man who experienced a left-hemisphere intracerebral haemorrhage. He reported some rapid forgetting of tasks, failure to do intended tasks, and forgetting appointments if not prompted by a reminder. He typically recorded reminders using Apple calendar on his smartphone to help him remember upcoming tasks and appointments, including established routine tasks. He was keen to avail of ApplTree to support his working memory difficulties. Indeed, his performance on the Delis-Kaplan Executive Function System (D-KEFS) indicated impairment in attention, processing speed, and executive functioning. He required pacing and "chunking" of information and additional time to process information. It was anticipated that the "narrow-deep" (whereby users enter one piece of information across multiple 'pages' to complete reminder entries) ApplTree interface might better meet his needs relative to Apple calendar.

EF was a 59 year old man who experienced three successive cardiovascular accidents, including left basal ganglia haemorrhage, left lateral medulla and right cerebellar infarct, and occipital lobe infarct. His neuropsychological assessment indicated significant impairment

across multiple domains, including overall memory functioning, PM, processing speed, and attention, and he self-reported significant impairments regarding prospective and retrospective memory function on the PRMQ. He also experienced hemianopia, which caused visual difficulties including reading; although, he found it easier to read on electronic devices (phone, laptop). His wife reported regular prompting and checking to ensure he completed PM tasks. EF also shared an electronic calendar with his wife (although he reported finding this overwhelming) and used a Smartwatch reminder tool. The Smartwatch did not provide details of the to-be-remembered task when the alarm sounded; EF typically inferred this based on environmental and contextual factors (e.g., time of day, day of the week). He was generally able to complete established, routine PM tasks (e.g., daily medication) but struggled to remember novel PM tasks (e.g., one-off events) and when there were changes to his routine (e.g., taking new medication on alternate days).

Ethics

Ethical approval for this study was granted by the South East Scotland Research Ethics Committee 01 (REC reference: 23/SS/0005; Appendix 2.1). Management approval was granted by the NHS Greater Glasgow and Clyde (GG&C) Health Board (Appendix 2.2). This study was also registered on ClinicalTrials.gov (Protocol ID: GN22ST389).

Measures

Memory Log (Jamieson et al., 2023). Participants recorded their weekly personally-meaningful PM tasks in the Memory Log. Their nominated person then recorded whether the participant completed each task (Yes/No), whether this was completed "early", "on time" or "late", and if the participant was prompted to complete the task (Appendix 2.7.).

Text message reminders. Participants were asked to send an SMS text message to the researcher three times per week throughout both study phases. Days and times varied randomly (across 7 days, 9am-5pm) to prevent possible practice effects. This served as an

additional ‘objective’ measure of PM performance. Successful completion of sending text messages was recorded by the researcher.

Subjective effort and worry regarding PM task completion. Participants and nominated persons were asked to rate their subjective effort and worry regarding participants’ PM tasks for the previous week. These were rated on 5-point likert scales ranging from 1=No effort/Never to 5=A great deal of effort/Always (Appendices 2.8. & 2.9).

The adapted 12-item *Unified Theory of Acceptance and Use of Technology* Questionnaire (UTAUT; Venkatesh, Thong & Xu, 2012) consists of seven domains (performance expectancy, effort expectancy, social influence, facilitating conditions, self-efficacy, anxiety, and behavioural intention). Participants were asked to rate perceived usability, usefulness, and intention to use ApplTree on a 7-point likert scale, ranging from Strongly Disagree to Strongly Agree after study completion (Appendix 2.10).

Neuropsychological assessment

Cognitive functioning was assessed using the following validated neuropsychological tests and measures:

- *Test of Pre-Morbid Functioning* (TOPF; Wechsler, 2011)
- *Prospective and Retrospective Memory Questionnaire* (PRMQ; Smith et al., 2000)
- *Rivermead Behavioural Memory Test* (RBMT-3; Wilson et al., 2008)
- *Trail Making* and *Verbal Fluency* subtests of the *Delis-Kaplan Executive Function System* (D-KEFS; Delis et al., 2001)
- *Modified Six Elements Test* of the *Behavioural Assessment of the Dysexecutive Syndrome* (BADS; Wilson et al., 1996)
- *Centre for Epidemiological Studies Depression Scale* (CESD; Radloff, 1977)

Setting, procedures, and data recording

Following assent, the researcher contacted potential participants to discuss the study information and answer any study-related questions by telephone. The Consent appointment was conducted in-person at the participant's and nominated person's home. At this appointment, information about current memory aid use and personally meaningful PM tasks were identified. The participant was provided with the text times for the duration of the study. The nominated person was provided with copies of the Memory Logs and asked to store Memory Logs privately so that they did not act as a memory aid or prompt for the participant. They were then shown how to complete the Memory Log (i.e., recording whether PM tasks were completed and, if so, whether these were completed on time and if prompting was required). The nominated person received a daily text message to remind them to complete the Memory Log.

Weekly appointments were completed by telephone throughout baseline and intervention phases. Each Friday, the participant identified personally meaningful PM tasks for the upcoming week with the nominated person and researcher (see Table 2.2. for examples). These were recorded on the Memory Log by the nominated person, and the researcher recorded these separately on their copy of the Memory Log. The participant then completed the weekly ratings of effort and worry and the next appointment was scheduled. The researcher then spoke separately with the nominated person, who reported the Memory Log data from the previous week, which the researcher recorded on their corresponding Memory Log. Finally, the nominated person completed their weekly ratings of effort and worry.

Table 2.2.

Examples of weekly PM tasks for each participant.

AB	CD	EF
Take son to swimming class Attend concert	Go to the gym Take dog to the vet	Take medication Go to the gym with friend

Baseline phase. Throughout the baseline phase, participants used their typical (electronic) reminder aids (e.g., Apple calendar on their phone, Smartwatch) to remember to complete their intended PM tasks identified in the Memory Log and to send the text messages to the researcher. Where participants relied on their nominated person to prompt them, nominated persons were asked to prompt at the time of or just after the PM task was due to commence (rather than in advance), unless it was potentially disadvantageous to do so (e.g., participant might miss an appointment). This was encouraged throughout both study phases.

Intervention

ApplTree training. Participants and nominated persons were provided with a 25-minute training video on ApplTree, which showed them how to download, navigate, and enter, edit and delete reminders using ApplTree (see Jamieson et al., 2023). This was to ensure standardised training in use of ApplTree across participants. The researcher then supported the participant to download ApplTree onto the participant's phone and to log into their unique user account for the study. Participants were asked to practice entering dummy reminders (e.g., medication, GP appointment) using ApplTree as part of the training session. They were provided with a copy of this video so that they could refer to it as required. Due to issues with downloading ApplTree for EF, he was unable to practice using ApplTree after watching the training video and the app was transferred to him after the session.

ApplTree intervention phase. Immediately after training, participants completed the intervention phase across five consecutive weeks. During this phase, participants were asked to enter their PM tasks, including text messages to the researcher, into ApplTree using the "narrow-deep" interface, with the assistance of their nominated person if required. EF's nominated person helped enter his reminders when his visual impairment impacted his ability to do so. Participants were able to continue using their existing memory aids during the intervention phase and all three chose to do so.

Neuropsychological assessment. Participants were invited to provide consent for the researcher to access their medical records to ascertain whether they had completed any of the neuropsychological tests previously. If they had and these were still considered valid by the Stroke Service Psychologists, these results were used. If tests were not completed previously or were no longer valid, the researcher arranged an appointment to complete these tests in-person. All participants requested that these be completed in their home and during the same session as ApplTree training to minimise burden. Tests were completed across one or two sessions as required.

End of study. Following completion of the intervention phase, participants completed the UTAUT and an end-of-study interview, where they provided subjective feedback regarding their experience of using ApplTree. Nominated persons could attend this session and contribute to this interview (e.g., where the nominated person entered reminders into ApplTree for the participant).

Sample size

According to the RoBiN-T, there should be at least three demonstrations of the treatment effect, hence we aimed to recruit a minimum of three participants. In their meta-analysis of SCED studies, Jamieson et al. (2013) found large effect sizes using non-

overlapping pairs methodology. It was anticipated that Tau-U analysis would have sufficient statistical power to detect large effect sizes in this study.

Data analysis

To assess the efficacy of ApplTree on PM performance, percentage of PM task completion (i.e., completed "on time" or "early" and unprompted) across each week throughout baseline and intervention phases were graphed for each participant. Visual analysis of trend, level, and stability of data were assessed within and between baseline and intervention phases (Lane & Gast, 2014). A stability envelope was applied to each participant's PM performance data, and to participants' and nominated persons' effort and worry data. This enables analysis of data variability by determining whether 80% of data points falls within 25% of the median within each study phase. Tau-U analysis was conducted to examine data non-overlap between baseline and intervention phases and to provide an overall effect size using aggregated data across both phases (Parker et al., 2011) via the website http://singlecaseresearch.org/. Tau-U values were interpreted using Vannest and Ninci's (2015) guidelines, where 0.20 improvement may be considered a small change, 0.20 to 0.60 a moderate change, 0.60 to 0.80 a large, and above 0.80 a large to very large change.

To assess the efficacy of ApplTree on text reminder performance, each data-point (i.e. each individual text) was graphed for each participant across both study phases. Text reminders were categorised as 'completed on time', 'completed late' (>15mins after designated time), or 'forgotten'. Visual and Tau-U analyses were conducted to examine data non-overlap and overall effect size. To assess the effect of ApplTree on participant's and nominated person's subjective ratings of effort and worry, ratings for both across each week throughout baseline and intervention phases were graphed for each participant and nominated person. Visual and Tau-U analyses were conducted to examine data non-overlap and overall

effect size. To examine the acceptability of ApplTree for participants and their nominated person, participants' UTAUT scores and a summary of subjective feedback regarding ApplTree are reported. Raw data for all participants is included in Appendix 2.12. Participants' text reminder data for both study phases are presented in Appendix 2.13.

RESULTS

PM task performance.

Participants' weekly PM performance across baseline (Phase A) and ApplTree intervention (Phase B) phases are graphed in Figure 2.1. (a) AB was randomised to 5-weeks baseline; (b) CD was randomised to 6-weeks baseline; and (c) EF to 7-weeks baseline.

AB. Performance was generally high in Phase A (*M*=84.17%, *SD*=18.45%, *Md*=87.5, *Range*=50-100%). Visual analysis indicated a stable profile, following application of a stability envelope to trend lines. Performance was stable within Phase B and higher than Phase A (*M*=93.46%, *SD*=9.76%, *Md*=100, *Range*=75-100%). Split-middle method of trend estimation indicated a slight (non-significant) decelerating, deteriorating trend in Phase A, and an accelerating, improving trend in Phase B. The effect of introducing ApplTree was not immediate. Tau-U analysis was used to determine performance change between Phases A and B, and revealed a small positive effect between baseline and intervention PM task performance. This was not statistically significant, *Tau-U*=.28, *p*=.46, *90% CI* [-.350, .910].

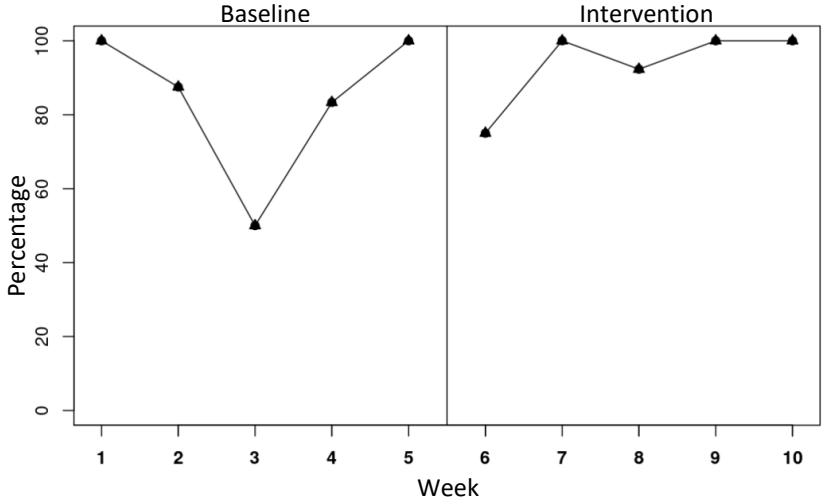
CD. Performance was generally high in Phase A (*M*=91.67%, *SD*=11.74%, *Md*=100, *Range*=75-100%). Visual analysis indicated a stable profile, following application of a stability envelope to trend lines. Split-middle method of trend estimation indicated a (non-significant) decelerating, deteriorating trend in Phase A. Performance was stable and at ceiling across Phase B (*M*=100%, *SD*=0%, *Md*=100). Tau-U analysis revealed a small positive effect between baseline and intervention PM task performance. This was not statistically significant, *Tau-U*=.33, *p*=.36, *90% CI* [-.267, .934].

EF. Despite experiencing issues with ApplTree, EF completed three of the five weeks intervention phase. Performance was generally high in Phase A (*M*=90.10%, *SD*=10.36%, *Md*=92.59, *Range*=65.36-100%) and relatively stable. Split-middle method of trend estimation was conducted and indicated that there was a (non-significant) decelerating, deteriorating trend in Phase A. Performance was at ceiling across Phase B and stable. Between-condition analysis, including mean, median and relative level change measures (*M*=100%, *SD*=0%, *Md*=100), indicated a positive from Phase A to B. Tau-U analysis revealed significant changes in PM task performance between baseline and intervention, *Tau-U*=.857, *p*=.04, *90% CI* [0.17, 1].

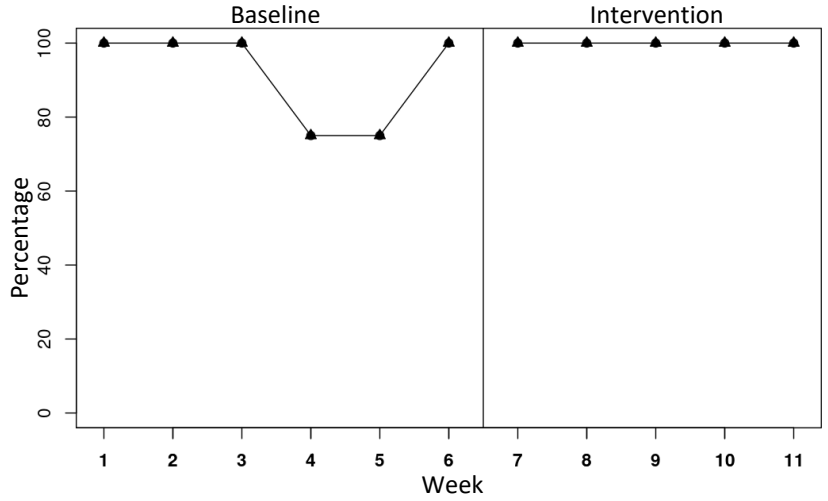
Figure 2.1.

Weekly PM performance (percentage of PM tasks completed "on time" or "early" unprompted) across study phases for (a) AB, (b) CD, and (c) EF.

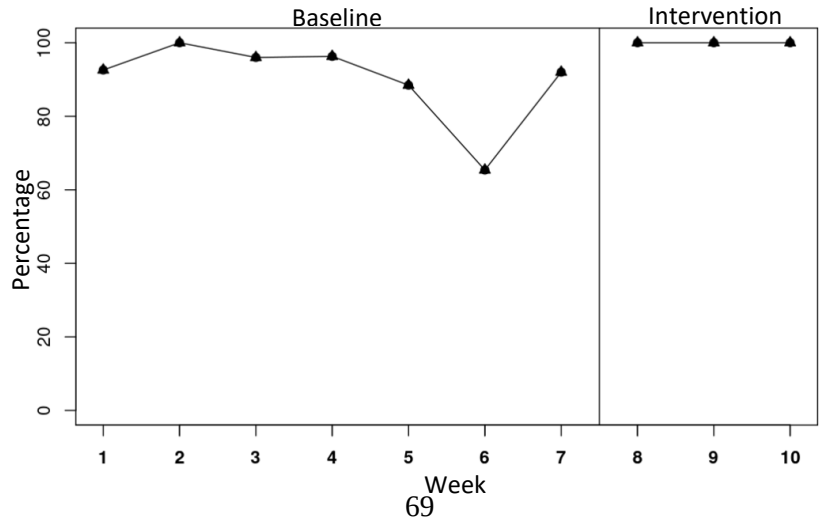
(a) AB



(b) CD



(c) EF



Text reminders.

AB. In both Phases A and B, 11/15 (73.33%) texts were 'completed on time', 1/15 (6.67%) were 'completed late', and 3/15 (20%) were 'forgotten'. Estimation of trend using the split-middle method revealed no change in trend during either phase, indicating a consistent, zero-celerating trend. Tau-U analysis indicated no significant differences in text reminder completion across phases, *Tau-U*=-.009, *p*=.96, *90% CI* [-0.353, 0.353].

CD. In Phase A, 17/18 (94.44%) texts were 'completed on time', and 1/18 (5.56%) were completed late. In Phase B, 13/15 (86.67%) texts were 'completed on time', and 2/15 (13.33%) were completed late. Estimation of trend using the split-middle method revealed no change in trend during either phase, indicating a consistent, zero-celerating trend. Tau-U analysis indicated no significant differences in text reminder completion across phases, *Tau-U*=-.078, *p*=.70, *90% CI* [-0.415, 0.259].

EF. In Phase A, 18/21 (85.71%) texts were 'completed on time', 1/21 (4.77%) was 'completed late', and 2/21 (9.52%) were 'forgotten'. In Phase B, 7/9 (77.77%) texts were 'completed on time', and 2/9 (33.33%) were 'forgotten'. Estimation of trend using the split-middle method revealed no change in trend during either phase, indicating a consistent, zero-celerating trend. Tau-U analysis indicated no significant differences in text reminder completion across phases, *Tau-U*=-.12, *p*=.37, *90% CI* [-0.475, 0.295].

Participants' ratings of effort and worry.

Participants' weekly ratings of effort and worry regarding PM task completion across baseline (Phase A) and ApplTree intervention (Phase B) phases are graphed in Figure 2.2.

AB. Effort ratings were somewhat high in Phase A (*M*=3.40, *SD*=.49, *Md*=2.0, *Range*=3.0-4.0). Visual analysis indicated a stable profile. Ratings were lower during Phase B (*M*=2.40, *SD*=0.49, *Md*=3.0, *Range*=2-3), and data were considered variable following application of a stability envelope to trend lines. Split-middle method of trend estimation

indicated a slight decelerating, deteriorating trend zero-celerating trend in each Phase. There was a decrease in effort ratings from Phase A to Phase B. Tau-U analysis revealed a moderate negative effect between baseline and intervention effort ratings, *Tau-U*=-.76, *p*=.047, *90% CI* [-1, -.13].

Worry ratings were relatively high in Phase A (*M*=3.40, *SD*=.49, *Md*=3.0, *Range*=3-4). Visual analysis indicated a stable profile, following application of a stability envelope to trend lines. Ratings were lower during Phase B (*M*=2.6, *SD*=.49, *Md*=3.0, *Range*=2-3). Split-middle method of trend estimation was conducted and indicated that there was a slight decelerating, deteriorating trend in Phase A, and a consistent, zero-celerating trend in Phase B. There was a decrease in worry ratings from Phase A to Phase B. Tau-U analysis revealed a moderate negative effect between baseline and intervention worry ratings, *Tau-U*=-.64, *p*=.009, *90% CI* [-1, -.01].

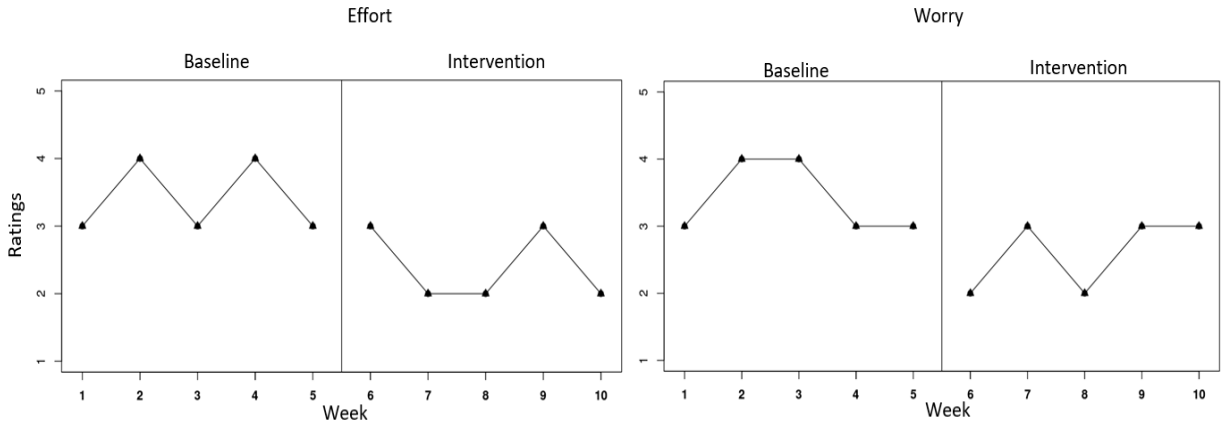
CD. Effort and worry ratings were at floor and stable throughout Phases A and B (*M*=1, *SD*=0, *MD*=1). Split-middle method of trend estimation indicated and a consistent, zero-celerating trend with no changes across Phase A and B.

EF. Effort ratings were mostly at ceiling within both Phases A (*M*=4.86, *SD*=.34, *Md*=5.0, *Range*=4-5) and B (*M*=5.0, *SD*=0, *Md*=5.0). Split-middle method of trend estimation indicated zero-celerating trends within both phases. With no significant changes between baseline and intervention effort ratings, *Tau-U*=.14, *p*=.73, *90% CI* [-.55, .83]. Worry ratings were generally high and stable in both Phases A and B (*M*=4.0, *SD*=0, *Md*=4.0) Split-middle method of trend estimation indicated and a consistent, zero-celerating trend with no changes across Phase A and B.

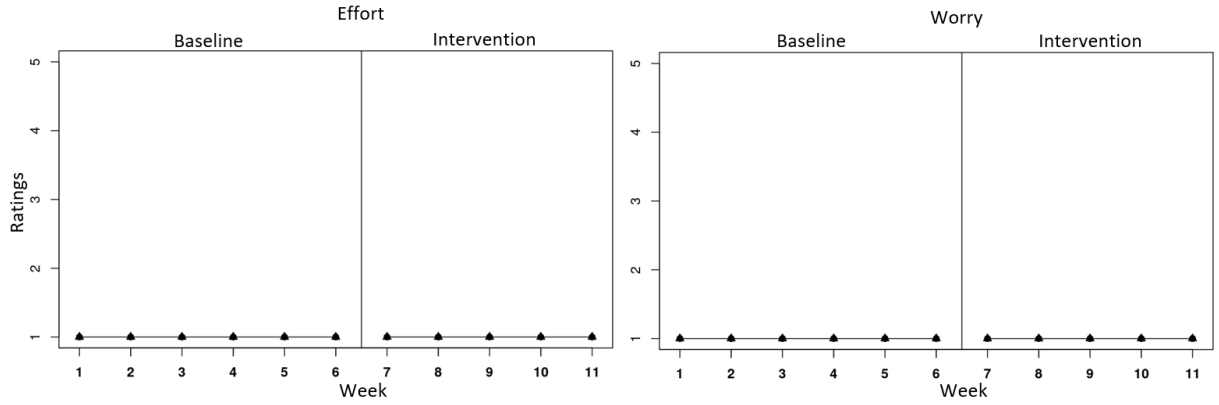
Figure 2.2.

Weekly ratings of effort and worry across study phases for (a) AB, (b) CD, and (c) EF.

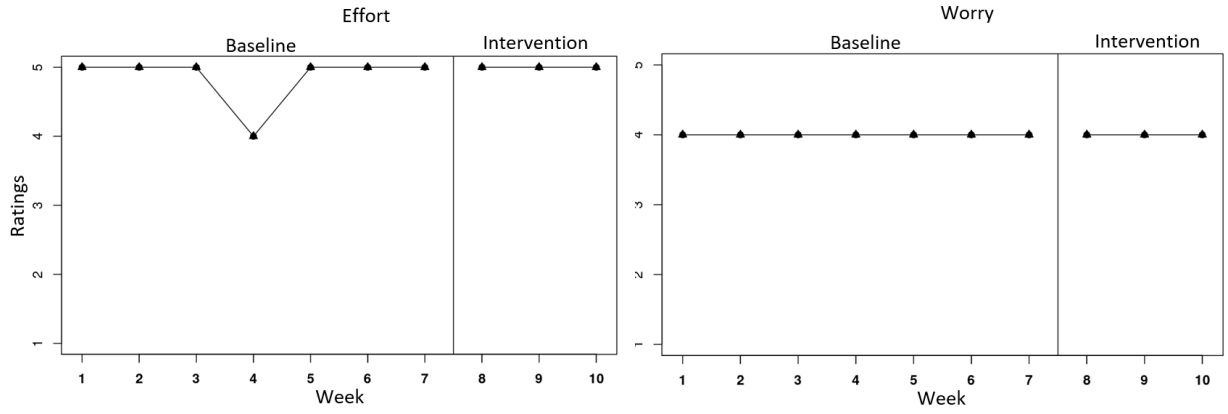
(a) AB



(b) CD



(c) EF



Nominated persons' ratings of effort and worry.

*AB. N*ominated person's worry ratings varied across Phase A (*M*=2.80, *SD*=.75, *Md*=3.0, *Range*=2-4). Ratings were lower during Phase B (*M*=2.20, *SD*=.4, *Md*=2.0, *Range*=2-3). Data were considered variable in both phases, following application of a stability envelope to trend lines. Split-middle method of trend estimation indicated a slight decelerating, deteriorating trend within each phase, with a decrease in effort ratings from Phases A to B. Tau-U analysis revealed a small negative effect between baseline and intervention effort ratings. This was not statistically significant, *Tau-U*=-.44, *p*=.25, *90% CI* [-1, .19].

Visual analysis of her worry ratings indicated that these were largely stable within both phases, with an accelerating, increasing trend in Phase A (*M*=3.40, *SD*=.49, *Md*=3.0, *Range*=3-4), and a consistent, zero-celerating trend in Phase B (*M*=3.0, *SD*=0, *Md*=3.0). Tau-U analysis revealed a small negative effect between baseline and intervention worry ratings. This was not statistically significant, *Tau-U*=-.40, *p*=.296, *90% CI* [-1, .23].

CD. Nominated person's effort and worry ratings were at floor and stable throughout Phases A and B (*M*=1, *SD*=0, *MD*=1). Split-middle method of trend estimation indicated and a consistent, zero-celerating trend with no changes across Phase A and B.

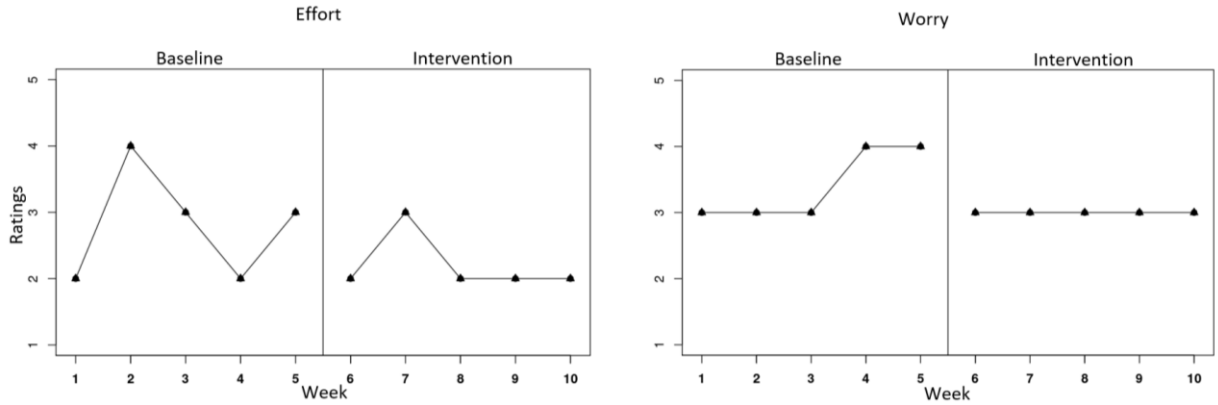
EF. Visual analysis of nominated person's effort ratings indicated that these were variable across Phase A (*M*=1.86, *SD*=.62, *Md*=2.0, *Range*=1-3). Ratings were higher and stable within Phase B (*M*=2.67, *SD*=.52, *Md*=3.0, *Range*=2-3). Split-middle method of trend estimation indicated an (non-significant) accelerating, increasing trend in Phase A and decelerating, decreasing trend in Phase B. Tau-U analysis revealed a moderate positive effect between baseline and intervention effort ratings. This was non-significant, *Tau-U*=.62, *p*=.14, *90% CI* [-.068, 1].

Nominated person's worry ratings were moderate and stable within Phase A (*M*=3.0, *SD*=0, *Md*=3.0). Ratings were variable within Phase B (*M*=3.0 *SD*=.9, *Md*=3.0, *Range*=2-4). Split-middle method of trend estimation indicated a- zero-celerating trend in Phase A. Tau-U analysis revealed no significant changes between baseline and intervention worry ratings, *Tau-U*=.04, *p*=1, *90% CI* [-.69, .69].

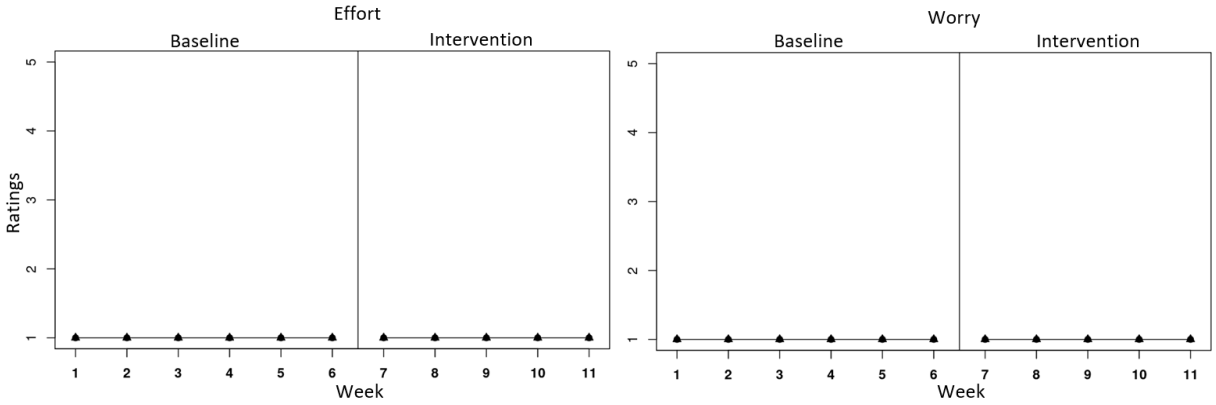
Figure 2.3.

Nominated person weekly ratings of effort and worry across study phases for (a) AB, (b) CD, and (c) EF.

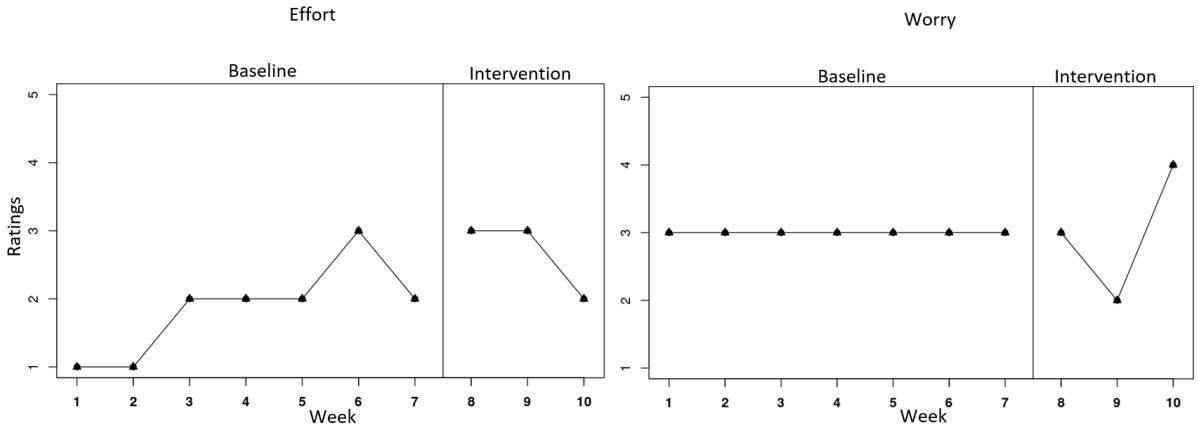
(a) AB



(b) CD



(c) EF



Acceptability and usability

Higher UTAUT scores indicated higher performance expectancy, effort expectancy[6], social influence, facilitating conditions, self-efficacy, anxiety, and behavioural intention regarding ApplTree use. Participants' subscale scores are reported in Table 2.3. AB's scores indicated relatively high performance expectancy and self-efficacy, and relatively low intention to continue using ApplTree. CD' scores indicated high performance expectancy and self-efficacy, low effort expectancy and anxiety, and strong intention to continue using ApplTree. EF's scores indicated relatively high self-efficacy and low effort expectancy, but low performance expectancy, high anxiety, and no intention to continue using ApplTree. This was understandable given their experiences during the intervention phase.

Table 2.3.

UTAUT scores

	AB	**CD**	**EF**
Performance expectancy	5.5	7	1.5
Effort expectancy	3	1	3.5
Social influence	6	7	3.5
Facilitating conditions	6	7	7
Self-efficacy	6	7	6
Anxiety	2.5	1	7
Behavioural intention	3	7	1

AB reported that ApplTree's features in relation to inputting and viewing reminders were accessible, but he found the 'narrow-deep' interface "clunky" due to having to enter details of reminders across multiple pages and remember to scroll down to then 'Save' the reminder. He said he preferred the 'broad-shallow' interface of his Apple calendar and found this more intuitive. He suggested that ApplTree's 'narrow-deep' interface may be more accessible for individuals with greater cognitive impairment or less familiarity with

[6] This item was reverse scored to ease interpretability (i.e., lower scores indicate lower expected effort to use ApplTree).

technological memory aids. AB may have preferred the alternative 'broad-shallow' ApplTree interface; however, this was not available in the current study. He said that the categories of reminders (e.g., medication, appointment) and associated colour-coordinated reminders within the 'Schedule' (calendar) view were useful. Although, he noted that his Apple calendar provides reminder details without needing to "click into" them to retrieve this, which was required for ApplTree. AB noted that both memory aids were helpful for study text reminders and wondered if it was harder for him to remember these tasks because they were set by the researcher, random, and not personally meaningful. He noted that the ApplTree alarm was unique and good at alerting him of tasks whereas his Apple calendar had a "subtle bleep".

CD said that he found ApplTree helpful and easy to use. He reported using a few apps for various to-be-remembered tasks and events, including Apple calendar for birthdays and appointments, 'Notes' for shopping, and another app for medication reminders, which required a lot of effort. He valued being able to store all of his reminders in one place using ApplTree, and identified the 'reminder categories' as a particularly useful feature. He said that he tried to use the 'repeat reminder' function for medication, and set reminders for birthdays and events in advance, but reported issues with limited space, which he said prevented him from using ApplTree as he wanted. However, he intended to continue using ApplTree after completing the study.

EF and his nominated person provided feedback together. Both were keen to avail of ApplTree and thought that it would be beneficial for EF in terms of ease of use and having a personal memory aid to support his independence. Whilst they experienced several disruptive issues with the app, the provided generally positive feedback about its interface. They drew comparisons between ApplTree and other reminding tools that they used currently and previously. EF said that he found the volume of reminders in the family's shared calendar

overwhelming and had difficulty identifying his personal tasks within these. He noted finding the colour-coordinated reminders within ApplTree helpful and subsequently adopted this system within the family calendar. EF's current memory strategies appeared to be complicated and effortful (inferring to-be-remembered tasks when his Smartwatch sounded by using contextual information, or checking the electronic calendar on his laptop if unsure). Had ApplTree worked as intended, this would likely have circumvented these issues and potentially reduced the effort associated with remembering PM tasks.

DISCUSSION

The aim of this study was to investigate the acceptability and efficacy of ApplTree for improving PM performance in stroke participants. Results indicated non-significant small-medium improvements in PM task completion for two participants (AB, CD), and significant large improvements for one participant (EF) from baseline to intervention phases. For EF, ApplTree did not work as intended and he ended the intervention phase early due to technical issues. These technical issues unintentionally increased his hypervigilance regarding PM tasks. All participants reported that ApplTree was easy to use and identified helpful features (e.g., 'reminder categories'), and some limitations that impacted engagement. CD intended to continue using ApplTree after the study.

Their weekly to-be-remembered tasks typically involved routine activities (e.g., taking medication, caring/domestic responsibilities), which were habitual and therefore potentially less prone to being forgotten. Participants also recorded infrequent appointments and events that they needed to remember. There were fewer of these than the routine activities and they were evenly spread across study phases for all participants. AB's and EF's nominated persons reported prompting and checking regarding these tasks prior to the study. CD's nominated person did not report prompting him prior to the study.

All participants reported currently using technological memory reminder tools (e.g., Apple calendar), which may have supported PM functioning and reduced forgetting. This is unsurprising given the accessibility and ubiquity of electronic memory aids, including smartphones, and their increased use in acquired brain injury (ABI) populations (Gillespie et al., 2011; Jamieson et al., 2017). Nonetheless, it was anticipated that ApplTree might be better than participants' existing electronic aids due to its specific design features, including its accessible user interface designed to support attention and short-term memory difficulties (Jamieson et al., 2020).

Participants' baseline performances were generally quite high. EF's performance during baseline was impacted by modifications to his medication regime (e.g., taking new medication every second day from Week 2). This change in routine seemed to prevent him from relying on his typical strategy of deducing the to-be-remember task when alerted by his smartwatch (which did not provide task information details) by using contextual information (e.g., time of day). Wilson (2021) also observed high PM performance during baseline in his study, which may have made it difficult to statistically determine any positive effect of ApplTree. He highlighted methodological considerations regarding how PM performance was measured (his Memory Log involved a Yes/No response format). In the current study, we adapted the Memory Log as per Jamieson et al. (2023) to include a more nuanced measure of PM task completion. In addition to task completion, we recorded whether tasks were completed "On Time", "Early", or "Late", and if the participant was "prompted". Participants completed almost every task across both phases (*AB* Phase A: 32/33, 96.97%; Phase B: 33/33, 100%; *CD* Phase A: 46/47, 97.87%; Phase B: 42/42, 100%; *EF* Phase A: 182/182, 100%; Phase B: 81/81, 100%). Variability in PM performance was generally in relation to 'lateness' and 'prompting'. *Tau-U* scores were also higher in the current study compared to Wilson (2021). These findings provide support for using this more nuanced

Memory Log in this and future studies, as it demonstrated greater sensitivity in detecting variations in PM performance than a simple categorical measure (see Appendix 2.14 for supplementary analysis).

We also investigated the effect of ApplTree on participants' and nominated persons' subjective experiences of effort and worry in relation to participants' PM performance. AB reported significant anxiety about his PM difficulties. CD considered his current system for remembering PM tasks (using three separate smartphone apps) effortful but manageable. EF's typical PM strategies required high levels of effort. Both AB's and EF's nominated persons indicated that participants' PM difficulties were a source of worry for them. CD's partner felt that he was generally able to manage PM tasks via his established routines and current strategies. AB showed significant moderate reductions in self-reported effort and worry regarding PM tasks from baseline to intervention phases. His nominated person indicated non-significant small reductions in effort and worry regarding his PM performance. CD and his nominated person's ratings were at floor throughout both study phases so it would not have been possible to detect further reductions. Although, after study completion, CD said that ApplTree's 'reminder categories' feature (e.g., shopping, events, appointments) was helpful as this allowed him to record his various PM tasks in one place, requiring less effort than his typical strategy. It is unfortunate that issues with space on ApplTree restricted his ability to use ApplTree exclusively. EF's effort and worry ratings remained high and stable throughout both phases. This was understandable given the stress he reported due to technical issues with ApplTree.

Memory impairments can significantly impact daily functioning, independence, and quality of life (Evans, 2013), and have both a practical and emotional impact on survivors and their families (e.g., Tang et al., 2020). Stroke survivors, caregivers, and health professionals have highlighted the need to address both stroke-related cognitive impairments,

and the social aspects of 'living with stroke', including improving survivors' confidence after stroke (Pollock et al., 2012). Assistive technology can help survivors to "regain and retain independence after a brain injury" and support confidence (Jamieson et al., 2014, p. 440). A strength of this study is that we examined the efficacy of ApplTree on PM performance, and explored the impact of this intervention on both participants' and their partners' subjective experiences of worry and effort in relation to participants' PM difficulties. Although we did not measure generalisation effects to other domains (e.g., social participation) and outcomes (e.g., confidence, carer burden). Future studies should investigate these factors in addition to the efficacy of assistive technological interventions to support post-stroke PM impairment.

Study limitations and implications

We faced challenges with recruitment in this study. With reference to the Risk of Bias in N of 1 Trials (RoBiN-T) scale (Tate et al., 2013) Item One, we were able to provide three demonstrations of the treatment effect (e.g., A-B-A-B, 6-phase multiple-baseline across participants). However, we were unable to complete planned replication (Item 14). When prospective participants were contacted, it was anecdotally observed that participants experiencing co-morbid mental health difficulties (e.g., anxiety) and/or social complexities (e.g., family-related difficulties) declined to take part. SCED involves rigorous design, allowing reliable conclusions to be drawn from study data. However, participants and their nominated persons in the current study were required to invest considerable amounts of time on study-related tasks, including completing weekly telephone calls with the researcher, three weekly text messages (for participants), Memory Log completion (for nominated persons), neuropsychological assessments, and end-of study interviews, over a period of ten to twelve weeks. The participants who took part in this study were able to function relatively well and had sources of support (e.g., nominated persons), which likely facilitated their participation in this study. However, these findings may not generalise to stroke survivors who have limited

social supports and are affected by physical health issues, mental health difficulties, and/or social complexities. Further research is needed to explore barriers and facilitators to research participation for this group so that future studies can ensure that they are supported to take part in studies, and thereby ensure more representative samples.

We did not include generalisation measures or a follow-up phase, both of which are recommended for SCED research (see Tate et al., 2016; Item 15). Therefore, it is unclear whether the observed effects were maintained regarding PM performance (and associated effort and worry) for participants following intervention completion, if potential intervention benefits generalised to other areas of everyday memory functioning, or if effects for ApplTree might be demonstrated for other participants. The text reminders were intended to add an additional measure of PM task performance. Results indicated that performance was generally at ceiling, with no changes from baseline to intervention. This task appeared to add little in terms of variability in PM task performance and future studies may consider omitting it to reduce burden on participants. Adjusting the task demands or titrating the task difficulty to match the individual's level of ability may also be a useful adaptation to facilitate the detection of treatment effects. Finally, all participants reported using strategies and electronic memory aids prior to and during the study, and had sources of support (e.g., their partners), which helped them to function generally well. Although, it was anticipated that ApplTree would provide a more effective electronic reminder tool. However, this may be another reason as to why participants in this study may not be representative of typical memory-impaired stroke survivors. We had no exclusion criteria in relation to current assistive technology or smartphone use. Perhaps future studies should focus on participants who do not currently use technological memory aids or for whom these have previously been unsuccessful.

Conclusions

ApplTree was associated with non-significant small-medium PM improvements for two participants, and significant moderate reductions in PM-related effort and worry for one participant. Importantly, this study highlights the utility of using a more nuanced Memory Log to capture changes in PM performance following intervention. Future research should consider the sensitivity of outcome measures in order to capture intervention effects. Where possible, studies should include generalisation measures to explore the potential impact of assistive technology for supporting cognition in related and personally-meaningful domains (e.g., confidence, carer burden).

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Appendix 1.1. PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Page 1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pages 4-5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 6
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pages 6-7
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Page 8
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix 1.2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Pages 9
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Page 10
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Pages 7, 10
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Page 10
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Pages 8-9
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Page 10

Section and Topic	Item #	Checklist item	Location where item is reported
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Page 10
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Page 10
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Page 10
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Page 10
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Pages 8-9, 10
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Page 11
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Page 9
Study characteristics	17	Cite each included study and present its characteristics.	Tables 1.1. & 1.2, pages 20-30
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Page 11, Tables 1.1. & 1.2, pages 20-30
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Tables 1.1. & 1.2, pages 20-30

Section and Topic	Item #	Checklist item	Location where item is reported
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Tables 1.1. & 1.2, pages 20-29
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Tables 1.1. & 1.2, pages 20-30
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pages 30, 34-35
	23b	Discuss any limitations of the evidence included in the review.	Pages 33-34, 39
	23c	Discuss any limitations of the review processes used.	N/A
	23d	Discuss implications of the results for practice, policy, and future research.	Pages 39-40
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Page 6
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Page 6
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Page 6
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	N/A
Competing interests	26	Declare any competing interests of review authors.	Page 1

Section and Topic	Item #	Checklist item	Location where item is reported
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	None

Appendix 1.2. PICO search strategies and results per database

Ovid Medline	**Subject Headings**	**Title and Abstract Search Terms**
Population	brain injuries/ OR brain hemorrhage, traumatic/ OR brain injuries, diffuse/ OR brain injuries, traumatic/ OR brain injury, chronic/ OR epilepsy, post-traumatic/ OR Epilepsy/ OR brain neoplasms/ OR brain ischemia/ OR stroke/ OR brain infarction/ OR hemorrhagic stroke/ OR ischemic stroke/ OR Encephalitis/ or aneurysm/ OR intracranial aneurysm/ OR Hypoxia/	(brain adj3 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*)).tw. (stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*).tw.
Intervention	Memory/ OR Memory Disorders/ OR cognition disorders/ OR cognitive dysfunction/	((neuro* OR memory OR cognit*) adj3 (rehab* OR interven* OR train* OR remediat* OR aid* OR compensat* OR restor*)).tw.
Comparator	randomized controlled trials as topic/ or single-case studies as topic/	((clinical* or random* or single-case or "n-of-1" or "single case" or "n of 1") adj3 (trial* or stud* or allocat*)).tw. OR RCT.tw

Ovid MEDLINE(R) ALL <1946 to 3rd April 2023>

1 brain injuries/ or brain hemorrhage, traumatic/ or brain injuries, diffuse/ or brain injuries, traumatic/ or brain injury, chronic/ or epilepsy, post-traumatic/ or brain neoplasms/ or brain ischemia/ 251718

2 stroke/ or brain infarction/ or hemorrhagic stroke/ or ischemic stroke/ 136475

3 Encephalitis/ 20400

4 aneurysm/ or intracranial aneurysm/ 51857

5 Hypoxia/ 72249

6 Epilepsy/ 84012

7 (brain adj2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*)).tw. 181058

8 (stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*).tw. 658511

9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 1040328

10 ((neuro* or memory or cognit*) adj3 (rehab* or interven* or train* or remediat* or aid* or compensat* or restor*)).tw. 51974

11 Memory/ 71880

12 Memory Disorders/ 23687

13 cognition disorders/ or cognitive dysfunction/ 98954

14 10 or 11 or 12 or 13 225964

15 randomized controlled trials as topic/ or single-case studies as topic/ 160592

16 ((clinical* or random* or single-case or n-of-1 or single case or n of 1) adj2 (trial* or stud* or allocat*)).tw. 1100911

17 RCT.tw. 30052

18 15 or 16 or 17 1165418

19 9 and 14 and 182398

Ovid Embase	**Subject Headings**	**Title and Abstract Search Terms**
Population	acquired brain injury/ OR brain injury/ OR head injury/ OR brain damage/ OR traumatic brain injury/ OR brain hemorrhage/ OR brain tumor/ OR brain ischemia/ OR cerebrovascular accident/ OR brain infarction/ OR encephalitis/ OR brain artery aneurysm/ OR aneurysm/ OR hypoxia/ OR brain hypoxia/ OR epilepsy/	(brain adj2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*)).tw. (stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*).tw.
Intervention	memory/ OR memory disorder/ OR cognition/ OR cognitive defect/	((neuro* OR memory OR cognit*) adj3 (rehab* OR interven* OR train* OR remediat* OR aid* OR compensat* OR restor*)).tw.
Comparator	randomized controlled trial/ or controlled clinical trial/	((clinical* or random* or single-case or n-of-1 or single case or n of 1) adj2 (trial* or stud* or allocat*)).tw. OR RCT.tw

Embase 1947-Present (3rd April 2023)

1 acquired brain injury/ or brain injury/ or head injury/ or brain damage/ or traumatic brain injury/ 252959

2 brain hemorrhage/ 131201

3 brain tumor/ 93530

4 brain ischemia/ 159550

5 cerebrovascular accident/ 275273

6 brain infarction/ 62801

7 encephalitis/ 41796

8 brain artery aneurysm/ or aneurysm/ 65227

9 hypoxia/ or brain hypoxia/ 148089

10 epilepsy/ 165846

11 (brain adj2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*)).tw. 265654

12 (stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*).tw. 1021537

13 memory/ 164326

14 memory disorder/ 43278

15 cognition/ 286201

16 cognitive defect/ 206763

17 ((neuro* or memory or cognit*) adj3 (rehab* or interven* or train* or remediat* or aid* or compensat* or restor*)).tw. 75596

18 randomized controlled trial/ or controlled clinical trial/ 956618

19 ((clinical* or random* or single-case or n-of-1 or single case or n of 1) adj2 (trial* or stud* or allocat*)).tw. 1578909

20 RCT.tw. 51551

21 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 1713676

22 13 or 14 or 15 or 16 or 17 653975

23 18 or 19 or 20 2114364

24 21 and 22 and 23 9419

25 limit 24 to conference abstract status 2129

26 24 not 25 7290

EBSCO Host CINAHL	**Subject Headings**	**Title and Abstract Search Terms**
Population	(MH "Head Injuries") OR (MH "Brain Damage, Chronic") OR (MH "Brain Injuries") OR (MH "Epilepsy, Post-Traumatic") OR (MH "Encephalitis") OR (MH "Epilepsy") OR (MH "Hydrocephalus") OR (MH "Hypoxia, Brain") OR (MH "Brain Neoplasms") OR (MH "Intracranial Hemorrhage") OR (MH "Cerebral Hemorrhage") OR (MH "Hypoxia-Ischemia, Brain") OR (MH "Cerebral Aneurysm") OR (MH "Cerebral Ischemia") OR (MH "Stroke") OR (MH "Cerebral Infarction") OR (MH "Hemorrhagic Stroke") OR (MH "Ischemic Stroke")	TI OR AB: (brain N2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*)) (stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*)
Intervention	(MH "Memory") OR (MH "Memory Disorders") OR (MH "Cognition") OR (MH "Cognition Disorders") OR (MH "Rehabilitation, Cognitive")	TI OR AB: ((neuro* OR memory OR cognit*) N3 (rehab* OR interven* OR train* OR remediat* OR aid* OR compensat* OR restor*))
Comparator	(MH "Clinical Trials") OR (MH "Randomized Controlled Trials")	TI OR AB: ((clinical* or random* or single-case or n-of-1 or single case or n of 1) N2 (trial* or stud* or allocat*)) OR RCT

EBSCOHost CINAHL (3rd April 2023)

#	Query	Results
S1	(MH "Head Injuries") OR (MH "Brain Damage, Chronic") OR (MH "Brain Injuries")	35,325
S2	(MH "Epilepsy, Post-Traumatic") OR (MH "Encephalitis") OR (MH "Epilepsy") OR (MH "Hydrocephalus") OR (MH "Hypoxia, Brain") OR (MH "Brain Neoplasms")	36,935
S3	(MH "Intracranial Hemorrhage") OR (MH "Cerebral Hemorrhage") OR (MH "Hypoxia-Ischemia, Brain")	13,072
S4	(MH "Cerebral Aneurysm") OR (MH "Cerebral Ischemia")	18,455
S5	(MH "Stroke") OR (MH "Cerebral Infarction") OR (MH "Hemorrhagic Stroke") OR (MH "Ischemic Stroke")	79,389

S6	TI ((brain N2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*))) OR AB ((brain N2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*)))	46,606
S7	TI ((stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*)) OR AB ((stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*))	160,811
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7	258,978
S9	(MH "Memory")	27,951
S10	(MH "Memory Disorders")	6,766
S11	(MH "Rehabilitation, Cognitive")	2,147
S12	(MH "Cognition") OR (MH "Cognition Disorders")	95,360
S13	TI (((neuro* OR memory OR cognit*) N3 (rehab* OR interven* OR train* OR remediat* OR aid* OR compensat* OR restor*))) OR AB (((neuro* OR memory OR cognit*) N3 (rehab* OR interven* OR train* OR remediat* OR aid* OR compensat* OR restor*)))	23,233
S14	S9 OR S10 OR S11 OR S12 OR S13	136,517
S15	(MH "Clinical Trials") OR (MH "Randomized Controlled Trials")	308,635
S16	TI (((clinical* or random* or single-case or n-of-1 or single case or n of 1) N2 (trial* or stud* or allocat*))) OR AB (((clinical* or random* or single-case or n-of-1 or single case or n of 1) N2 (trial* or stud* or allocat*)))	412,343
S17	TI RCT OR AB RCT	28,998
S18	S15 OR S16 OR S17	566,698
S19	S8 AND S14 AND S18	1,815

EBSCOHost PsycINFO	**Subject Headings**	**Title and Abstract Search Terms**
Population	DE "Brain Injuries" OR DE "Traumatic Brain Injury" OR DE "Head Injuries" OR DE "Cerebral Hemorrhage" OR DE "Subarachnoid Hemorrhage" OR DE "Brain Neoplasms" OR DE "Cerebral Ischemia" OR DE "Anoxia" OR DE "Epilepsy" OR DE "Encephalitis" DE "Cerebrovascular Accidents" OR DE "Cerebral Infarction"	TI OR AB: (brain N2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*)) (stroke* or CVA or "cerebrovascular accident*" or encephalitis or epilep* or hypoxi*)
Intervention	DE "Memory" OR DE "Memory Disorders" OR DE "Neuropsychological Rehabilitation" OR DE "Cognitive Rehabilitation" OR DE "Memory Training" OR DE "Neurorehabilitation" OR DE "Cognitive Remediation" OR DE "Cognition" OR DE "Cognitive Impairment"	TI OR AB: ((neuro* OR memory OR cognit*) N3 (rehab* OR interven* OR train* OR remediat* OR aid* OR compensat* OR restor*))
Comparator	DE "Randomized Clinical Trials" OR DE "Randomized Controlled Trials" OR DE "Single-Case Experimental Design"	TI OR AB: ((clinical* or random* or single-case or "n-of-1" or "single case" or "n of 1") N2 (trial* or stud* or allocat*)) OR RCT

EBSCOHost PsycINFO (3rd April 2023)

#	Query	Results
S1	DE "Brain Injuries" OR DE "Traumatic Brain Injury" OR DE "Head Injuries"	29,233
S2	DE "Brain Damage"	17,855
S3	DE "Brain Neoplasms"	5,220
S4	DE "Cerebral Hemorrhage" OR DE "Subarachnoid Hemorrhage"	4,092
S5	DE "Cerebral Ischemia" OR DE "Anoxia"	9,251
S6	DE "Epilepsy"	31,436

S7	DE "Encephalitis"	3,735
S8	DE "Cerebrovascular Accidents"	24,061
S9	DE "Cerebral Infarction"	2,172
S10	TI ((brain N2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*))) OR AB ((brain N2 (damage* or injur* or infarc* or hemorr* or haemorr* or ischem* or ischaem* or aneurys* or neoplasm* or tumor* or tumour* or cancer* or malign*)))	49,637
S11	TI ((stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*)) OR AB ((stroke* or CVA or cerebrovascular accident* or encephalitis or epilep* or hypoxi*))	91,255
S12	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11	157,175
S13	DE "Memory" OR DE "Memory Disorders" OR DE "Neuropsychological Rehabilitation" OR DE "Cognitive Rehabilitation" OR DE "Memory Training" OR DE "Neurorehabilitation"	110,798
S14	DE "Cognitive Remediation"	1,018
S15	DE "Cognition" OR DE "Cognitive Impairment"	122,451
S16	TI (((neuro* OR memory OR cognit*) N3 (rehab* OR interven* OR train* OR remediat* OR aid* OR compensat* OR restor*))) OR AB (((neuro* OR memory OR cognit*) N3 (rehab* OR interven* OR train* OR remediat* OR aid* OR compensat* OR restor*)))	39,956
S17	S13 OR S14 OR S15 OR S16	246,677
S18	DE "Randomized Clinical Trials" OR DE "Randomized Controlled Trials"	1,395
S19	DE "Single-Case Experimental Design"	147
S20	TI (((clinical* or random* or single-case or n-of-1 or single case or n of 1) N2 (trial* or stud* or allocat*))) OR AB (((clinical* or random* or single-case or n-of-1 or single case or n of 1) N2 (trial* or stud* or allocat*)))	160,757
S21	TI RCT OR AB RCT	10,318
S22	S18 OR S19 OR S20 OR S21	162,790
S23	S12 AND S17 AND S22	1,314

Appendix 1.3. PEDro-P scale (Maher et al., 2003)

PEDro scale

1.	eligibility criteria were specified	no ❑ yes ❑ where:
2.	subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ❑ yes ❑ where:
3.	allocation was concealed	no ❑ yes ❑ where:
4.	the groups were similar at baseline regarding the most important prognostic indicators	no ❑ yes ❑ where:
5.	there was blinding of all subjects	no ❑ yes ❑ where:
6.	there was blinding of all therapists who administered the therapy	no ❑ yes ❑ where:
7.	there was blinding of all assessors who measured at least one key outcome	no ❑ yes ❑ where:
8.	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ❑ yes ❑ where:
9.	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ❑ yes ❑ where:
10.	the results of between-group statistical comparisons are reported for at least one key outcome	no ❑ yes ❑ where:
11.	the study provides both point measures and measures of variability for at least one key outcome	no ❑ yes ❑ where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Notes on administration of the PEDro scale:

All criteria	**Points are only awarded when a criterion is clearly satisfied**. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

Appendix 1.4. Risk-of-Bias in N-of-1 Trials (RoBiNT) Scale (Tate et al., 2013)

Internal validity (IV) scale			
1. Design with control	2 points: 1 point: 0 points:	at minimum ABAB with 4 phases; concurrent multiple baseline design with six phases, 3 tiers; alternating treatment design with sets of alternating sequences; changing criterion design with 4 steps; for medical N of 1 3x AB pairs ABA or 3phase variant; multiple baseline design (MBD) with 4-5 phases; ATD with <3 sets of alternating sequences AB or AB with follow up, non concurrent MBD	SCORE
2. Randomisation	2 points 1point: 0 points:	Randomise: sequence and/or onset for all phases Restricted randomisation; counterbalancing No information; randomisation of other aspects of the study	
3. Sampling of behaviour	2 points: 1 point: 0 points:	5 or more points in every phase At least 3 points in every phase <3 data points in any phase	
4. Blinding of people involved in intervention	2 points: 1 point: 0 points	Double blinding of participant and practitioner Participant or practitioner blinded Neither participant or practitioner are blinded	
5. Blinding of Assessors	2 points: 1 point: 0 points:	Assessors blind to all phases; use of computer/machine free from human involvement, outcomes self-reported and participant is blind Independent assessor(s) but not blind to phase Neither participant nor practitioner are blind to phase	
6. Inter-rater agreement	2 points: 1 point: 0 points:	Machine degenerated data A reasonably objective measure used or agreement is less than or equal to 70% Agreement is <70%; subjective measures used; consensus ratings alone	
7. Treatment Adherence	2 points: 1 point: 0 points:	Machine delivered intervention or adherence assessed (i) against clear rating system, (ii) assessor is independent of practitioner/patient (iii) >20% of data is sampled (iv) resulting in >80% adherence Adherence meets 2/4 criteria above and includes (a) assessor independent to practitioner and (b) adherence >70% Adherence <70%, assessor not independent of patient, components only loosely related to adherence	

External validity (EV) scale			
8. Baseline characteristics	2 points: 1 point: 0 points:	Analysis of baseline characteristics and age, sex, aetiology and severity of condition Analysis of baseline characteristics or age, sex, aetiology and severity of condition No analysis of baseline condition or incomplete listing of the four participant characteristics	
9. Setting	2 points: 1 point: 0 points:	Description of the general location and detailed description of the specific environment Description of either general location or specific environment but detail are sparse Neither are provided	
10. DV (target behaviour)	2 points: 1 point: 0 points:	Target behaviour (b/h) is operationalised in precise terms and the methods of measurement are described Target b/h is operationally described but description and or method of measurement is not clear or precise Target b/h is not operationally defined	
11. IV	2 points: 1 point: 0 points:	Detailed description of content of intervention including any equipment/manuals and 3 procedural details: number, duration and frequency of sessions General description of intervention, and 2/3 procedural details Intervention described only in general terms, <2/3 details	
12. Raw data record	2 points: 1 point: 0 points:	Raw data record w data point for every session. If trials>10, raw data for 3 or more cases If trials>10 raw data for less than 3 cases, complete raw data for 2 participants, or provision of data record but data is aggregated or averaged or provision of data record but a prior decision not to record data for every session. No raw data; omitted data, data only reported for select phases.	
13. Data analysis	2 points: 1 point: 0 points:	Systematic visual analysis (VA) with specific protocol or VA aided by quasi-statistical methods or statistical analysis with rational. Systematic/aided VA with selection of analytic techniques or statistical analysis w no rational or prior decision re the level of the target b/h consisting of an empirically derived clinically meaningful change VA without data analysis; analysis note conducted on target b/h, arbitrary selection of level of target b/h.	
14. Replication	2 points: 1 point: 0 points:	1 original + 3 replications 1 original + 1 or 2 replications No replication	

15. Generalisation	2 points: 1 point: 0 points:	Specific generalisation measure probed in every phase Specific generalisation measure probed in at least pre and post treatment phases No generalisation measure	

Appendix 1.5. Memory outcome measures used in included studies

Validated and adapted neuropsychological assessments and tests

BVMT-R: Benedict, R.B.H., Schretlen, D., Groninger, L., Dobraski, M., & Shpritz, B. (1996). Revision of the Brief Visuospatial Memory Test: Studies of normal performance, reliability, and validity. *Psychological Assessment, 8*, 145–153.

Benton Visual Retention Test: Benton, A.L. (1974) *The Revised Visual Retention Test.* N.Y. Psychology Corporation, New York.

CVLT: Delis, D., Kramer, J.H., Kaplan, E., & Ober, B. (2000). *The California Verbal Learning Test - Second Edition*. San Antonio, TX: The Psychological Corporation.

VLMT: Helmstaedter, C., & Durwen, H. (1990). Verbaler Lernund Merkfahigkeitstest: Ein praktikables und differenziertes Instrumentarium zur Prufung der verbalen Gedachtnisleistungen. *Schweiz Arch Neurol Neurochir Psychiatr, 141*(1), 21–30.

RAVLT: Lezak, M., Howieson, D. B., & Loring, D. W. (2004). *Neuropsychological assessment* – Fourth Edition. New York: Oxford University Press.

MCGCF: Loring, D.W., & Meador, K.J. (2003). The Medical College of Georgia (MCG) Complex Figures: Four Forms for Follow-Up. In J.A. Knight & E. Kaplan Edition, *The Handbook of Rey-Osterrieth Complex Figure: Clinical and Research Applications*. Lutz, FL: Psychological Assessment Resources, pp 313–321.

RCFT: Meyers, J. E., & Myers, K. R. (1995). *Rey Complex Figure Test and Recognition Trial: Professional Manual*. Odessa, FL: Psychological Assessment Resources, Inc.

Oxford Recurring Faces Test: Newcombe, F. (1985). Neuropsychology qua interface. *Journal of Clinical and Experimental Neuropsychology, 7*, 663–681.

Stylus Maze Test: Newcombe, F., Ratcliff, G., & Damasio, H. (1987). Dissociable visual and spatial impairments following right posterior cerebral lesions: Clinical, neuropsychological and anatomical evidence. *Neuropsychologia, 25*, 149–161.

ROCFT: Osterrieth, P.A. (1944). Le test de copie d'une figure complex: Contribution a`l'e´tude de la perception et de la memoire [The test of copying a complex figure: A contribution to the study of perception and memory]. *Archives de Psychologie, 30*, 286–350.

RPA-ProMem: Radford, K., Lah, S., Say, M.J., & Miller, L. A. (2011a). Validation of a new measure of prospective memory: The Royal Prince Alfred Prospective Memory Test. *Clinical Neuropsychologist, 25*, 127–140.

15 Words Test: Saan, R.J., & Deelman, B.G. (1986). *Vijftien woorden test A en B. Groningen: Afdeling Neuropsychologie RUG*. Interne publikatie.

TCFT: Taylor, L.B. (1969). Localisation of cerebral lesions by psychological testing. *Clinical Neurosurgery, 16*, 269-287.

Name-Face Paired Association Memory Test: Venema, J.W. (1989). *De Evaluatie van de Naam-gezichtentaak*. Unpublished report Nr. 8938. Department of Neuropsychology, University of Groningen.

WMS: Wechsler, D. (1997). *Wechsler Memory Scale - Third Edition*. San Antonio, TX: The Psychological Corporation.

WAIS-IV: Wechsler, D. (2008). *WAIS-IV Technical and Interpretive Manual*. San Antonio: Pearson Inc.

RBMT: Wilson, B.A., Greenfield, E., Clare, L., Baddeley, A., Cockburn, J., Watson, P., Tate, R., Sopena, S., & Nannery, R. (2008). *The Rivermead Behavioural Memory Test - Third Edition (RBMT-3).* The Psychological Corporation. Pearson Assessment. London, UK.

Validated and adapted self- and others-reported measures

Meta-memory in adulthood Questionnaire: Hertzog C, Dixon R.A., & Hultsch, D.F. (1990). Meta-memory in adulthood: Differentiating knowledge, belief and behavior. In T.M. Hess Edition., *Aging and Cognition:Knowledge, Organization and Utilization*. Amsterdam, Netherlands: Elsevier Science Publishers, pp. 161-203.

Memory Questionnaire: Reinink, E.R., & Deelman, B.G. (1987). *Geheugenvragenlijst voor het meten van alledaagsegeheugen problemen bij patient en met traumatisch hersenletsel.* Unpublished report Nr. 8727. Department of Neuropsychology, University of Groningen.

CAPM-Self & -Other: Roche, N.L., Fleming, J.M., & Shum, D. (2002). Self-awareness of prospective memory failure in adults with traumatic brain injury. *Brain Injury, 16*(11), 931–945.

EMQ-R: Royle, J., & Lincoln, N.B. (2008). The Everyday Memory Questionnaire-revised: Development of a 13-item scale. *Disability & Rehabilitation, 3*0, 114–121.

Other measures of memory function

GAS: Kiresuk, T.J., & Sherman, R.E. (1968). Goal Attainment Scales: A general method for evaluating comprehensive community mental health programs. *Community Mental Health Journal, 4*(6), 443–453.

Appendix 2.1. NHS Research ethical approval documentation

Lothian NHS Board

South East Scotland Research Ethics Committee 01

2nd Floor, Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
www.hra.nhs.uk

Enquiries to: Sandra Wyllie
Mobile: 07814 764241
Email: sandra.wyllie@nhslothian.scot.nhs.uk

16 February 2023

Professor Jonathan Evans
The Administration Building
Gartnavel Royal Hospital
1055 Great Western Road, Glasgow
G12 0XH

Dear Professor Evans

Study title:	**Investigating the efficacy of AppITree, a smartphone reminding application, on prospective memory performance in individuals who have experienced a stroke using Single Case Experimental Design (SCED)**
REC reference:	**23/SS/0005**
IRAS project ID:	**316792**

Thank you for your letter of 26 January 2023, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies

2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

NHS
Lothian

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Glasgow Clinical Trials Insurance]	1	07 October 2022
GP/consultant information sheets or letters [Study recruitment information for clinicians]	1	07 October 2022
GP/consultant information sheets or letters [Assent to contact proforma]	1	07 October 2022
GP/consultant information sheets or letters [Letter to GP]	1	26 January 2023
Interview schedules or topic guides for participants [End of study interview questions]	1	26 January 2023
IRAS Application Form [IRAS_Form_20122022]		20 December 2022
Laboratory Manual [Instruction videos for ApplTree application]	1	07 October 2022
Non-validated questionnaire [Memory Log]	1	07 October 2022
Non-validated questionnaire [Adapted Unified Theory of Acceptance and Use of Technology]	2	04 November 2022
Non-validated questionnaire [Weekly text message reminder task example]	1	07 October 2022
Non-validated questionnaire [Nominated person subjective ratings of effort and worry]	1	07 October 2022
Non-validated questionnaire [Participant subjective ratings of effort and worry]	1	07 October 2022
Non-validated questionnaire [Memory Log Prompt Text]	1	26 January 2023
Other [REC Letter]	1	26 January 2023
Other [REC Responses]	1	26 January 2023
Participant consent form [Participant Consent Form]	3	26 January 2023
Participant consent form [Nominated Person Consent Form]	3	26 January 2023
Participant information sheet (PIS) [Participant Information Sheet]	3	26 January 2023
Participant information sheet (PIS) [Nominated Person Information Sheet]	3	26 January 2023
Research protocol or project proposal [Research protocol]	3	26 January 2023
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1	04 November 2022
Summary CV for student [Student summary CV]	1	07 October 2022
Summary CV for supervisor (student research) [Supervisor CV]	1	04 November 2022
Summary CV for supervisor (student research) [Supervisor CV]	1	26 October 2022
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study protocol flowchart]	2	07 October 2022
Validated questionnaire [Behavioural Assessment of the Dysexecutive Syndrome 6 elements subtest]	1	07 October 2022
Validated questionnaire [Center for Epidemiologic Studies Depression Scale]	1	07 October 2022

Validated questionnaire [Delis–Kaplan Executive Function System]	1	07 October 2022
Validated questionnaire [Prospective Retrospective Memory Questionnaire]	1	07 October 2022
Validated questionnaire [Rivermead Behavioural Memory Test]	1	07 October 2022
Validated questionnaire [Test of Premorbid Functioning]	1	07 October 2022

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 316792 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Lucy Kershaw
Chair

Email:sandra.wyllie@nhslothian.scot.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

After ethical review guidance for sponsors and investigators – Non CTIMP Standard Conditions of Approval]

Copy to: Dr Colette Montgomery Sardar
Lead Nation - Scotland: gram.nrspcc@nhs.scot

Appendix 2.2. NHS Greater Glasgow and Clyde Management approval documentation

Coordinator: Mr Graeme Piper
Telephone Number: 0141 314 0222
E-Mail: Graeme.Piper@ggc.scot.nhs.uk
Website: https://www.nhsggc.org.uk/about-us/professional-support-sites/research-innovation/

Research & Innovation
Dykebar Hospital, Ward 11
Grahamston Road
Paisley, PA2 7DE
Scotland, UK

20th February 2023

Dr Corinna Stewart
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

NHS GG&C Board Approval

Dear Dr Stewart

Study Title:	Investigating the efficacy of AppTree, a smartphone reminding application, on prospective memory performance in individuals who have experienced a stroke using Single Case Experimental Design (SCED)
Principal Investigator:	Dr Corinna Stewart
GG&C HB site	NHS Greater Glasgow and Clyde (all sites)
Sponsor	NHS Greater Glasgow and Clyde
R&I reference:	UGN22ST389
REC reference:	23/SS/0005
Protocol no: (including version and date)	V3 26.01.2023

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file. Researchers must follow NHS GG&C local policies, including incident reporting.

2. **For all studies** the following information is required during their lifespan.
   a. First study participant should be recruited within 30 days of approval date.
   b. Recruitment Numbers on a monthly basis
   c. Any change to local research team staff should be notified to R&I team
   d. Any amendments – Substantial or Non Substantial

e. Notification of Trial/study end including final recruitment figures
f. Final Report & Copies of Publications/Abstracts
g. You must work in accordance with the current NHS GG&C COVID19 guidelines and principles.

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely

Graeme Fiper
Research Co-ordinator

CC:

Appendix 2.3. Participant Information Sheet

Appendix 2.4. Nominated Person Information Sheet

Appendix 2.5. Participant Consent Form

Appendix 2.6. Nominated Person Consent Form

Appendix 2.7. Memory Log

Appendix 2.8. Participant Ratings of Effort and Worry

Appendix 2.9. Nominated Person Ratings of Effort and Worry

Appendix 2.10. Adapted Unified Theory of Acceptance and Use of Technology (UTAUT) Questionnaire

Appendix 2.11. University of Glasgow approved proposal for the current study

All documents listed in Appendices 2.3-2.11 are available on the following Open Science Forum link: https://osf.io/rkewg/?view_only=4d6ea79c4d154175a957898d8d677d88

Appendix 2.12. Raw study data

Table 1. Percentage of PM tasks completed early or on time without prompting for all participants across baseline (grey) and intervention (white) phases.

Week	1	2	3	4	5	6	7	8	9	10	11
AB	100	87.5	50	83.33	100	75	100	92.31	100	100	N/A
CD	100	100	100	75	75	100	100	100	100	100	100
EF	92.59	100	96	96.3	88.46	65.38	92	100	100	100	N/A

Table 2. Participant ratings of effort and worry across baseline (grey) and intervention (white) phases.

	Week	1	2	3	4	5	6	7	8	9	10	11
AB	Effort	3	4	3	4	3	3	2	2	3	2	N/A
	Worry	3	4	4	3	3	2	3	2	3	3	N/A
CD	Effort	1	1	1	1	1	1	1	1	1	1	1
	Worry	1	1	1	1	1	1	1	1	1	1	1
EF	Effort	5	5	5	4	5	5	5	5	5	5	N/A
	Worry	4	4	4	4	4	4	4	4	4	4	N/A

Table 3. Nominated persons ratings of effort and worry across baseline (grey) and intervention (white) phases.

	Week	1	2	3	4	5	6	7	8	9	10	11
AB	Effort	2	4	3	2	3	2	3	2	2	2	N/A
	Worry	3	3	3	4	4	3	3	3	3	3	N/A
CD	Effort	1	1	1	1	1	1	1	1	1	1	1
	Worry	1	1	1	1	1	1	1	1	1	1	1
EF	Effort	1	1	2	2	2	3	2	3	3	2	N/A
	Worry	3	3	3	3	3	3	3	3	2	4	N/A

Appendix 2.13. Text reminder data

Participants were asked to send 3 text messages to the researcher per week on random days and times across 7 days per week, between 9am and 5pm. Text reminder data for all participants across baseline (grey) and intervention (white) phases.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AB	1	2	2	0	0	2	2	0	2	2	2	2	2	2	2	2	2	0	1	2	2	2	2	2	2	0	2	2	2	0	1	2	2	0	0	2	2	0	2	X	X	X
CD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	2	1	2	2	2	1	2	2	2	2	2	2	2	2	2	2
EF	2	2	2	2	2	2	2	2	2	0	2	2	2	2	2	1	2	2	0	2	2	2	2	2	2	2	0	2	2	0	2	2	2	2	2	2	2	2	2	X	X	X

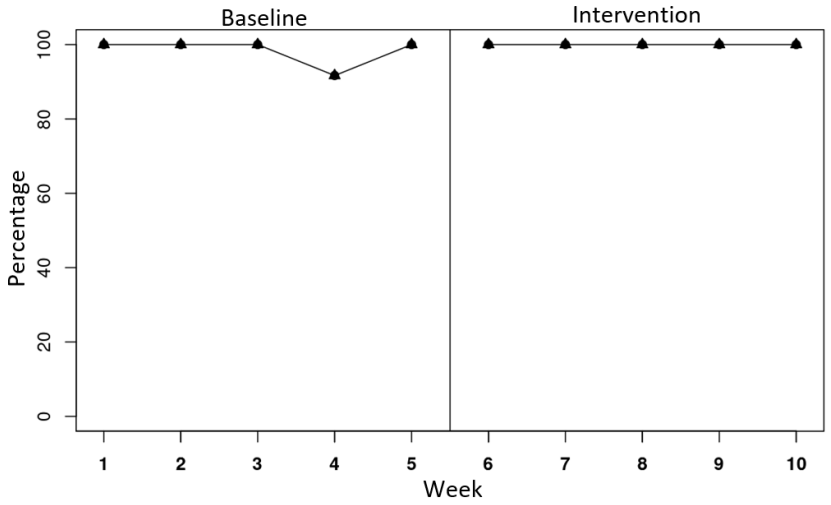
0=Forgot; 1=Completed late (>15mins post-intended time); 2=Completed on time (≤15mins of intended time)

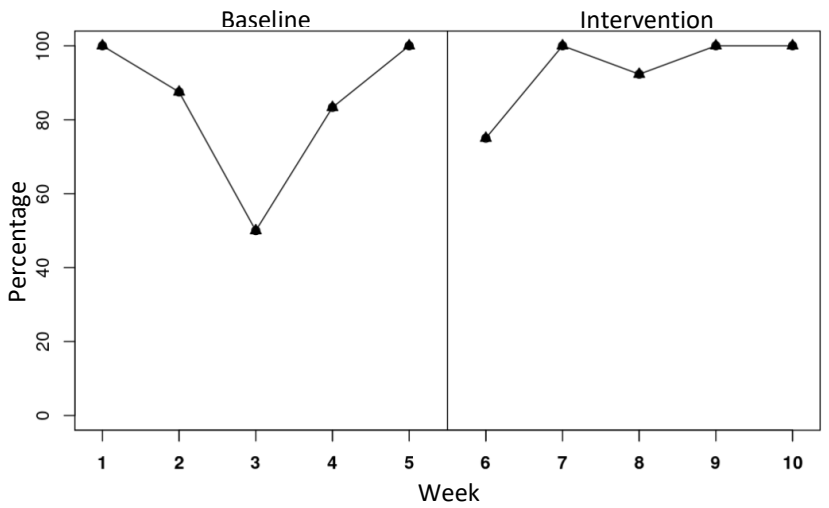
Appendix 2.14. Supplementary data analysis

Figure 1.

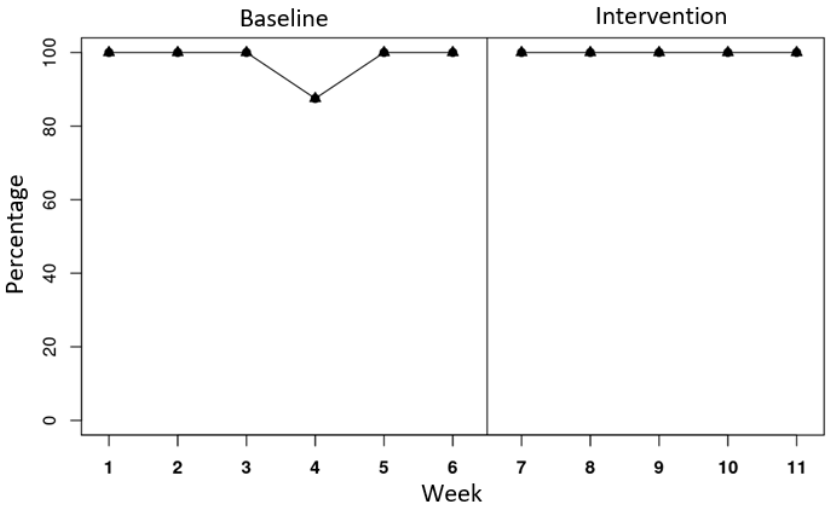
Comparison of two different measures of weekly prospective memory (PM) performance: 1. Percentage of weekly PM task completion using Yes/No format as per Wilson (2021) (Left), versus 2. Percentage of weekly PM tasks completed "on time" or "early" and unprompted, used within the current study (Right). PM performance data are presented across study phases for (a) AB, (b) CD, and (c) EF.

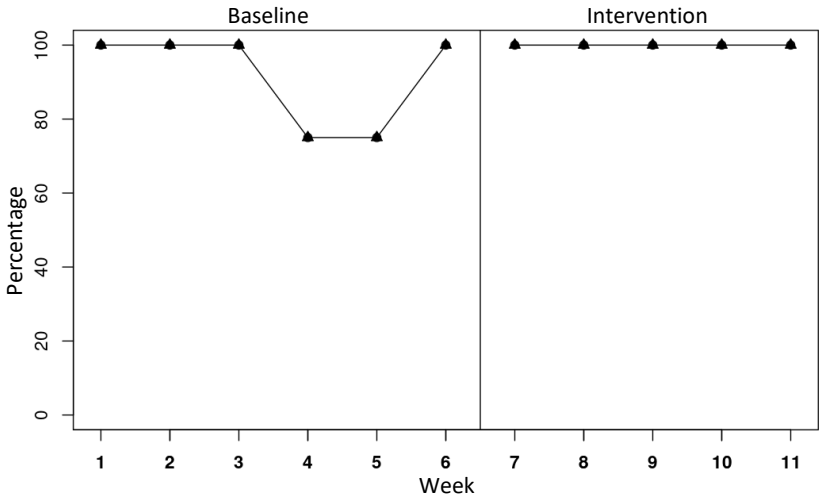
(a) AB



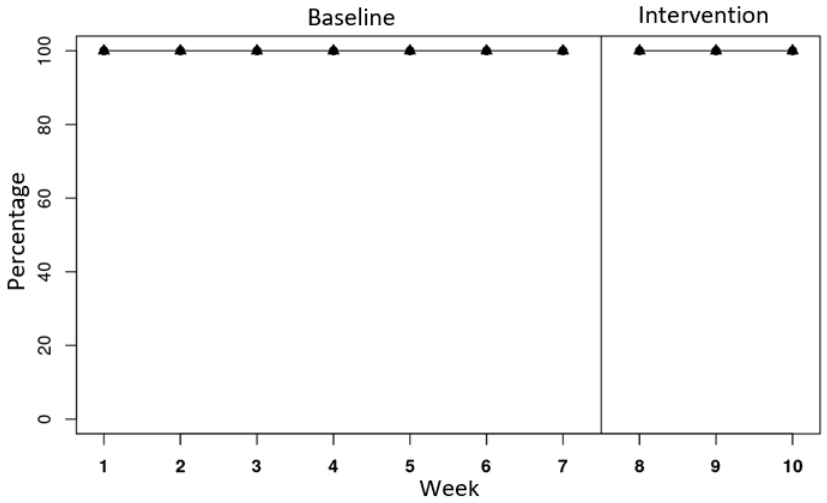


(b) CD


Baseline
Intervention
Percentage
0
20
40
60
80
100
1
2
3
4
5
6
7
8
9
10
11
Week


Baseline
Intervention
Percentage
0
20
40
60
80
100
1
2
3
4
5
6
7
8
9
10
11
Week

(c) EF


Baseline
Intervention
Percentage
0
20
40
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80
100
1
2
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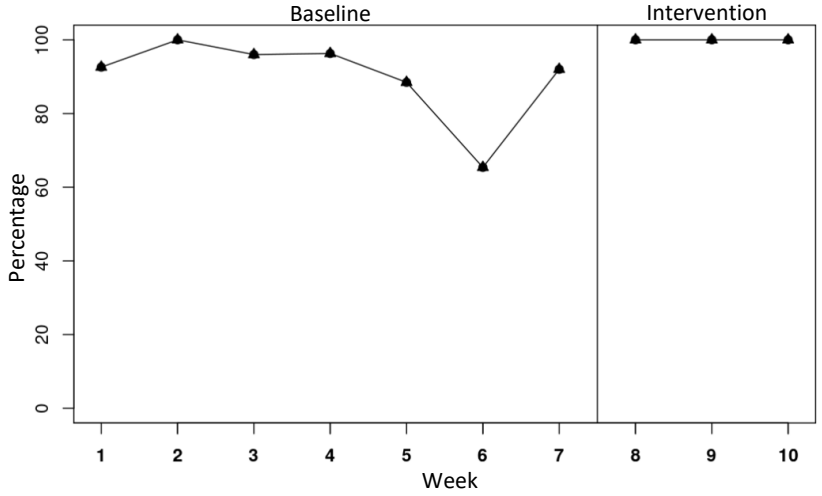
10
Week


Baseline
Intervention
Percentage
0
20
40
60
80
100
1
2
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4
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8
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10
Week

Appendix 2.15. The Single-Case Reporting guideline In BEhavioural interventions (SCRIBE) 2016 Checklist

The Single-Case Reporting guideline In BEhavioural interventions (SCRIBE) 2016 Checklist

Item number	Topic	Item description	Notes
TITLE and ABSTRACT			
1	Title	Identify the research as a single-case experimental design in the title	Page 47
2	Abstract	Summarise the research question, population, design, methods including intervention/s (independent variable/s) and target behaviour/s and any other outcome/s (dependent variable/s), results, and conclusions	Page 51
INTRODUCTION			
3	Scientific background	Describe the scientific background to identify issue/s under analysis, current scientific knowledge, and gaps in that knowledge base	Pages 52-55
4	Aims	State the purpose/aims of the study, research question/s, and, if applicable, hypotheses	Pages 55-56
METHODS			
	DESIGN		
5	Design	Identify the design (e.g., withdrawal/reversal, multiple-baseline, alternating-treatments, changing-criterion, some combination thereof, or adaptive design) and describe the phases and phase sequence (whether determined *a priori* or data-driven) and, if applicable, criteria for phase change	Page 56
6	Procedural changes	Describe any procedural changes that occurred during the course of the investigation after the start of the study	N/A
7	Replication	Describe any planned replication	Pages 58, 81
8	Randomisation	State whether randomisation was used, and if so, describe the randomisation method and the elements of the study that were randomized	Page 56
9	Blinding	State whether blinding/masking was used, and if so, describe who was blinded/masked	Page 56
	PARTICIPANT/S or UNIT/S		
10	Selection criteria	State the inclusion and exclusion criteria, if applicable, and the method of recruitment	Page 57-58
11	Participant characteristics	For each participant, describe the demographic characteristics and clinical (or other) features relevant to the research question, such that anonymity is ensured	Pages 59-61
	CONTEXT		
12	Setting	Describe characteristics of the setting and location where the study was conducted	Page 63
	APPROVALS		
13	Ethics	State whether ethics approval was obtained and indicate if and how informed consent and/or assent were obtained	Page 61
	MEASURES and MATERIALS		
14	Measures	Operationally define all target behaviours and outcome measures, describe reliability and validity, state how they were selected, and how and when they were measured	Pages 61-63
15	Equipment	Clearly describe any equipment and/or materials (e.g., technological aids, bio feedback, computer programs, intervention manuals or other material resources) used to measure target behaviour/s and other outcome/s or deliver the interventions	Pages 57, 61-63
	INTERVENTIONS		
16	Intervention	Describe intervention and control condition in each phase, including how and when they were actually administered, with as much detail as possible to facilitate attempts at replication	Pages 64-65
17	Procedural fidelity	Describe how procedural fidelity was evaluated in each phase	Page 64
	ANALYSIS		
18	Analyses	Describe and justify all methods used to analyse data	Pages 66-67
RESULTS			
19	Sequence completed	For each participant, report the sequence actually completed, including the number of trials for each session for each case. For participant/s who did not complete, state when they stopped and the reasons	Page 58
20	Outcomes and estimation	For each participant, report results, including raw data, for each target behaviour and other outcome/s	Figures 2.1, 2.2 Appendices 2.12, 2.13
21	Adverse events	State whether or not any adverse events occurred for any participant and the phase in which they occurred	None
DISCUSSION			
22	Interpretation	Summarise findings and interpret the results in the context of current evidence	Pages 77-78, 82-83
23	Limitations	Discuss limitations, addressing sources of potential bias and imprecision	Pages 82-83 Pages
24	Applicability	Discuss applicability and implications of the study findings	82-83
DOCUMENTATION			
25	Protocol	If available, state where a study protocol can be accessed	Page 61, Appendix 2.11
26	Funding	Identify source/s of funding and other support; describe the role of funders	N/A