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# ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application with Community-Dwelling Adults Who Have Sustained a Stroke

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Submitted in partial fulfilment of the requirements for the degree of

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## Chapter 1

## The Efficacy of Smartphone and Other Portable Electronic Personal Assistance Devices as Reminding Tools in Tasks of Prospective Memory in Adults Following Stroke: A Systematic Review

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#### Abstract

A systematic review was conducted to assess the efficacy of portable electronic personal assistant devices (PEPADs) in the rehabilitation of prospective memory (PM) following stroke. Methodological quality of included studies was also assessed. Seven electronic databases were searched as well as hand searching of references. Quantitative investigational studies of PEPADs for memory impairment following stroke with adults were considered. The Physiotherapy Evidence Database scale (PEDro) and the Risk of Bias in N of 1 Trials (RoBiN-T) were used to assess risk of bias. A narrative synthesis of findings is presented. Two single case evaluation design studies (SCEDs) and three controlled trials met inclusion criteria. The mean PEDro score was 5/10, the mean RoBiN-T score was 14/30. Mobile phones were the most investigated PEPAD. Study design was heterogenous. Small-large effect sizes were evident when PEPADs were introduced and large effect sizes following their removal. Most participants completed more PM tasks using a PEPAD than a paper-based memory aid in one study. One study found continued PEPAD use at long-term follow-up. PEPADs are a promising avenue in the rehabilitation of post-stroke PM impairment. However, the evidence base is limited. More rigorously designed, long-term SCED and group studies are required to inform clinical practice.

Keywords; stroke, smartphone, cognitive rehabilitation, prospective memory, memory aid

#### Introduction

Stroke is a life-threatening, cerebrovascular accident which results in cerebral dysfunction (Zhelev et al., 2019). Adults aged 65+ years (older adults) are more likely to experience a stroke than younger adults (Michael & Shaughnessy, 2006) and up to two thirds of stroke patients are discharged from hospital with some form of impairment (Adamson et al., 2004). Common post-stroke impairments include physical disability, psychological disorders, and cognitive impairment (Ferro et al., 2016). The most commonly reported post-stroke cognitive impairment is memory, affecting approximately one third of stroke survivors (Novitzke, 2008).

Memory impairments can affect a person's ability to recall past events (retrospective memory) as well as affect their ability to carry out intended actions in future (prospective memory). Prospective memory (PM) is defined as the realising of delayed intentions (Ellis, 1996). Impairments in PM can affect a person's ability to carry out activities of daily living, such as attending appointments and taking medications (Wolf et al., 2009), which can be deleterious to the person's long-term functional independence (Baumann et al., 2011). Memory impairments are strong, negative predictors of quality of life and affect quality of life to a larger extent than other post-stroke impairments such as communication and physical disabilities (Mitchell et al., 2010). It is clear that the cognitive sequelae of stroke can be debilitating and the rehabilitation of such impairment warrants substantive focus (Fish et al., 2007).

#### Cognitive Rehabilitation (CR)

CR utilises an individualised, problem-solving approach to re-establish old, or develop new, strategies and approaches to compensate for a person's acquired cognitive difficulties, supporting the person to improve their everyday functioning and enhance their quality of life (Kudlicka et al., 2019; Cicerone et al., 2000). CR was identified as one of the top ten research priority areas by researchers and stroke survivors (James Lind Alliance, 2021). CR of memory following stroke can employ either a restorative approach, which aims to restore memory function through repetitive memory training, or a compensatory approach, which uses environmental adaptations, and internal and external strategies to aid memory performance (Spreij et al., 2014). Memory strategies can either be 'internal', using mnemonic devices and rehearsal, or 'external', using memory aids such as diaries and calendars; the latter of which have been recommended for post-stroke memory impairment (Cicerone et al., 2011).

#### Memory aids

External memory aids can be non-electronic or electronic, and aim to improve memory performance through providing reminders to complete intended tasks. Although non-electronic memory aids are effective in the rehabilitation of memory (Sohlberg et al., 2007) and are low-cost in comparison to electronic memory aids, there are some practical disadvantages to their use. Non-electronic memory aids provide 'passive reminders' (Dowds et al., 2011; Andreassen et al., 2017), thus, the person must remember to check the memory aid to remind them to complete a future task or 'remember to remember' (Crystal & Wilson, 2015). There are a wide variety of electronic memory aids available including digital alarm clocks and calendars, mobile phones and personal digital assistants (PDAs), as well as virtual assistant technologies such as Amazon's Alexa, amongst others. Many of these electronic memory aids and assistive technologies could be helpful in the rehabilitation of memory disorders following stroke through the provision of 'active reminder' prompts which alert the person to complete a task. Whilst there are several terms used to refer to these technologies, one common umbrella term is Electronic Personal Assistive Devices (EPADs).

#### **EPADs**

The efficacy of EPADs in improving memory in the field of CR has been investigated for several decades (de Joode et al., 2012). Some of the EPADs investigated include large everyday electronic devices, such as televisions (Lemoncello et al., 2011) and personal computers (Lindqvist & Borell, 2012). Recently, more portable devices have been investigated in memory rehabilitation following acquired brain injury (ABI), including pagers, mobile phones and smartphones. Several Portable Electronic Personal Assistant Devices (PEPADs) have been found to be efficacious in enhancing PM performance (Wilson et al., 2001; Fish et al., 2008; Stapleton et al., 2007), although, their use remains relatively low with people living with an ABI (Jamieson et al., 2017).

#### Issues in using PEPADs in PM rehabilitation

A range of social, physical and practical factors may influence a person's use of assistive technology following ABI (Baldwin et al., 2011), including how acceptable it is to use, whether its use is relevant in daily life (Gell et al., 2015), and whether the person is motivated to use it (Heart & Kalderon, 2013). Despite an increase in the use of technology, older adults are less likely than younger adults to own devices such as smartphones which could be used as a PEPAD (Onyeaka et al., 2021). Studies have found a negative association between age and technology use (Evans et al., 2003) and between visual and memory impairments and technology use (Gell et al., 2015). These findings highlight how the ability to learn how to operate an electronic memory aid and then successfully maintain its use in the

long-term, are important issues in the field of PEPADs in the rehabilitation of memory impairment following an ABI (Boman et al., 2010). Studies in this field have been criticised for lacking clarity in reporting the training participants received and the absence of evidence of long-term outcomes (Cicerone et al., 2019). These factors warrant significant consideration in the use of PEPADs in the cognitive rehabilitation of PM impairment following stroke, where several of the above factors such as age, memory impairment and access to support in using EPAD technology, may intersect.

#### **Previous reviews**

Systematic reviews have reported on the efficacy of EPADs, including some PEPADs, in the rehabilitation of PM impairment within TBI and mixed ABI studies (Jamieson et al., 2014; Charters et al., 2015; Mahan et al., 2017). Concerns regarding methodological quality and long-term outcomes in this field have been raised (Jamieson et al., 2014). A scarcity of research investigating the efficacy of PEPADs in post-stroke PM rehabilitation is apparent from these reviews, making it difficult to ascertain whether PEPADs are efficacious in the rehabilitation of PM impairment following stroke.

#### **Current review**

This systematic review aims to evaluate the efficacy of PEPADs in the rehabilitation of post-stroke PM impairment. Intervention studies recruiting stroke participants, mixed ABI populations with at least 50% stroke participants or studies reporting individual participant outcome data, if less than 50% stroke participants, were considered for inclusion. The objectives of this study were to:

- Evaluate the efficacy of PEPADs in the rehabilitation of post-stroke PM impairment
- Review long term outcomes relating to the efficacy of PEPADs
- Report on the types of PEPADs investigated
- Comment on whether participants received training in the use of the PEPADs
- Assess the methodological quality of studies

#### Method

A protocol was registered on Prospero, reference number CRD42020224530, <u>https://www.crd.york.ac.uk/prospero/display\_record.php?RecordID=224530</u>) on 15/12/2020. The reporting of this review is in accordance with the PRISMA 2020 checklist (Page et al., 2021). As it was anticipated that the studies would vary widely in their design, and a meta-analysis was not possible, a narrative synthesis of findings is presented instead.

#### Eligibility criteria

Human studies in peer-reviewed journals written in English, were eligible for inclusion. Studies were required to report quantitative PM data. Inclusion based on study design or date of publication was not considered due to the limited number of studies in the field. Studies included pre-post designs, Randomised Clinical Trials (RCTs), Controlled Clinical Trials (CCTs) and Single Case Experimental Designs (SCED). Methodology papers, dissertations, review papers, conference reports and books were excluded.

#### Participants

Participants ≥18 years with subjective or objective PM impairment due to a medically confirmed stroke of any aetiology, without any pre-existing PM impairments, severe mental health difficulties, neurological conditions or learning disabilities. Group studies were required to consist of ≥50% stroke patients or report individual data.

#### Intervention

Experimental studies which investigated smartphone-based reminder applications or any other PEPAD were included. As a wide variety of technological interventions were identified, discussion was had between two raters on what was considered to be a PEPAD. Any EPAD which could feasibly be held, operated and transported in one hand was considered to be a PEPAD.

#### Comparator

Within-group and between-group study designs with either a waiting list control or an active, nontechnological memory aid control condition, as well as SCED studies utilising baseline and intervention phases and/ or return to baseline phases, were considered for inclusion.

#### Outcome

Studies were required to report quantitative PM outcomes using either formal PM assessment or self/other reported PM performance. SCED studies must report changes in PM outcomes between phases, such as changes in PM event completions.

#### Information sources

The following electronic databases were searched; MEDLINE, Embase, PsycINFO, CINAHL, PubMed, Scopus and Web of Science, for all studies from inception until the date of the search execution (12/10/2020).

#### Search strategy

A systematic database search was conducted using keywords gathered from studies in the field in order to identify articles for screening against the eligibility criteria. The search strategy used truncated terms to accommodate for UK, English/ US, English spelling differences and plurals, and was modified for imputation as required across each of the seven databases (Appendix 1.2).

#### **Study Selection**

The titles and abstracts of the articles identified through the search strategy were screened to determine whether they met the inclusion criteria for the review by the first rater, JW. A second rater (HP) screened 25% of papers identified through the execution of the search strategy. There was a 99% agreement between the two raters on papers to be included. Disagreements related to EPADs which were considered portable. Inclusion criteria was then refined to consider EPADs which could be used and transported in one hand. Of the articles which met the inclusion criteria, the full-text of the article was screened against the PICO criteria identified above.

#### Data collection process

In addition to the variables presented in the characteristics of included studies table (Table 1.1), additional study data was extracted into an excel spreadsheet with a column for each variable which was checked for accuracy by HP. The additional variables included the number of stroke patients in each study, the stroke aetiologies, demographics of participants and the study inclusion criteria.

#### Risk of bias

The methodological quality of included studies was evaluated according to the study design. For group studies, the PEDro scale (Maher et al., 2003) was used and for SCED studies, the RoBiN-T scale was used.

The PEDro scale (Appendix 1.3) consists of 11 items where a zero or one-point score is awarded on each item, with the exception of item one which is omitted from scoring, giving a total score out of ten. The PEDro has demonstrated reliability and validity, and good to substantial kappa consensus values with 2-3 raters (Maher et al., 2003). The PEDro scale is a comprehensive measure in the assessment of study methodologies in stroke rehabilitation (Bhogal et al., 2005) and has been utilised in studies utilising several different methodological designs (Moseley et al., 2015). The average study score using the PEDro scale is 5.1 (PEDro, 2021).

The RoBiN-T (Appendix 1.4) consists of two subscales; a seven-item internal validity subscale and an eight-item external validity subscale. A zero, one or two-point score is awarded for each of the 15 items, over the two subscales, according to the scoring criteria outlined in the RoBiN-T manual, with a total score out of thirty. The RoBiN-T total and subscale scores have demonstrated good validity and inter-rater reliability for pairs of raters (Tate et al., 2014).

In this review, studies were evaluated independently by two raters, JW and HP, using the two methodological rating scales above. HP assessed 20% of the papers to establish inter-rater reliability. There was a 91% agreement between the two raters suggesting adequate inter-rater reliability. Discrepancies were then resolved through discussion between the two raters.

#### Results

#### **Included Articles**

The records identified according to the systematic review inclusion criteria are displayed in the PRISMA flow chart below (Figure 1.1). Of the 1079 total papers identified, 205 duplicates were removed and therefore, 874 papers were title and abstract screened to determine whether they met the inclusion criteria for the review. Twenty-three papers were full text and reference screened of which five met the inclusion criteria and were included in the review.

### Table 1.1

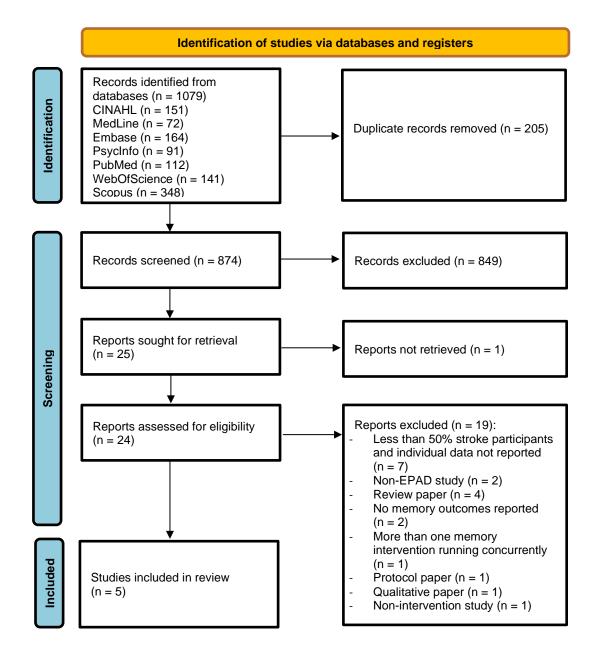
Characteristics of Included Studies

Reference	Method quality rating score	Number of stroke patients	Study Design	Technology used	Training provided	Reminders and tasks to be completed	Follow up period	Findings
Svoboda et al (2015)	RoBiNT 15/30 Internal 4/14, external 11/16	4	Within subjects ABABB multi- case, experim -ental design	Smartphone or PDA	Yes, median number of trials to reach 98% accuracy = 87.5, range (42- 229)	Set up reminder calendar events to make 10 phone calls	Yes	Friedman test revealed a significant difference in prospective memory mistakes across study phases (X <sup>2</sup> (3) = 8.63, p = .035. Post-hoc Wilcoxon signed-ranks test demonstrated a statistically non-significant difference in the number of prospective memory mistakes made at long-term follow-up relative to baseline A <sup>1</sup> (z = -1.19, p = .23, $r = -0.37$ ) and return to baseline B <sup>1</sup> (z =77, p = .44, $r = -0.24$ ) or short-term follow-up B <sup>2</sup> (z = -1.90, p = .058, $r = -0.60$ ).
Kamwesig -a et al (2018)	PEDro 4/11	28	Pre-post design	Mobile phone	Yes, duration and training methods not stipulated	Two daily SMS reminders to complete memory tasks and a once daily text to rate own memory performance	No	Mann Whitney U analysis of self-report Stroke Impact Scale (Ugandan version) demonstrated no significant differences in memory scores between the intervention and control group at baseline $p = .2$ or at eight-week follow-up, $p = .4$ . Mean change in scores between baseline and follow-up $p = .2$ .
Jamieson et al (2019)	RoBiNT 12/30 Internal 3/14, external	2	ABA Single Case Experim	Motor365 smartwatch with smartphone pairing	10- minute demonst- ration and 20-	Daily tasks of memory successfully completed and recorded	No	Non-overlapping pairs analysis showed a non-significant change in memory performance when the smartwatch was introduced for participant one, NAP03 p = 1.0, and for participant two NAP .28 p = .20.

	9/16		-ental Design		minute assessme nt. 100% accuracy required to go into trial. Training manual provided.	on a daily memory log. SMS messages to send after each memory event completed		Memory performance significantly decreased during the return to baseline phase for participant one NAP81, p < .01 (medium effect of phase change), and for participant two NAP58, p < .01 (small effect of phase change).
Fish et al (2008)	PEDro 6/11	36	Random -ised crossov- er design	Pager	Not stated	Daily tasks of memory successfully completed and recorded on a daily memory log	No	Between-group Mann Whitney U comparisons revealed significant effect of pager vs baseline; group A with pager Vs B without ( $z = 2.93$ , $p = <.01$ , $r = 0.49$ ), group B with pager, group A without ( $z = 2.51$ , $p = .01$ , $r = 0.42$ ). Within group differences over study; significant positive effect of the introduction of pager relative to first baseline; group A ( $z = 4.17$ , $p = <.01$ , $r = 0.70$ ), group B ( $z = 3.06$ , $p = <.01$ , $r = 0.21$ ) and return to baseline (only group A had this phase) in group A ( $z = -3.36$ , $p <.01$ , $r = -0.56$ ). Participants completed significantly more memory events ( $z = < 1.643$ ) using the pager than without (33/36, 92%); completing on average 34% more prospective memory tasks
McDonald et al (2011)	PEDro 5/11	4	Random -ised crossov- er design	PC with Google calendar linked mobile phone	90 minutes followed by 10- minute assessme nt; 80% accuracy required	Daily tasks of memory successfully completed and recorded on weekly monitoring forms	No	EPAD data missing for 1 of 4 stroke participants. One participant achieved 100% of memory targets across all three phases. One participant completed 34% more memory targets relative to baseline and 41% more relative to the standard diary phase. One participant completed 75% more memory targets relative to the standard diary phase (baseline phase data missing)

#### Figure 1.1

Prisma Flow Diagram of the Records Identified According to the Systematic Review Inclusion Criteria



#### **Excluded** papers

Seven papers reported less than 50% stroke participants and no individual stroke participant data was reported (O'Neill et al., 2018; de Joode et al., 2013; Gracey et al., 2017; Lannin et al., 2014; Wilson et al., 2001; Boman & Bartfai, 2009; Svoboda et al., 2012). Four were review papers (Martínez et al., 2020; Caprani et al., 2006; Brandt et al., 2020), two papers did not report any memory outcomes (Groussard et al., 2018; Andreassen et al., 2020), two studies utilised interventions which were not considered to be PEPADs (Boman et al., 2010; Lemoncello et al., 2011), one study was a qualitative study (Lindqvist & Borell, 2012), one paper was a non-intervention study (Wong et al., 2017), one paper utilised a PEPAD in conjunction with other EPADs (Boman et al., 2007) and one other paper was a protocol (Andreassen et al., 2017).

#### Risk of bias

Two papers were evaluated using the RoBiN-T (Svoboda et al., 2015; Jamieson et al., 2019), (M = 14.5, SD = 0.71). Both studies scored 11/16 and scored the maximum 2 points on 3/8 items of the external validity subscale; dependent variable, independent variable and data analysis. On the internal validity subscale, both studies scored 4/14 and both studies scored 0 on 5/7 items of the internal validity subscale; randomisation, blinding of researcher, blinding of participant, inter-rater reliability and treatment adherence. Three group studies were evaluated using the PEDro (Fish et al., 2008; McDonald et al., 2011; Kamwesiga et al., 2018), scores ranged from 4 to 6/10 (M = 5, SD = 1.00). All three studies scored 0 on items relating to the blinding of participants, therapists and assessors.

#### Demographic information and stroke aetiology

Individual demographic information from SCED studies was combined with averages from group studies (Table 1.2). It was not possible to report on demographic variables for all participants due to group level data being reported in three studies. Where this data is unknown, it is reported as unspecified. Where sex was reported, participants were 51.4% female. Stroke aetiology was 48.6% ischaemic stroke, 45.9% haemorrhagic and 5.4% unknown. Time since stroke; 35.1% were  $\leq 12$  months, 5.4% were 13-24 months and 5.4% were  $\geq 25$  months. The remaining 34 (45.9%) participants were from one study (Fish et al., 2008); the mean time since injury was reported as 3.3 years.

#### Table 1.2

Participant	Data f	from Ir	ncluded	Studies
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Total number of stroke participants	74
Aetiology of stroke	Haemorrhagic = 34
	lschaemic = 36
	Unspecified = 4
Time after stroke	≤12 months = 26
	13-24 months = 4
	≥25 months = 4
	Unspecified = 40
Sex	M = 36
	F = 38
Average age	51.6 years (SD = 7.71)

Three studies reported individual stroke participant data on memory outcomes (Svoboda et al., 2015; Jamieson et al., 2019; McDonald et al., 2011). The remaining two studies reported only group level memory outcome data (Fish et al., 2008; Kamwesiga et al., 2018).

#### Type of PEPADs

All five studies utilised a unique combination of PEPAD technologies. One study (Jamieson et al., 2019) utilised a smartphone with Google calendar software synced via Bluetooth to a smartwatch. One study investigated the use of either a smartphone or a PDA with calendar software (Svoboda et al., 2015). One investigated a mobile telephone without internet technology (Kamwesiga et al., 2018). Another study investigated the use of a mobile phone linked to a PC with Google calendar software (McDonald et al., 2011). The final study investigated a pager system (Fish et al., 2008).

#### Training

Two studies provided participants with training manuals in addition to direct training with a member of the study team (Jamieson et al., 2019; McDonald et al., 2011). Training was provided by a range of professionals including assistant psychologists, registered psychologists and researchers. All but one study reported that participants demonstrated competence in the use of the device to the researchers (Kamwesiga et al., 2018). Three studies stipulated an

assessment of competence with a percentage cut-off required in order for the participant to continue in the study; 100%, 98% and 80% respectively (Jamieson et al., 2019; Svoboda et al., 2015; McDonald et al., 2011). Three studies reported training duration in minutes, training time varied (M = 69, SD = 39.81). Only one study reported training that lasted longer than one session (Svoboda et al., 2015).

#### Summary of individual study results

Effect sizes were reported in two studies (Jamieson et al., 2019; McDonald et al., 2011). Two studies reported sufficient data for an effect size to be calculated by the review author (Fish et al., 2008; Svoboda et al., 2015).

#### Comparisons to non-active control/baseline phases

One study which achieved 6/10 on the PEDro scale, reported a statistically significant improvement in PM performance with a large effect size following the introduction of a pager and a significant decrease in PM performance with a large effect size following its removal (Fish et al., 2008). One study, which scored 15/30 on the RoBiN-T, found no significant improvement in PM performance following the introduction of the PEPAD, but a significant deterioration following its removal (Jamieson et al., 2019). Of the two stroke participants with available data in one study, which achieved 5/10 on the PEDro scale, one participant completed more memory tasks using the PEPAD than at baseline, the other reported 100% memory task performance across all study phases (McDonald et al., 2011). One study which achieved 4/10 on the PEDro scale reported no significant between or within-group differences were reported in relation to baseline in the remaining study (Kamwesiga et al., 2018).

#### Long-term follow up

One study which achieved 15/30 on the RoBiN-T, reported long-term outcomes (Svoboda et al., 2015). PEPAD usage for PM tasks was not significantly different at long-term relative to short-term follow-up, although a large effect size was calculated from group data.

#### Comparisons to active control interventions

Two stroke participants completed between 41-75% more memory events with the PEPAD than when using a paper diary. A third participant reported a 100% memory task completion rate across all three phases and a fourth had missing PEPAD phase data (McDonald et al., 2011).

#### Discussion

This review aimed to evaluate the efficacy of PEPADs in both the short and long-term, report on the types of PEPADs investigated, highlight whether participants received training in their use, report on participant feedback regarding the PEPAD and assess the methodological quality of the included studies.

#### **PEPADs**

A trend is apparent from the chronology of the studies; older studies used pagers and mobile phones without internet connectivity whereas more recent studies utilised smartphones and smartwatch technology with internet connectivity. This may reflect the development of newer, internet-connected, technologies which are ubiquitous in modern society and support users with everyday tasks, such as Amazon's Alexa virtual assistant, and thus superseding older communication technologies (Wong et al., 2017). An exception to this trend was found in a recent study in sub-Saharan Africa which utilised a traditional mobile phone without internet capabilities (Kamwesiga et al., 2018). Mobile phones are reported to be increasingly accessible and affordable, and perceived to be very important in enhancing functioning in everyday living for sub-Saharan stroke survivors and families (Kamwesiga et al., 2017). This highlights the importance of considering wider individual and societal contexts in the development and evaluation of cognitive rehabilitation strategies, such as PEPADs, for PM impairment following stroke by clinicians and researchers.

Calendar software was used to send reminder prompts to the user's PEPAD in three of the five studies (Svoboda et al., 2015; Jamieson et al., 2019; McDonald et al., 2011). Studies have found that reminder prompts can result in a higher memory task completion rate than using paper calendars (Dowds et al., 2011), a finding replicated by McDonald et al. (2011). A possible explanation of this finding may be that electronic calendars do not require the person to remember to check their calendar like they would with a paper calendar. Instead, electronic calendars deliver an active reminder prompt directly to the user's PEPAD, at a pre-set time, notifying them of their intention to complete a pre-specified task, at a pre-specified time. Interestingly, the only mobile phone-based study which did not use an electronic calendar, instead participants received a text message listing their chosen memory tasks to be completed twice daily, found no difference in task completion rates between the PEPAD and non-PEPAD control group. This highlights that PEPADs with calendar functions that provide active reminder

prompts to complete prespecified tasks at pre-specified times may be efficacious in the rehabilitation of PM impairment following stroke.

Although four of the five studies utilised mobile/smartphones, each study had a unique combination of PEPAD and reminder software. Therefore, this review concurs with earlier reviews that it is not practical to assess the efficacy of an individual type of PEPAD (Dewar et al., 2018). Instead, it may be more meaningful to review whether PEPADs are efficacious and acceptable to people affected by specific clinical presentations, such as TBI or stroke, in order to inform clinical guidelines for individual conditions.

#### Efficacy

This review highlighted a mixed picture of the efficacy of PEPADs in the rehabilitation of PM impairment following stroke. One study, with four stroke participants, reported an increase in PM performance using the PEPAD in comparison to a paper-based diary in two participants and in one participant in comparison to no memory aid. The remaining stroke participant reported a 100% memory task completion across all study phases. Interestingly, two of four stroke participants reported a baseline PM task completion rate of over 92% (McDonald et al., 2011). Other studies have also reported high baseline PM performance making it difficult to report any measurable, positive effect of the PEPAD despite self-reported PM difficulties (Evald, 2018). There may be several possible explanations of this high baseline performance, such as a novelty effect of taking part in the study and study-related stimuli (Jamieson et al., 2019) or that prior to the baseline phase commencing, participants established new routines involving the study target memory events (McDonald et al., 2011). Insight into memory difficulties on self-report measures (Wilson et al., 2001) and the degree of the person's cognitive and executive impairment (Stapleton et al., 2007) have also been highlighted as important factors in establishing the efficacy of PEPADs following ABI. Although it was not possible to draw conclusions on whether PEPADs or non-technological memory aids are superior in the rehabilitation of PM following stroke, this finding may indicate that patients and clinicians have an array of efficacious memory aids to trial if either PEPADs or paper-based memory aids are not beneficial or practical for the person (de Joode et al., 2012; Lannin et al., 2014).

Although findings relating to the introduction of PEPADs on PM performance following baseline were mixed, findings revealed lower PM performance when the PEPAD was removed in both SCED studies. Interestingly, when baseline and return to baseline PM performance were compared, findings varied considerably. Whilst previous studies have reported better PM

performance in the return to baseline phase than in the baseline phase (Wilson et al., 2001), highlighting a potential role of repeated performance of memory events during the intervention leading to habit formation (Baldwin et al., 2011), one study in this review found the opposite; better baseline PM performance than return to baseline performance. One possible explanation that the authors considered was reduced motivation due to having received the intervention and then it being withdrawn (Jamieson et al., 2019). Future studies may consider an ABB design with a second intervention phase, for example a paper-based diary, to potentially maintain motivation throughout the study. Another explanation may be that baseline performance was artificially elevated due to a researcher cueing effect, whereby the introduction of the PM tasks acted as a cue to complete PM tasks and therefore, baseline PM performance was not a true reflection of participants pre-study PM performance (Fish et al., 2007).

Overall, a tentative positive effect of PEPADs emerges from the limited literature base; PEPADs may result in the completion of more PM tasks through active prompt reminders and be an alternative to non-technological memory aids.

#### Long-term outcomes

Cicerone et al (2000) highlighted the importance of long-term follow-up with people using memory aids, particularly as this relates to the ability to generalise treatment effects beyond the context of the rehabilitation intervention. In this review, one mixed ABI aetiology study reported promising long-term outcomes of PEPAD use at 19-month follow-up (Svoboda et al., 2015). However, from the graphical data reported, it was not possible to identify the stroke participants and only group level statistical analysis was reported. Although it is unknown whether any of the stroke participants continued to report a positive effect of device use, trends observed from the graph indicate continued use for most study participants. The dearth of available evidence regarding the use or efficacy of PEPADs for post-stroke PM impairment means that limited conclusions can be drawn regarding the generalisability of treatment gains beyond the initial study period.

#### Training

Previous reviews have highlighted that participants may require considerable training in the operation of EPADs (Cicerone et al., 2005), but in one study, most participants stated they were not concerned about the duration of training as it was important in increasing their confidence in operating the device (de Joode et al., 2012). Three of the five studies in this review provided detailed descriptions of training protocols and durations (which varied considerably), with a

mean of less than 70 minutes. This highlights that a relatively short but thorough training in the use of PEPADs from clinicians may be effective in improving participant confidence in the use of PEPADs as reminder tools for tasks of PM following stroke. Two studies provided participants with reference materials in the operation of the EPAD in addition to training. Stroke participants have highlighted that watching someone use the PEPAD in person and watching training videos are two of the most important strategies in learning how to use PEPADs (Wong et al., 2017). Future studies may benefit from reporting training durations, protocols and reference materials, as well as any assessment of competence in the use of the PEPAD.

Additionally, the support participants receive from a nominated person in the use of PEPADs has been identified as a means of improving their value (de Joode et al., 2012), with some studies explicitly adopting a family-orientated approach (Kamwesiga et al., 2018). Future studies may benefit from reporting whether the participant and a nominated person who supports them in the use of the PEPAD were assessed as competent in its use. Two studies in this review provided details of the assessment of participant competence in using the PEPAD in order to progress in the study, but no study reported such competence for a nominated person. In order to support participants in the use of PEPADs during the study, research team members also require competence in its use (Wong et al., 2017). Therefore, it may be useful for future studies to report the training the trainer received and assessment of their level of competence in using the PEPAD in order to improve confidence in any potential treatment effect of the PEPAD investigated.

#### Methodological quality

The methodological quality of SCED research has been reported to be very variable (Tate et al., 2013). Practical difficulties in achieving some aspects of internal validity have been highlighted in previous SCED studies investigating PEPADs in the rehabilitation of PM memory (Jamieson et al., 2014). One issue is the ability to blind participants and assessors during the intervention. Both studies reviewed using the RoBiN-T scored 0 points for blinding of participant and blinding of assessors and scored less than 30% of the points available on the RoBiN-T measure of internal validity. Furthermore, none of the three group studies scored a point on any PEDro item relating to blinding or scored more than 50% of the points available on the internal validity subscale either. Whilst blinded assessors and concealed allocations group/ treatment conditions could enhance internal validity, the feasibility of achieving blinding in non-pharmacological trials has been regarded as difficult to achieve and maintain (Boutron et al., 2004). Future studies could take steps to address other, more practical risks of potential bias, such as randomisation to

treatment or study phase in SCED studies. In addressing these practical risks, greater confidence in the effect of the PEPAD may be afforded.

According to Tate et al. (2014), two critical conditions for SCEDs are that studies must have discrete phases of intervention application and/or a withdrawal phase, and that the dependent variable is measured repeatedly in all study phases. Although the RoBiN-T does not penalise a study for having only one data point per phase on the scoring criteria for item 1: Design, it is worth noting that the Svoboda et al. (2015) study only reported one data point during each phase, which may call in to question whether this is in fact a SCED, according to Tate et al. (2014). In addition to meeting the RoBiN-T scoring criteria, the Svoboda et al. (2015) study reported individual memory outcome data in addition to group level data and therefore, the RoBiN-T was regarded as a useful tool to comment on the methodological quality of this study.

Baseline conditions varied considerably in the included studies, from the cessation of the use of all existing memory aids to continued use of any current memory aid, to employing ABA and ABB study designs. These variations in design and baseline memory aid conditions complicate comparisons of effect of PEPADs across the limited number of studies. It could also be argued that withdrawal designs which instruct participants to stop using any memory aids for a number of weeks, particularly participants who report high baseline PM performance using them, could be deleterious to their everyday functioning and be considered unethical.

#### Limitations

There are several limitations to this review. Only 25% of abstracts were screened by a second reviewer and one author full-text screened articles for inclusion. It may be that some articles which may have met the study inclusion criteria were excluded during screening.

Seven mixed ABI aetiology papers which included stroke participants were excluded from the review as individual data was not reported or not received which could have impacted the conclusions of this review. Should this data become available, a more comprehensive understanding of the efficacy of PEPADs in the rehabilitation of PM impairment may emerge to inform clinical guidelines and practice. Future mixed aetiology group studies would benefit from publishing individual data or raw data so that future reviews can pool data according to various factors, such as aetiology, cognitive presentation or study design.

Heterogeneity in study design and analysis precluded a meaningful meta-analysis. Instead, a narrative report of outcomes and methodologies was employed. This limits the ability to draw

conclusions of effect in this review and limits the interpretation of the limited data available for the efficacy of PEPADs in the rehabilitation of PM impairment following stroke. Furthermore, due to the high degree of heterogeneity in study design and statistical analysis, a considerable variability in the presentation of data, the presence of missing data and not receiving the requested individual participant data from some authors, it is very difficult to draw conclusions on the broad efficacy of PEPADs, or recommend any specific PEPADs, in the rehabilitation of PM impairment following stroke from the studies included in this review.

#### Conclusion

Electronic technologies as external memory aids have been recommended as a 'practice standard' in the rehabilitation of PM following stroke and TBI (Cicerone et al., 2019). Although several studies have found that PEPADS, including pagers and smartphones, are efficacious in memory rehabilitation following ABI, a dearth of studies investigating the efficacy of PEPADs in the rehabilitation of PM impairment following stroke was found. A mixed but promising evidence base emerged as well as an apparent trend in the type of PEPAD technologies being investigated with several more recent studies investigating calendar software linked to a mobile phone or smartphone. However, this review highlights that the long-term efficacy of PEPADs in the rehabilitation of PM following stroke remains to be established. The methodological quality of included studies were also rated as quite low, with low scores observed on measures of internal validity. Whilst some concerns regarding internal validity could be ameliorated through blinding and randomising participants to treatment or study phase, this may be difficult to achieve in practice, particularly in SCED studies. These findings highlight how further, innovatively designed research investigating both the short- and long-term efficacy of PEPADs in the rehabilitation of PM impairment following stroke are required in order to inform clinical guidelines.

In summary, PEPADs may enhance PM performance on tasks of everyday living and may be a valuable alternative to, if not an improvement on, non-technological external memory aids. This may have clinical implications in increasing the number of efficacious memory aids available to people with post-stroke PM impairment whilst considering the patient's personal and societal context and preference.

#### Conflicts of interests and funding information

No conflicts of interests to disclose. No funding was received for this study.

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Chapter 2

## ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application with Community-Dwelling Adults Who Have Sustained a Stroke

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# Plain language summary

### Title

ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application with Community-Dwelling Adults Who Have Sustained a Stroke

### Background

Up to a third of people report difficulties with memory following stroke. Difficulties remembering to do things at a future point or 'prospective memory' (PM) can affect a person's ability to complete everyday tasks of daily living, such as attend appointments, and limit their independence. Memory aids can be helpful in reducing memory difficulties following stroke by reminding someone to complete an intended task. Memory aids can be paper-based; such as wall calendars, which a person must remember to check for upcoming events, or electronic, such as smartphones which can alert a person about upcoming tasks. One smartphone application developed as an electronic memory aid is ApplTree. Users can enter details of upcoming events and set a reminder to alert them at a specific time to an upcoming event.

#### Aims

This study aimed to investigate whether the use of ApplTree would lead to a significant increase in the number of everyday tasks of PM successfully completed by stroke participants in comparison to using their current memory aid(s). This study also aimed to investigate whether participants regarded ApplTree as a usable and acceptable memory aid.

#### Method

Three community-dwelling stroke survivors with self- or other-reported difficulties with PM identified some everyday tasks of PM which were important to them. Participants recorded these tasks in advance of their occurrence on a memory log during each day of the study. Participants then used their current memory aids for either 5-, 6- or 7-weeks (without ApplTree) before receiving training in how to use ApplTree. Participants then entered the identified tasks on to ApplTree and set reminders to complete them over a 5-week period. Each participant nominated their partner to record whether they remembered to complete the identified tasks at the time they intended to, at the end of each day. At the end of the study, participants completed a questionnaire about their experience using ApplTree.

# Results

Although all three participants reported PM difficulties, all three participants reported a high number of PM tasks completed using their own memory aids. ApplTree did not result in a significant increase in the number of PM tasks completed. However, all participants predicted that they would continue to use ApplTree over the next 3 months and reported scores which indicated that ApplTree was acceptable and usable.

# Conclusions

Participant scores on the questionnaire indicated that ApplTree was acceptable and usable. All participants reported that they intended to use ApplTree over the next 3 months. A high number of PM tasks using participants current paper-based memory aids was observed which meant that, for two participants, there was little room to evaluate any positive effect of using ApplTree. Possible explanations for high PM performance reported in this study are discussed, such as whether the participant's current, paper-based memory aids were sufficient to help with completing everyday tasks of PM. Recommendations for future research in this area are discussed.

Word count: 500

# Abstract

Electronic memory aids have been recommended in practice guidelines on the rehabilitation of prospective memory (PM) following stroke. ApplTree is a smartphone reminder application which delivers user-programmed, active-reminder prompts of tasks of PM. This study investigated the efficacy, usability and acceptance of ApplTree with three community-dwelling stroke participants with reported PM difficulties. An AB, multiple baseline, single case experimental design study was conducted. Participants identified everyday tasks of PM, were randomised to a 5-, 6- or 7-week baseline without ApplTree, followed by training in the use of ApplTree and a 5-week intervention phase using ApplTree. Each participant nominated a person to record whether they remembered to complete these tasks using a memory log during both phases. Visual and statistical analysis of memory log data using Tau-U revealed that ApplTree did not result in a statistically significant increase in PM task completions. However, participants reported that they predicted they would continue to use ApplTree over the next 3 months and reported scores which indicated that ApplTree was both acceptable and usable. Reasons for high baseline PM performance, which may have affected the ability to evaluate ApplTree's efficacy statistically, are discussed, as well as limitations and potential directions for future research.

Keywords; stroke, smartphone, cognitive rehabilitation, prospective memory, memory aid

# Introduction

Stroke is a life-threatening, cerebrovascular accident (Zhelev et al., 2019). Up to two thirds of stroke survivors are discharged from hospital with some form of impairment (Adamson et al., 2004). Commonly reported impairments include physical disability, psychological disorders, social difficulties and cognitive impairments (Ferro et al., 2016), including executive function and memory deficits (Salis et al., 2019).

Up to one in three stroke survivors report difficulties with memory (Novitzke, 2008). Memory difficulties can affect a person's ability to recall past events (retrospective memory), and a person's ability to remember to carry out intended actions in the future (prospective memory). Ellis (1996) defined prospective memory (PM) as the realising of delayed intentions. PM intentions may be time-based (e.g. call John at 10am), or event-based (e.g. post letter in the post-box at the end of the road on the way to work) (Crystal & Wilson, 2015). Impairments in PM can have deleterious effects on a person's ability to carry out activities of daily living, such as attending appointments and taking medications and decrease long-term functional independence (Baumann et al., 2011). It may not be surprising, then, that researchers, clinicians, stroke survivors and their families, have identified cognitive rehabilitation (CR) as one of the top ten priority areas for stroke research according to the James Lind Alliance (2021). CR adopts an individualised, problem-solving approach to support an individual during their functional recovery, in domains such as memory, with the aim of enhancing quality of life (das Nair et al., 2016). One approach to the CR of memory difficulties is the use of internal memory strategies, such as the repeated rehearsal of information or tasks. Another approach is the use of external memory aids, such as paper calendars (Spreij et al., 2014).

#### Memory aids

External memory aids, such as electronic devices and paper notebooks, have been recommended as a 'practice standard' for improving PM impairment following stroke (Cicerone et al., 2019). Whilst there are many different memory aids, they can fall under one of two broad categories; non-electronic or electronic, both of which have been found to be efficacious in the rehabilitation of PM impairment (Sohlberg et al., 2007).

Non-electronic memory aids can include low-cost items such as paper diaries and calendars which serve to remind the person to complete a task of PM. This requires the person to remember to check the memory aid in order to remind themselves of upcoming events; in other words, they must remember to remember (Crystal & Wilson, 2015). This type of memory aid may therefore be referred to as providing 'passive reminders' (Dowds et al., 2011).

Electronic memory aids, on the other hand, can assist in tasks of PM by providing the user with 'active reminder' prompts to complete PM intentions. Studies in acquired brain injury (ABI) have found that active reminder prompts delivered by electronic memory aids can lead to a higher likelihood of completing PM tasks than using a paper calendar (Dowds et al., 2011). Several electronic memory aids, also known as Electronic Personal Assistant Devices (EPADs), have been found to be efficacious with people experiencing memory difficulties following stroke, such as pagers (Fish et al., 2008), mobile phones (Andreassen et al., 2020) and smartphones (Svoboda et al., 2015). Smartphones can be linked to interactive electronic calendar applications in which the user can enter the details of future tasks and events and set reminders, which alert the user, through various sensory modalities, to complete the programmed tasks (Gillespie et al., 2011). By delivering active reminder prompts, and thereby reducing the need for the person to engage in the self-initiated checking of upcoming PM tasks that paper-based memory aids require, smartphone-based active reminders could be helpful in the rehabilitation of PM following stroke. For instance, MindMate, a smartphone-based electronic calendar application, has been investigated in older adults with Alzheimer's dementia and was found to lead to an increased likelihood of completing tasks of PM (McGoldrick et al., 2019).

#### EPADs in post-stroke PM rehabilitation

Several studies have investigated the efficacy of EPADs in the rehabilitation of PM within acquired- or traumatic- brain injury populations, however, there are fewer studies which have reported outcomes for EPADs in in the rehabilitation of PM in stroke populations specifically.

A randomised crossover study with 36 stroke participants found that a pager system 'NeuroPage', which sent reminder messages to participant's pagers resulted in significantly more personally meaningful memory goals being completed than without its use (Fish et al., 2008). Participants were reported to complete, on average, 34% more PM tasks with the pager and a significant decrease in PM performance was found following its removal. However, this group of stroke participants were relatively young, with a mean age of 43.55 years. This is significant, in that whilst promising findings have been reported in the use of EPADs in the rehabilitation of PM impairment following ABI, a negative association between age and technology use has been reported (Evans et al., 2003), as well as a negative association between age and brain injury outcome (Skaansar et al., 2020).

One mixed ABI aetiology study by McDonald et al. (2011), reported increased PM performance in two of four stroke participants using a smartphone linked to Google Calendar in comparison to a paper diary condition and a significant increase in the number of PM tasks completed with the EPAD in comparison to no memory aid use. However, missing data and high baseline PM task performance limited conclusions regarding the efficacy of the EPAD in comparison to the paper diary condition for half of the stroke participants. Another smartphone-based calendar application developed for people with memory difficulties following ABI is ApplTree (Jamieson, 2015).

### ApplTree

ApplTree is an interactive calendar software application which allows users to enter details of future tasks and events, and can be programmed to send prompts to the user's smartphone in order to remind them to complete the scheduled event, at the pre-specified time (Jamieson et al., 2020). ApplTree allows users to enter fully customisable reminders for upcoming events and can prompt the user to add any additional events. Once reminders have been entered, the user can select the sensory modality of the reminder alert, either vibrate only or vibrate and sound. ApplTree has two user interface options for entering reminders. One interface is 'broadshallow', where the user enters data on one screen, requiring the user to navigate multiple pieces of information and scrolling is required. The other interface is referred to as 'narrowdeep' and involves the user having small amounts of information presented over several successive screens as they work through the process of entering reminders. The 'narrow-deep' interface reduces attentional demand on the user and is easier to use than the 'broad-shallow' interface (Jamieson et al., 2020). A pilot feasibility randomised controlled trial of ApplTree, concerned primarily with efficacy, is currently collecting outcomes on memory performance and gathering feedback regarding how best to implement a mobile reminder application intervention (Jamieson, 2019a).

#### Issues in EPAD use

There are a range of social, physical and practical factors which may influence a person's use of EPADs, such as smartphones (Baldwin et al., 2011). For example, insight into memory difficulties (Wilson et al., 2001), the acceptability and relevance of the device in daily life (Gell et al., 2015), and cognitive and executive functioning impairments (Stapleton et al., 2007). Despite the reported efficacy of EPADs in the rehabilitation of PM impairment, some EPADs are limited in that the user is unable to programme the EPAD with PM tasks directly, for instance NeuroPage

required the researcher to update the programme to send the prompt to the user's pager. Training and support in the use of EPADs which allow users to programme their own goals has been highlighted in the field of PM rehabilitation (Heart & Kalderon, 2013), with practice guidelines and standards highlighting that some participants may require considerable training to learn how to operate such devices (Cicerone et al., 2005). Stroke participants have reported two strategies as helpful when learning how to use an EPAD; watching someone use it in-person and instructional training videos (Wong et al., 2017). When considering the use of EPADs in the cognitive rehabilitation of PM impairment following stroke, several of the above factors may intersect, such as age, memory impairment and access to support in using EPAD technology. Despite these factors and considerations, prospective users and clinicians have reported optimism about the use of assistive technologies such as EPADs in the field of neurorehabilitation (de Joode et al., 2010).

#### Current study

With the potential usefulness of smartphone-based calendar applications in delivering active reminder prompts of PM intentions, this study aimed to assess the efficacy, acceptability and usefulness of the smartphone reminder application 'ApplTree' in tasks of everyday PM with stroke survivors reporting PM difficulties. The Single-Case Reporting guideline In BEhavioural interventions (SCRIBE) 2016 Checklist (Tate et al., 2016) was followed in the reporting of this study.

The primary hypothesis was that the introduction of ApplTree, in providing reminder prompts of personally-meaningful tasks of PM, would lead to a significant increase in the number of PM tasks successfully completed.

The secondary hypothesis was that ApplTree will be regarded as acceptable and usable.

# Method

#### Design

This study utilised a Single Case Experimental Design (SCED) with three community-dwelling stroke participants. SCEDs have received increased acceptance in the field of rehabilitation and are one way of achieving the aim of evaluating change during a study by addressing whether the changes observed are due to the effect of the intervention or other external factors (Wilson, 2011). A multiple baseline, across participants design was used. This design allows for a degree of experimental control whilst countering the ethical concerns of removing a potentially

effective intervention, as per withdrawal designs (Byiers et al., 2012). During phase 'A' (baseline), stroke participants completed pre-set tasks of PM memory which were recorded on a memory log by a person they nominated (their nominated person) on a daily basis, without the use of ApplTree. Participants were able to use any other memory aids they were currently using. During phase 'B' (intervention), stroke participants and their nominated person completed the same memory log procedure as at baseline, but were alerted by ApplTree to the PM tasks they had programmed on to the app. PM performance during phase A was a control and compared to PM performance during phase B. The independent variable was therefore phase of study and the dependent variable was the proportion of PM tasks completed.

Participants were randomly assigned to either a 5-, 6- or 7-week baseline phase using an electronic randomiser programme Social Psychology by the Network (http://www.randomizer.org). Due to recruitment difficulties, baselines were non-concurrent, with the third participant beginning the baseline phase two weeks after participants one and two. Following the baseline phase, participants received training in the use of ApplTree with the researcher before beginning the intervention phase which lasted 5 weeks. The study therefore met SCED standards which state that a minimum of three data points must be present in each phase, with three opportunities to demonstrate the experimental effect (Kratochwill et al., 2012). As participants received training in the use of ApplTree by the researcher, it was not possible to blind participants or researchers to the study phase. Although one replication of the study was planned, it was not possible to recruit the three additional participants required.

#### Ethics

Management approval was granted by NHS Highland (Highland 1694) (Appendix 2.2). Ethical approval was granted by the North of Scotland Research Ethics Committee 1 (20/NS/0108) (Appendix 2.3). A substantial amendment was submitted and approved (Appendix 2.4) to expand recruitment from adults aged 65+ years to adults aged 18+ years.

#### **Participants**

The Stroke Coordinator in the Chest Heart and Stroke Team at NHS Highland identified and approached potential participants who had to have had a medically confirmed stroke with selfor other-reported PM difficulties. Participants were required to own, and presumed competent in the use of, a smartphone with reliable internet connection, as well as share accommodation with their nominated person. Participants were made aware that their participation was contingent on the participation of their nominated person.

# Exclusion criteria:

- Non-fluent English speakers
- Aged <18 years
- Index stroke <6 months prior to recruitment
- Diagnosed, pre-existing neurological condition
- Severe psychiatric diagnosis (e.g. psychosis, depression)
- Pre-existing dementia or ABI diagnosis
- Diagnosed or suspected learning disability
- Cognitive impairment of sufficient severity that would prevent the participant using ApplTree
- Don't currently use a smartphone
- Physical, visual or auditory impairments which, if uncorrected with assistive aids, prevent the operation of a smartphone

### Procedure

Prospective participants provided consent to be contacted by the researcher and were provided with a participant information sheet (Appendix 2.5) and a nominated person information sheet (Appendix 2.6). Study-related questions were answered by the researcher prior to obtaining informed consent from the stroke participants (Appendix 2.7) and their nominated person (Appendix 2.8). Information regarding current memory aid use and the identification of personally meaningful memory tasks were gathered during a telephone interview, alongside subjective reports of any cognitive and psychological difficulties prior to randomisation (Appendix 2.9). Participants completed the following assessments of cognitive function via video call (due to covid-19 restrictions):

- Test of Pre-Morbid Functioning (Wechsler, 2011)
- Wechsler Memory Scale-IV, Auditory Memory Index (Wechsler, 2009)
- Delis–Kaplan Executive Function System, Verbal Fluency subtest (Delis et al., 2001)
- Centre for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977)

None of the participants had completed any of these assessments prior to the study. The nominated person completed the Prospective and Retrospective Memory Questionnaire (PRMQ) proxy-rater (Smith et al., 2000) which has better psychometric properties than the self-report version (Arnold & Bayen, 2019). The nominated person also maintained a memory log

(Appendix 2.10) throughout the baseline and intervention phases which detailed the participant's memory tasks for each day of the week (see table 2.1 below for sample memory tasks).

#### Table 2.1

Sample Memory Tasks for Each Participant

	Sample memory tasks from weekly memory log
Dorticipant 1	<ul> <li>Take morning medication</li> </ul>
Participant 1	<ul> <li>Call friend</li> </ul>
Participant 2	<ul> <li>Dentist appointment</li> </ul>
Farticipant 2	<ul> <li>Complete urology chart</li> </ul>
Participant 3	<ul> <li>Walk the dog</li> </ul>
Farticipant 5	<ul> <li>Take morning and evening medication</li> </ul>

The researcher contacted each participant and their nominated person by telephone on a Friday to remind them to complete the memory log and support the participant to identify any upcoming events. Participants entered their memory tasks into ApplTree on their smartphone using the 'narrow-deep' interface with the assistance of their nominated person if required, chose when the reminder for each event would activate and selected the modality of the reminder alert (vibrate or vibrate and sound). Participants agreed to keep their phone beside them and on a setting which allowed them to hear and/or feel the reminder alert. Memory logs were sent at the end of each week to the researcher via email.

Assistive technologies must be acceptable and relevant in tasks of daily living (Gell *et al.*, 2015), therefore, participants completed an adapted version of the Unified Theory of Acceptance and Use of Technology (UTAUT; Venkatesh *et al.*, 2003) at the end of the intervention phase (Appendix 2.11). The UTAUT is a theory-driven measure of the acceptance and usage of information technologies and has been investigated in a range of settings (Chao, 2019). The UTAUT has been reported to explain up to 70% of the variance in intention to use an information technology system (Venkatesh *et al.*, 2003) and consists of eight domains, each consisting of items rated on a 7-point likert scale, giving both domain and overall scores. Participants were also asked about the strengths and weaknesses of ApplTree.

# Participant characteristics

Although participant characteristics are reported for three participants (see table 2.2), a fourth participant withdrew consent prior to completing the cognitive assessments and randomisation due to a deterioration in their physical health.

### Training

Participants and their nominated person received a link to a 20-minute video on how to download and use the functions of ApplTree (which they were able to refer back to throughout the study) prior to a 30-minute training session with the researcher via video call. The researcher demonstrated how to navigate between the calendar and reminder input sections, how to enter, edit and delete reminders, as well as how to use the calendar section to view upcoming memory tasks (appendix 2.12). Participants were set a task to enter a medication reminder to demonstrate competence in using the app. All participants achieved this task without any direction from the researcher.

# Table 2.2

	Participant 1	Participant 2	Participant 3
Age	63	73	63
Sex	Male	Female	Male
Stroke aetiology	Left middle cerebral artery infarct	Left occipital infarct	Bilateral basal ganglia infarct, bilateral fronto-parietal white matter infarcts
Time since index/ most recent stroke	21 months	84 months	52 months
Weekly memory log completed by	Partner	Partner	Partner
Memory aid use during baseline	Wall calendar	Paper diary, wall calendar	Wall calendar
PRMQ retrospective	24 (Low average score)	1 (Exceptionally low score)	1 (Exceptionally low score)
PRMQ prospective	24 (Low average score)	1 (Exceptionally low score)	1 (Exceptionally low score)
PRMQ total	50 (Average score)	1 (Exceptionally low score)	2 (Below average score)
TOPF estimated WMS-IV DMI	32 (Average score)	34 (Average score)	25 (Average score)
WMS-IV Logical memory immediate recall	1 (Exceptionally low score)	84 (High average score)	0.1 (Exceptionally low score)
WMS-IV Logical memory delayed recall	2 (Below average score)	50 (Average score)	0.1 (Exceptionally low score)
WMS-IV Verbal paired associates immediate recall	5 (Below average score)	25 (Average score)	2 (Below average score)
WMS-IV Verbal paired associates delayed recall	1 (Exceptionally low score)	9 (Low average score)	5 (Below average score)
WMS-IV AMI	1 (Exceptionally low score)	37 (Average score)	0.1 (Exceptionally low score)
(DKEFS) Verbal Fluency	16 (Low average score)	63 (Average score)	2 (Exceptionally low score)
CES-D raw score	7	17*	11

Participant Characteristics and Cognitive Profiles with Percentiles and Classifications

Key; PRMQ = Prospective and Retrospective Memory Questionnaire proxy-version, TOPF = Test of Pre-Morbid Functioning, WMS-IV = Wechsler Memory Scale fourth edition, DMI = Delayed Memory

Index, AMI = Auditory Memory Index, DKEFS = Delis–Kaplan Executive Function System \* = clinical range

#### Data Analysis

The percentage of successful PM task completions was calculated from weekly memory log data and presented as graphs for visual analysis. Visual analysis allows researchers to evaluate changes in behavioural variables within conditions; analysing level (amount of behaviour), trend (change in behaviour) and variability (stability) of the data, and also between conditions; to interpret the consistency (data pattern over time), overlap (proportion of data at the same level) and immediacy (abruptness of change) of data (Ledford et al., 2017).

Baseline PM task performance and changes in PM task performance between baseline and intervention were analysed using Tau-*U*. This non-parametric data analysis method uses pairwise comparisons of data points to analyse non-overlapping data whilst controlling for baseline trend, thus allowing for the statistical analysis of change in PM performance between phases (Parker & Vannest, 2009). This allows for the determination of the effect of the intervention and the computation of effect size (Cliff, 1993). Non-overlapping pairs effect size guidelines published by Parker and Vannest (2009) stipulate effects ranging from; 0–.65 as weak, .66–.92 as medium and .93–1.0 as large. Tau-*U* has demonstrated statistical power of 91-115% of parametric equivalents (Vannest et al., 2011) and reliably detects medium and large effect sizes in small sample sizes (Parker et al., 2014). Several studies have demonstrated large effect sizes in *N*=3 SCED studies of app-based reminder technologies (Jamieson et al., 2013; McGoldrick et al., 2019). Therefore, it was expected that Tau-*U* would have sufficient power to detect a large effect size if one existed in the current study. Participant responses on the UTAUT are reported descriptively and information relating to the strengths and weaknesses of ApplTree are reported qualitatively.

### Results

#### Visual analysis summary

To assess whether ApplTree resulted in a greater likelihood of completing PM tasks, visual analysis of weekly memory log data during both phases was undertaken. In line with reporting standards (Lane and Gast, 2014), the trend, level, variability, immediacy of the effect, overlap and consistency of data are reported. A stability envelope which allows analysis of the variability of data by determining whether 80% of data points fell within 25% of the phase median, was applied to each participant's data (Appendix 2.13).

### Participant 1

Participant 1's memory task performance was high during phase A and phase B (see figure 2.1). PM task performance increased from 340/406 (83.7%) during phase A to 246/290 (84.8%) during phase B. Estimation of trend using the split-middle method indicated an increasing, therapeutic trend during phase A and a decreasing, contra-therapeutic trend during phase B. Data were stable during both study phases.

The effect of introducing ApplTree in phase B was not immediately evident through visual analysis. Within-condition analysis of trend revealed a change from an accelerating, improving trend to a decelerating, deteriorating trend. Absolute and relative level change measures indicated a negative (decreasing) change in PM task completions across conditions, whereas mean and median level changes indicated a small positive (increasing) change in PM task completions. A significant effect of phase A trend was found during within-phase analysis (Tau- $U_{A vs A}$ ) = 0.81, p = .01) and therefore baseline trend was corrected during the phase A-phase B Tau-U analysis which revealed a statistically non-significant change. Analysis of PM task performance between phase A and phase B using Tau-U revealed a statistically non-significant decrease in PM task performance from phase A to phase B (Tau- $U_{A vs B-trend A}$ ) = -.31, p = .37, 90% CI [-0.89, 0.27].

#### Participant 2

Participant 2's memory task performance was also consistently high during both phases and at ceiling in phase B (see figure 2.1). PM performance increased from 48/49 (98.0%) during phase A, to 42/42 (100%) during phase B. Estimation of trend using the split-middle method revealed no change in trend during either phase, indicating a consistent, zero-celerating trend in PM performance throughout the study. Data were stable during both phases (Appendix 2.12).

The effect of introducing ApplTree in phase B was not immediately evident through visual analysis due to 10 of 11 data points at ceiling. Within-condition analysis indicated a small increase in PM performance. Median and relative level change measures indicated no change across conditions, whereas mean and relative level change measures indicated a small increase in PM performance between conditions. Analysis of PM task performance between phase A and phase B using Tau-U revealed a statistically non-significant decrease in PM task performance (Tau- $U_{Avs B}$ ) = 0.17, p = .63, 90% CI [-0.43, 0.77].

#### Participant 3

Participant 3's memory task performance was also high but stable during both phases of the study. PM performance decreased from 60/63 (95.2%) during phase A to 43/46 (93.5%) during phase B. Estimation of trend using the split-middle method indicated no change in trend during phase A and an increasing, therapeutic trend during phase B. Data were stable during both phases.

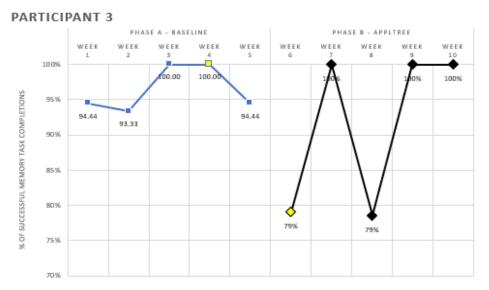
An effect of introducing AppITree in phase B was immediately evident through visual analysis. Within-condition analysis of trend revealed a change from no trend to an accelerating, improving trend. Mean, absolute and relative level change measures indicated a negative (decreasing) change in PM task completions across conditions, whereas median level changes indicated a small positive (increasing) change in PM task completions. Analysis of PM task performance between phase A and phase B using Tau-*U* revealed a statistically non-significant change in PM task performance (Tau- $U_{AVS B}$ ) = -0.04, *p* = .92, 90% CI [-0.67, 0.59], from phase A to phase B. Missing data for week 4 in phase A and week 1 in phase B, were replaced using the minimum-maximum method. This conservative method uses the best baseline score (in this study, the highest PM performance) and the worst intervention score (in this study, the lowest PM performance) in place of the missing data. The minimum-maximum method is recommended when data is missing at random and when the proportion of missing data is between 5-30% (Peng & Chen, 2021). Substituted data is highlighted in yellow (see figure 2.1).

#### Between conditions analysis

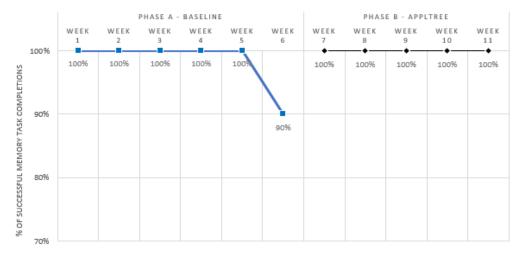
No patterns in consistency emerged within or across data sets. All data points were within the data envelope and were therefore considered stable.

# Figure 2.1

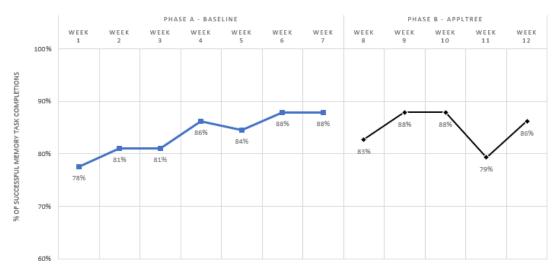
Participant's Weekly Memory Log Data Presented in order of Length of Baseline (5, 6, 7 weeks).











# Acceptability and usability

Participants completed the UTAUT in order to evaluate how usable and acceptable they found ApplTree (See table 2.3 below). Data presented for each UTAUT dimension represents the mean response of items.

# Table 2.3.

Mean UTAUT Subtest and Total Scores by Each Participant

UTAUT Dimension	Participant 1	Participant 2	Participant 3	Sum of mean dimension scores
Performance expectancy	6.0	6.0	6.7	18.7
Effort expectancy	6.8	6.3	6.0	19.1
Attitude towards the technology	5.7	6.3	6.7	18.7
Social influence	6.0	4.0	7.0	17.0
Facilitating conditions	6.5	5.0	6.5	18.0
Self-efficacy	6.0	5.5	6.3	17.8
Anxiety*	1.3	4.8	1	7.1
Behavioural intention	5.0	6.3	7	18.3
Sum of mean dimension scores minus anxiety dimension	42.3	39.4	46.2	$\ge$

Mean (1dp) dimension scores out of a total of 7. Higher scores represent better user experience. \*Scored negatively; higher score represents higher anxiety.

All three participants gave scores which indicate they predicted they would use ApplTree over the next three months.

# Qualitative interview

Participants were asked follow-up questions regarding the strengths and weaknesses of ApplTree following the completion of the UTAUT.

Participant 1 said that ApplTree was a great idea and was good for reminding them of upcoming appointments which they had previously relied on prompts from their nominated person or had to remember to check their wall calendar, to complete. They reported that ApplTree may be helpful for people who live alone or didn't have anyone to provide them with reminders. They

went on to say that reminders to complete menial tasks, such as filling a water bottle, became annoying, but reminders for important things, such as appointments were great. They concluded that although they were not good at using technology, ApplTree was easy to use.

Participant 2 reported that ApplTree helped most by reminding them to complete new tasks for which they had not established routines, such as taking a new medication. They said that the reminder prompts with sound were the best feature and that they reliably received set reminders which meant they didn't worry about forgetting anything. They also said that ApplTree reminders meant that they did not have to remember to check their paper notebook for upcoming events and tasks. They said that although they were not very good at using their phone, ApplTree was easy to use and that they entered reminders with their nominated person.

Participant 3 said that ApplTree was a brilliant concept and very handy. They said that the vibrate and sound setting made it easy to know when they had a reminder and that their nominated person supported them to enter reminders as they were quicker at doing that. Their nominated person said ApplTree was a "god send" as they previously prompted the person about all upcoming events which ApplTree now does for them. Participant 3 said that ApplTree had helped to establish a new medicine routine and that set reminders on ApplTree for events that they would've forgotten to check their wall calendar for previously. They did, however, report that the custom reminder setting did not function and therefore they had to select from the default reminder time options i.e. 1 hour before the event.

# Discussion

This study aimed to investigate whether a smartphone reminder application, ApplTree, would lead to a significant increase in the number of PM tasks successfully completed by stroke participants with PM difficulties following a baseline period using their current memory aid and whether participants would regard ApplTree as acceptable and usable.

#### Efficacy

High levels of baseline PM performance have been previously reported in ABI studies investigating EPADs in memory rehabilitation (Evald, 2018). However, baseline PM performance for two of the three participants in the current study appear to be very high; one participant scored at ceiling for 5/6 (83%) of data points and another participant reported a minimum baseline data point of 93%. There may be several reasons why baseline PM performance was remarkably high.

Pre-injury memory aid use has been identified as predictive of post-injury memory aid use. One study reported that people using wall calendars were more likely to be considered independent than those using any other memory aid (Evans et al., 2003). As all three participants were using a wall calendar before and during the baseline phase, one explanation may be that participants' current paper-based memory aids were sufficient to support PM task performance.

Another plausible explanation of this finding, also highlighted in previous studies, may be that introducing daily PM tasks acted as a cue to complete PM tasks, which meant that reported baseline PM performance was not a true reflection of pre-study PM performance (Fish et al., 2007). Another explanation may be that the memory log inadvertently acted as an additional paper memory aid or resulted in a practise effect; the nominated person of two participants stated that the participant may have benefited from keeping this log and referring to it throughout the day. The potential novelty effect of taking part in a study and/ or the effect of study-related stimuli have also been previously raised in EPAD research (Jamieson et al., 2019). However, a therapeutic, baseline trend was only observed for one participant and the nominated person of all three participants said that they continued to provide prompts during the baseline phase, provided roughly the same number of prompts before the baseline phase as they did during it, and did not think that the participant's PM functioning had improved in comparison to pre-study PM functioning.

Another possible interpretation of the high baseline performance could be that weekly contact with the researcher who listened and responded to concerns regarding memory, in addition to recording the use of current paper-based memory aids, provided an inadvertent therapeutic effect. Weekly, phone-based communication between researchers and participants was identified as helpful during a computerised cognitive training intervention for PM difficulties with community-dwelling stroke survivors (Withiel et al., 2020) and all three participants stated that they enjoyed weekly contact with the researcher and trying something new.

This study relied upon the participant and their nominated person recording the same tasks on ApplTree as they did on the memory log and accurately completing the memory log. The nominated person of two participants stated that the participant added some tasks to the memory log after the event and, in order to avoid confrontation or argument, the nominated person recorded the task as being successfully remembered. This may contribute to an interpretation that high baseline PM performance as reported may not accurately represent actual PM performance of some participants. Whilst electronic memory aids have been recommended as a 'practice standard' in the rehabilitation of PM following stroke (Cicerone et al., 2019), the current study was unable to demonstrate a statistically significant effect of the introduction of ApplTree on PM task completions, despite reported PM difficulties. This finding adds to a mixed but small pool of studies investigating the effects of EPADs on PM performance with stroke participants. Previous studies have demonstrated that stroke participants reporting a high proportion of PM task completions at baseline (without the use of any memory aids) and during a standard, paper diary phase, also reported a high proportion of PM task completions during an electronic memory aid phase (McDonald et al., 2011). It may be that people reporting high PM performance don't differentially benefit from active vs passive reminders of PM intentions, which may have clinical implications in supporting people to use whichever memory aid is most beneficial or best matches their personal context and preference.

Other studies have found that using EPADs helped participants form and preserve routines and that the reliability of the EPAD may be an important factor (Fish et al., 2008). Participants two and three in the current study stated that ApplTree was helpful in establishing new routines and reliably alerted them to their programmed PM tasks. This finding supplements previous findings that reminder technologies may be beneficial in everyday tasks of living including establishing routines (Andreassen et al., 2020).

#### Acceptance and usability

All three participants reported overall UTAUT scores which indicated a positive experience of using ApplTree. Although participants gave positive scores on the facilitating conditions domain, indicating they had the knowledge to use ApplTree, two participants reported that their nominated person assisted them in entering all PM tasks on to ApplTree due to low confidence and low speed in using their phone. This may highlight the importance of involving partners and/or carers in the training and use of EPAD reminder technologies, not least because involving family members in cognitive rehabilitation interventions has been identified as a top 10 research priority area in stroke by the James Lind Alliance (2021), but because knowledge and experience in using EPADs may be influential factors in their use (de Joode et al., 2012). This finding corroborates previous findings that support from a nominated person is a means of improving the value that EPADs and reminder technology can provide (de Joode et al., 2012).

The relevance of assistive technology in the person's daily life has been identified as an important influencing factor in their use (Gell et al., 2015). Participant one said that as both they

and their nominated person lived together and both were quite happy to receive and give PM prompts respectively, they felt they did not really need ApplTree. Whilst it is unknown whether this affected participant one's experience of using ApplTree, it remains important that participants recruited to EPAD and reminder application studies express an interest in learning how to use the EPAD as a memory aid (Evald, 2018), particularly as motivation may be variable for participants who are able to adequately use another or current memory aid (de Joode et al., 2012). Participant one's interview also raises the importance of setting personally meaningful goals in rehabilitation research that reflect the complexity of PM goals people may wish to accomplish in their everyday lives which future studies may wish to ensure, rather than ensuring that a quantity of goals are set in evaluating the efficacy of PEPADs. Despite participant two reporting a relatively higher anxiety score and a neutral social influence score on the UTAUT, indicating that they perceived their nominated person was not sure whether using ApplTree was important, all participants reported that they either predicted, planned or intended to use ApplTree over the next 3 months. However, these findings should be interpreted with caution due to the small sample size, the completion of this measure immediately post-intervention and also a potential social desirability bias present due the researcher being the single point of interaction with participants throughout the study. Nevertheless, findings indicate that ApplTree was regarded as both acceptable and usable.

#### Limitations

There are several limitations to the current study. High baseline PM task completions may not be representative of other stroke survivors reporting PM difficulties or of participant's everyday PM performance prior to commencing the study. Future studies may add a column to the PM log for the nominated person to note whether the participant was prompted to complete the task in order to establish whether the amount of prompts they receive change during the study. Participants were either retired or volunteers, and lived with their nominated person only. PM tasks, and potentially completion rates, may be different for employed or younger stroke survivors. High baseline PM task completions as recorded on memory logs also made it difficult to statistically determine any positive effect of the introduction of ApplTree. Other measures in addition to memory logs may be helpful in establishing the efficacy of reminder technologies, such as measures of caregiver strain which are associated with PM difficulties following stroke (Baumann et al., 2011) in addition to quality of life measures.

Guidance on changing phases in SCED studies recommend continuing the baseline phase, until the level is stable, when participant data indicates a therapeutic trend (Ledford et al., 2017).

Baseline data for one participant was observed to have a therapeutic trend in this study. PM scores during the final two baseline data phase points indicated that any beneficial effect of the baseline phase had plateaued and thus the phase change occurred as planned at seven weeks. Another potential methodological limitation was the presence of missing data which could be a threat to the internal validity and conclusions of the study. Although a consensus has not been established regarding the amount of missing data in designs using visual and statistical inferences, and there are several methods which could be used, missing data met the criteria for use of the conservative, minimum-maximum method, which is considered to yield valid statistical inferences when utilised under missing at random conditions (Peng & Chen, 2021). The missing data method and rationale was also reported as per the SCRIBE (2016) guidelines.

This study did not utilise a long-term follow-up phase and was therefore unable to add to the limited evidence base regarding the long-term efficacy of reminder applications in post-stroke PM rehabilitation. As new memory aid use can wane within months (Baldwin et al., 2011), future studies may consider assessing the acceptability and usability of reminder applications, continued device use and self- and proxy-report measures of PM at long-term follow-up.

Although participants successfully entered a fictitious appointment reminder, without support from the researcher, to demonstrate competence in using ApplTree, previous studies have utilised cut off scores in order to progress to the intervention phase (McDonald et al., 2011) or continued training until a perfect score was obtained (Jamieson et al., 2019b). Future studies may benefit from reporting the training participants and a nominated person received in using reminder technologies and assess proficiency in their use. To the best of their knowledge, the author is unaware of any EPAD reminder study in stroke rehabilitation which has reported on the competence of a nominated person and the participant in the use of a reminder technology.

Recruitment was quite difficult in the current study. There may be several reasons for this, including the design of the study and factors associated with the target population, amongst others. When prospective participants were contacted, it was anecdotally noted that older potential participants tended to be more apprehensive about their ability to use their smartphone to the perceived level required or did not own a smartphone. This may be intrinsic to the rapid development of newer technologies in society, such as smartphones, which older adults are less likely to own and use (Onyeaka et al., 2021). Additionally, whilst one advantage of SCEDs is that reliable conclusions can be drawn from relatively fewer participants, due to their rigorous design (Krasny-Pacini & Evans., 2018), participants in the current study were required to invest considerable amounts of time in completing baseline assessments,

interviews, memory logs and weekly contact with the researcher, over a period of 10-12 weeks. Participants also received weekly support in using and problem-solving issues using ApplTree, for six weeks. Whilst the research team was able to offer this level of support, in clinical contexts, it may be difficult for community rehabilitation teams to offer similar levels of support.

Although one participant reported that they enjoyed the ApplTree reminder tone, two participants stated that they received too many reminders and that this became distracting and annoying; highlighting that reminders must not add further stress to participants and also be meaningful (Ferguson et al., 2015). Furthermore, the nominated person of participant two reported a 'bug' after the study ended which affected the ability of the user to enter a customised reminder time. As the participant achieved ceiling PM performance during three of five intervention phase data points, this was unlikely to have greatly affected the efficacy results, but may have affected their views on the acceptability and usability of ApplTree. Communicating with participants and their nominated person throughout the study about the number of reminders that would sound each day and that 'bugs' may present from time-to-time, may help set expectations and open channels of communication with the researcher in order to manage any frustration or apathy towards the reminders or ApplTree itself.

### Conclusion

Findings indicated that ApplTree did not result in a statistically significant increase in the completion of everyday tasks of PM with stroke survivors reporting PM difficulties. High reported baseline PM performance meant that the ability to analyse data for any statistically significant positive effects of ApplTree was not possible in two thirds of participants. The dearth of research into the effects of reminder applications on PM task completions in stroke rehabilitation may partially reflect difficulties experienced during this study with recruitment, missing data and high baseline PM performance. Although one participant reported relatively higher anxiety in the use of ApplTree, all three participants predicted that they would continue to use ApplTree over the next 3 months and reported scores which indicated that ApplTree was an acceptable and usable memory aid for them. Further research utilising measures of quality of life, caregiver strain and the acceptance and usability of the PEPAD, in addition to PM log data, may be required to effectively evaluate the effectiveness of reminder applications.

#### Conflicts of interests and funding information

No conflicts of interests to disclose. No funding was received for this study.

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   *Cochrane Database of Systematic Reviews, (4).* DOI: 10.1002/14651858.CD011427.pub2

# Appendices

### Appendix 1.1. Author requirements for submission to Neuropsychological Rehabilitation.

### About the Journal

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

Please note that this journal only publishes manuscripts in English.

*Neuropsychological Rehabilitation* accepts the following types of article: original articles, scholarly reviews, book reviews.

### **Open Access**

You have the option to publish open access in this journal via our Open Select publishing program. Publishing open access means that your article will be free to access online immediately on publication, increasing the visibility, readership and impact of your research. Articles published Open Select with Taylor & Francis typically receive 32% more citations\* and over 6 times as many downloads\*\* compared to those that are not published Open Select.

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\*Citations received up to Jan 31st 2020 for articles published in 2015-2019 in journals listed in Web of Science®. \*\*Usage in 2017-2019 for articles published in 2015-2019.

### Peer Review and Ethics

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

### **Preparing Your Paper**

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

**Clinical trials:** must conform to the Consort guidelines http://www.consort-statement.org. Submitted papers should include a checklist confirming that all of the Consort requirements have been met, together with the corresponding page number of the manuscript where the information is located. In addition, trials must be pre-registered on a site such as clinicaltrials.gov or equivalent, and the manuscript should include the reference number to the relevant pre-registration.

#### Structure

Your paper should be compiled in the following order: title page; abstract; keywords; main text introduction, materials and methods, results, discussion; acknowledgments; declaration of interest statement; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figures; figure captions (as a list).

#### Word Limits

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

#### Format-Free Submission

Authors may submit their paper in any scholarly format or layout. Manuscripts may be supplied as single or multiple files. These can be Word, rich text format (rtf), open document format (odt), or PDF files. Figures and tables can be placed within the text or submitted as separate documents. Figures should be of sufficient resolution to enable refereeing.

• There are no strict formatting requirements, but all manuscripts must contain the essential elements needed to evaluate a manuscript: abstract, author affiliation, figures, tables, funder information, and references. Further details may be requested upon acceptance.

• References can be in any style or format, so long as a consistent scholarly citation format is applied. Author name(s), journal or book title, article or chapter title, year of publication, volume and issue (where appropriate) and page numbers are essential. All bibliographic entries must contain a corresponding in-text citation. The addition of DOI (Digital Object Identifier) numbers is recommended but not essential.

- The journal reference style will be applied to the paper post-acceptance by Taylor & Francis.
- Spelling can be US or UK English so long as usage is consistent.

Note that, regardless of the file format of the original submission, an editable version of the article must be supplied at the revision stage.

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#### Checklist: What to Include

- 1. Author details. Please ensure everyone meeting the International Committee of Medical Journal Editors (ICMJE) requirements for authorship is included as an author of your paper. All authors of a manuscript should include their full name and affiliation on the cover page of the manuscript. Where available, please also include ORCiDs and social media handles (Facebook, Twitter or LinkedIn). One author will need to be identified as the corresponding author, with their email address normally displayed in the article PDF (depending on the journal) and the online article. Authors' affiliations are the affiliations where the research was conducted. If any of the named co-authors moves affiliation during the peer-review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after your paper is accepted. Read more on authorship.
- 2. Should contain an unstructured abstract of 200 words.
- 3. You can opt to include a **video abstract** with your article. Find out how these can help your work reach a wider audience, and what to think about when filming.
- Between 5 and 5 keywords. Read making your article more discoverable, including information on choosing a title and search engine optimization.
- 5. **Funding details.** Please supply all details required by your funding and grant-awarding bodies as follows: *For single agency grants*

This work was supported by the [Funding Agency] under Grant [number xxxx].

For multiple agency grants

This work was supported by the [Funding Agency #1] under Grant [number xxxx]; [Funding Agency #2] under Grant [number xxxx]; and [Funding Agency #3] under Grant [number xxxx].

- 6. **Disclosure statement.** This is to acknowledge any financial interest or benefit that has arisen from the direct applications of your research. Further guidance on what is a conflict of interest and how to disclose it.
- 7. **Data availability statement.** If there is a data set associated with the paper, please provide information about where the data supporting the results or analyses presented in the paper can be found. Where applicable, this should include the hyperlink, DOI or other persistent identifier associated with the data set(s). Templates are also available to support authors.
- 8. **Data deposition.** If you choose to share or make the data underlying the study open, please deposit your data in a recognized data repository prior to or at the time of submission. You will be asked to provide the DOI, pre-reserved DOI, or other persistent identifier for the data set.
- 9. **Geolocation information.** Submitting a geolocation information section, as a separate paragraph before your acknowledgements, means we can index your paper's study area accurately in JournalMap's geographic literature database and make your article more discoverable to others. More information.
- 10. **Supplemental online material.** Supplemental material can be a video, dataset, fileset, sound file or anything which supports (and is pertinent to) your paper. We publish supplemental material online via Figshare. Find out more about supplemental material and how to submit it with your article.
- 11. Figures. Figures should be high quality (1200 dpi for line art, 600 dpi for grayscale and 300 dpi for colour, at the correct size). Figures should be supplied in one of our preferred file formats: EPS, PS, JPEG, TIFF, or Microsoft Word (DOC or DOCX) files are acceptable for figures that have been drawn in Word. For information relating to other file types, please consult our Submission of electronic artwork document.
- 12. **Tables.** Tables should present new information rather than duplicating what is in the text. Readers should be able to interpret the table without reference to the text. Please supply editable files.
- 13. **Equations.** If you are submitting your manuscript as a Word document, please ensure that equations are editable. More information about mathematical symbols and equations.
- 14. Units. Please use SI units (non-italicized).

Appendix 1.2. Systematic review literature search strategies.

### Medline and Embase search terms

"cognitive\* impair\*" OR "memory impair\*" OR "memory difficult\*" OR "stroke" OR "CVA" OR "cerebrovascular accident\*" OR "post stroke"

### AND

"prospective memory" OR "remind\*" OR "prompt\*" OR "goal set\*" OR "goal manage\*" OR "memory"

### AND

"mobile app\*" OR "mobile" OR "mobile telephone" OR "smartphone" OR "smartphone app\*" OR "PDA" OR "personal digital assistant" OR "EPADS" OR "electronic portable assistive device\*" OR "assistive device\*" OR "pager" OR "electronic aid\*" OR "electronic device\*" OR "electronic organi\*" OR "electronic reminder\*"

# AND

"cognitive rehab\*" OR "memory rehab\*" OR "memory intervention\*" OR "memory aid\*" OR "external memory aid\*" OR "technolog\*" OR "assistive technolog\*" OR "compensat\* strateg\*" OR "cognitive prosthe\*" OR "cognitive orthos\*" OR "memory orthos\*" OR "memory prosthe\*" OR "memory compensat\*"

### **CINAHL** search terms

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# PsycInfo search terms

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#### PubMed search terms

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#4	•••	>	Search: ((((("prospective memory") OR (remind*)) OR (prompt*)) OR ("goal set*")) OR ("goal manage*")) OR (memory)	482,272	05:59:35
#2		•	Search: ((((((((((("mobile app*") OR (mobile)) OR ("mobile telephone")) OR (smartphone)) OR ("smartphone app*")) OR ("PDA")) OR ("personal digital assistant")) OR ("EPADS")) OR ("electronic portable assistive device*")) OR ("assistive device*")) OR (pager)) OR ("electronic aid*")) OR ("electronic device*")) OR ("electronic organi*")) OR ("electronic reminder*")	150,182	05:57:03
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#### Scopus search terms

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### Web of Science search terms

Appendix 1.3. The PEDro 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 on key outcome		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 <u>Points are only awarded when a criterion is clearly satisfied</u>. 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. The RoBiN-T scale (Tate et al., 2013).

#### Internal validity subscale

- Design: Does the design of the study meet requirements to demonstrate experimental control?
- Randomisation: Was the phase sequence and/ or phase commencement randomised?
- 3. Sampling: Were there a sufficient number of data points (as defined) in each of baseline and intervention phases?
- 4. Blind participants/therapists: Were the participants and therapists blinded to the treatment condition (phase of study)?
- 5. Blind assessors: Were assessors blinded to treatment condition (phase of study)?
- 6. Inter-rater reliability (IRR): Was IRR adequately conducted for the required proportion of data, and did it reach a sufficiently high level (as defined)?
- 7. Treatment adherence: Was the intervention delivered in the way it was planned?

#### External validity and interpretation subscale

- 8. Baseline characteristics: Were the participant's relevant demographic and clinical characteristics, as well as characteristics maintaining the condition adequately described?
- **9. Therapeutic setting:** Were both the specific environment and general location of the investigation adequately described?
- **10. Dependent variable (target behaviour):** Was the target behaviour defined, operationalised, and the method of its measurement adequately described?
- 11. Independent variable (intervention): Was the intervention described in sufficient detail, including the number, duration and periodicity of sessions?
- 12. Raw data record: Were the data from the target behaviour provided for each session?
- 13. Data analysis: Was a method of data analysis applied and rationale provided for its use?
- 14. Replication: Was systematic and/or intersubject replication incorporated into the design?
- 15. Generalisation: Were generalisation measures taken prior to, during, and at the conclusion of treatment?

ltem number	Topic	Item description
TITLE an	TITLE and ABSTRACT	
-	Title	Identify the research as a single-case experimental design in the title
2	Abstract	Summarize the research question, population, design, methods including interventions (independent variable/s) and target behavior/s and any other outcome/s (dependent variable/s), results, and conclusions
INTRODUCTION	UCTION	
ŝ	Scientific background	Describe the scientific background to identify issues under analysis, current scientific knowledge, and gaps in that knowledge base
4	Aims	State the purpose/aims of the study, research question/s, and, if applicable, hypotheses
METHOD	6	
	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
9	Procedural changes	Describe any procedural changes that occurred during the course of the investigation after the start of the study
L	Replication	Describe any planned replication
8	Randomization	State whether randomization was used, and if so, describe the randomization method and the elements of the study that were randomized
6	Blinding	State whether blinding/masking was used, and if so, describe who was blinded/masked

**Appendix 2.1** Single-Case Reporting guideline In BEhavioural interventions (SCRIBE) 2016 Checklist (Tate et al., 2016).

	PARTICIPANT/S or UNIT/S	
10	Selection criteria	State the inclusion and exclusion criteria, if applicable, and the method of recruitment
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
	CONTEXT	
12	Setting	Describe characteristics of the setting and location where the study was conducted
	APPROVALS	
13	Ethics	State whether ethics approval was obtained and indicate if and how informed consent and/or assent were obtained
	MEASURES and MATERIALS	TERIALS
14	Measures	Operationally define all target behaviors and outcome measures, describe reliability and validity, state how they were selected, and how and when they were measured
15	Equipment	Clearly describe any equipment and/or materials (e.g., technological aids, biofeedback, computer programs, intervention manuals or other material resources) used to measure target behavior/s and other outcome/s or deliver the interventions
	INTERVENTIONS	
16	Intervention	Describe the 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
17	Procedural	Describe how procedural fidelity was evaluated in each phase

fidelity

RESULTS	S	
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
20	Outcomes and estimation	For each participant, report results, including raw data, for each target behavior and other outcome/s
21	Adverse events	State whether or not any adverse events occurred for any participant and the phase in which they occurred
DISCUSSION	SION	
22	Interpretation	Summarize findings and interpret the results in the context of current evidence
23	Limitations	Discuss limitations, addressing sources of potential bias and imprecision
24	Applicability	Discuss applicability and implications of the study findings
DOCUM	DOCUMENTATION	
25	Protocol	If available, state where a study protocol can be accessed
26	Funding	Identify source/s of funding and other support; describe the role of funders

Analyses Describe and justify all methods used to analyze data

Appendix 2.2. Management approval granted by NHS Highland (Highland 1694).

TEMP009 Version 5 October 2020

Dr Beth Sage Research, Development & Innovation Director NHS Highland RD&I Office Centre for Health Science Old Perth Road Inverness IV2 3JH



E-mail: beth.sage@nhs.scot

5 November 2020

NHS Highland RD&I Ref: HIGHLAND 1694 NRSPCC Ref: NA

Mr John Wilson 23 Bishops Park INVERNESS IV3 5SZ

John.wilson17@NHS.scot

Dear Mr Wilson,

## Management Approval for Non-Commercial Research

I am pleased to tell you that you now have Management Approval for the research project entitled: 'Smartphone app for memory impairment in post-stroke older adults V1 A Single Case Experimental Design Study of a Smartphone Reminding Application With Community Dwelling Older Adults Who Have Sustained A Stroke (AppITree) [Protocol V1.1 08/07/2020].

I acknowledge that:

- The project is sponsored by NHS Highland
- The project has no external funding.
- Ethics approval for the project has been obtained from the North of Scotland Research Ethics Committee (Reference Number: 20/NS/0108)
- As single centre study, sponsored by NHSH, the project does not require an Organisational Information Document

The following conditions apply:

- The responsibility for monitoring and auditing this project lies with NHS Highland.
- This study will be subject to ongoing monitoring for Research Governance purposes and may be audited to ensure compliance with the UK Policy Framework for Health and Social Care Research (2018, V3.3 07/11/17, however prior written notice of

MARCH AND AUDIT will be given.



- Any researchers coming into NHS Highland for the purposes of carrying out research with patients will require a Letter of Access before starting the study at this site. Please contact a member of the RD&I Governance team at <u>nhsh.nhshighlandresearchpassports@nhs.scot</u> for further assistance, if this is required.
- The paperwork concerning all incidents, adverse events and serious adverse events thought to be attributable to a participant's involvement in this project should be notified to the NHS Highland RD&I Governance team. Please email documents to RD&I Facilitator at <a href="https://www.nhsh.RandD@nhs.scot">nhsh.RandD@nhs.scot</a>.
- You are reminded that all amendments (substantial or non-substantial) to the protocol and associated study documents or to the REC application should be notified to the NHS Highland RD&I Office to obtain amendment approval (<u>nhsh.RandD@nhs.scot</u>). Guidance can be found at <u>https://www.nhsresearchscotland.org.uk/services/permissions-co-ordinatingcentre/permissions</u>
- If applicable, monthly recruitment rates should be notified to the NHS Highland RD&I Office, detailing date of recruitment and the participant trial ID number. This should be done by e-mail on the first week of the following month, to Debbie McDonald, Data Manager (<u>deborah.mcdonald@nhs.scot</u>). Please quote your RD&I Highland reference number (Highland 1689).
- Please report any other changes in resources used, or staff involved in the project, to the NHS Highland RD&I Office (<u>nhsh.RandD@nhs.scot</u>).

# Please quote your RD&I Highland reference number (Highland 1694) on all correspondence.

Yours sincerely,

Frances Hines RD&I Manager

cc Jo Fraser, RD&I Administration Assistant, NHS Highland Research, Development & Innovation Division, Ground Floor Phase 3, Centre for Health Science, Old Perth Road, Inverness, IV2 3JH

<u>Prof Jonathan Evans</u>, Academic Supervisor, Mental Health and Wellbeing, University of Glasgow, <u>jonathan.evans@glasgow.ac.uk</u> Appendix 2.3. Ethics approval; North of Scotland Research Ethics Committee 1 (20/NS/0108).

#### North of Scotland Research Ethics Committee (1)

Summerfield House 2 Eday Road Aberdeen AB15 6RE

Telephone: 01224 558458 Email: gram.nosres@nhs.scot **NHS** Grampian

30 September 2020

Mr John Wilson 23 Bishops Park INVERNESS IV3 5SZ

Dear Mr Wilson

# Study title: ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application With Community-Dwelling Older Adults Who Have Sustained A Stroke. REC reference: 20/NS/0108 Protocol number: 1 IRAS project ID: 286103

The Research Ethics Committee reviewed the above application at the meeting held on 24 September 2020. Thank you and Prof Jon Evans for attending to discuss the application.

#### **Ethical opinion**

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

#### Conditions of the favourable opinion

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

Number	Condition
1.	The following changes should be made to the Participant Information Sheets:
	<ul> <li>The word 'Carer' in the title 'Carer Information Sheet' should be changed to 'Nominated Person'.</li> </ul>
	<ul> <li>Under the heading 'Procedures', the term 'nominated person' in the Participant Information Sheet should be used instead of 'carer/significant other member' with an explanation that this nominated person could be their significant other or carer.</li> </ul>
	The Participant Information Sheet should cover the risk of incidental findings from the cognitive assessments and implications of unexpected results.  The full CDBR statement should be included the HRA transportance.
	<ul> <li>The full GDPR statement should be included - the HRA transparency</li> </ul>

	<ul> <li>wording was available at: <u>https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/</u></li> <li>A statement that each person's participation (participant and nominated person) was contingent on each other participating in the study should be included.</li> <li>A statement that data would be retained if participants lost capacity to consent during the study should be included.</li> <li>A statement that direct quotes would be published and pseudonyms would be assigned in publication should be included.</li> </ul>
2.	<ul> <li>The Consent Forms should be amended as follows:</li> <li>Consent Form Participant: the optional consent items 5, 6, 7 and 8 should be changed to yes/no boxes.</li> <li>Consent Form Carer should be changed to Consent Form Nominated Person and the optional consent items 3 and 5 should be changed to yes/no boxes.</li> </ul>

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and <u>provide copies of any revised documentation</u> <u>with updated version numbers and dates</u>. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

<u>Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS</u> <u>management permission (in Scotland) should be sought from all NHS organisations involved</u> <u>in the study in accordance with NHS research governance arrangements.</u> 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**

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. <u>Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs)</u>, except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee ( see here for more information on requesting a deferral: <u>https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/</u>

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

#### Publication of Your Research Summary

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: <u>https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/</u>

# 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 HRA 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: <a href="https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/">https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/</a>

# 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

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

#### Ethical review of research sites

#### NHS/HSC Sites

The favourable opinion applies to all NHS/HSC sites taking part in the study taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS 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 documents reviewed and approved at the meeting were:

Document	Version	Date
Covering letter on headed paper [Ethics Covering Letter]	1	16 July 2020
GP/consultant information sheets or letters [GP Letter]	1	06 July 2020
Interview schedules or topic guides for participants [Interview Questions]	1.0	25 August 2020
IRAS Application Form [IRAS Form 27082020]	286103/144 9261/37/37 4	27 August 2020
IRAS Checklist XML [Checklist_01092020]		01 September 2020
Non-validated questionnaire [Weekly Monitoring Form]	1	13 July 2020
Other [Daily Text Message Wording]	1.0	25 August 2020
Other [MHRA confirmation of Non-Medical Device]		26 November 2018
Other [Project Proposal Reviewer Feedback - University of Glasgow]		15 June 2020
Participant consent form [Carers]	1.0	25 August 2020
Participant consent form [Consent Form V1.1 25.08.2020]	V1.1	25 August 2020
Participant information sheet (PIS)	1.1	25 August 2020
Participant information sheet (PIS) [Carer]	1.0	25 August 2020
Research protocol or project proposal	1.1	08 July 2020
Summary CV for Chief Investigator (CI) [John Wilson]		28 August 2020
Summary CV for student [John Wilson]	1	15 July 2020
Summary CV for supervisor (student research) [Jon Evans]	1.1	10 July 2020
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Procedure Flow Chart]	1	14 July 2020
Validated questionnaire [PRMQ Proxy Rater Form]	1	13 July 2020
Validated questionnaire [UTAUT Questionnaire]	1	13 July 2020

Validated questionnaire [CES-D Questionnaire]	1	13 July 2020
Validated questionnaire [TOPF assessment cover page]	1	14 July 2020
Validated questionnaire [DKEFS assessment cover page]	1	14 July 2020
Validated questionnaire [WMS Older Adult assessment cover	1	14 July 2020
page]		

#### Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Mrs Sophie Welch declared an interest in this study as she provided doctoral training at the University of Glasgow, but had not provided advice on this particular study. The Committee agreed that Mrs Welch could remain in the meeting for the review of this application.

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: <u>http://www.hra.nhs.uk/about-the-hra/governance/guality-assurance/</u>

#### HRA Learning

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

IRAS project ID: 286103	Please quote this number on all correspondence
-------------------------	--

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

Yours sincerely

#### Professor Nigel Webster Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments "After ethical review – guidance for researchers" [SL-AR2 for other studies]
Copy to:	Ms Frances Hines Lead Nation - Scotland: <u>nhsg.NRSPCC@nhs.net</u>

# North of Scotland Research Ethics Committee (1)

# Attendance at Committee meeting on 24 September 2020

#### **Committee Members:**

Name	Profession	Present	Notes
Ms Emma Berry	Research Engagement and Involvement (REI) Officer	Yes	
Dr Suzanne Breeman	Trial Manager	Yes	
Mr Richard Caie	Retired Ship Captain	Yes	
Dr Jennifer Caldwell	Alternate Vice-Chair & Education Consultant - Occupational Therapy	No	
Ms Abiola Crown	Fountain of Love Church Outreach Officer/Time to Heal Manager (Volunteer)	Yes	
Mrs Gillian Findlay	Assistant Psychologist, NHSG Psychological Resilience Hub	No	
Mrs Katie Gordon	Retired Physiotherapist	Yes	
Mrs Morag Howard	Radiography Services Manager	Yes	
Mr Dee Jurksa	Bank Operating Theatre Care Assistant	Yes	
Mr Terry Mackie	Retired Architect	No	
Professor David Parkin	Consultant Gynaecological Oncologist	Yes	
Mr Bartosz Was	Clinical Trials Pharmacist	Yes	
Professor Nigel Webster	Chair & Emeritus Professor of Anaesthesia and Intensive Care Medicine	Yes	Chair
Mrs Sophie Welch	Vice-Chair & Coach Practitioner	Yes	

#### Also in attendance:

Name	Position (or reason for attending)	
Dr Rachel Hardie	Scientific Officer	
Ms Sarah Lorick	Assistant Ethics Co-ordinator	

Appendix 2.4. Substantial amendment approval.

## North of Scotland Research Ethics Committee (1)

Summerfield House 2 Eday Road Aberdeen AB15 6RE

Telephone: 01224 558458 Email: gram.nosres@nhs.scot



09 October 2020

Mr John Wilson 23 Bishops Park INVERNESS IV3 5SZ Dear Mr Wilson Study title: ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application With Community Dwolling Older Adults Who Have Sustained

	Smartphone Reminding Application With
	Community-Dwelling Older Adults Who Have Sustained
	A Stroke.
REC reference:	20/NS/0108
Protocol number:	1
IRAS project ID:	286103

Thank you for your e-submission of 09 October 2020. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 30 September 2020.

#### Documents received

The documents received were as follows:

Document	Version	Date
IRAS Checklist XML [Checklist 09/10/2020]		09 October 2020
Participant consent form	1.2	05 October 2020
Participant consent form [Nominated Person]	1.1	05 October 2020
Participant information sheet (PIS)	1.2	05 October 2020
Participant information sheet (PIS) [Nominated Person]	1.1	05 October 2020

#### Approved documents

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

Document	Version	Date
Covering letter on headed paper [Ethics Covering Letter]	1	16 July 2020

GP/consultant information sheets or letters [GP Letter]	1	06 July 2020
	1.0	
Interview schedules or topic guides for participants [Interview Questions]		25 August 2020
IRAS Application Form [IRAS Form 27082020]		27 August 2020
	9261/37/37	
	4	
IRAS Checklist XML [Checklist 09/10/2020]		09 October 2020
Non-validated questionnaire [Weekly Monitoring Form]	1	13 July 2020
Other [Daily Text Message Wording]	1.0	25 August 2020
Other [MHRA confirmation of Non-Medical Device]		26 November 2018
Other [Project Proposal Reviewer Feedback - University of Glasgow]		15 June 2020
Participant consent form	1.2	05 October 2020
Participant consent form [Nominated Person]	1.1	05 October 2020
Participant information sheet (PIS)	1.2	05 October 2020
Participant information sheet (PIS) [Nominated Person]	1.1	05 October 2020
Research protocol or project proposal	1.1	08 July 2020
Summary CV for Chief Investigator (CI) [& Student John Wilson]		28 August 2020
Summary CV for supervisor (student research) [Jon Evans]	1.1	10 July 2020
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Procedure Flow Chart]	1	14 July 2020
Validated questionnaire [PRMQ Proxy Rater Form]		
Validated questionnaire [UTAUT Questionnaire]		
Validated questionnaire [CES-D Questionnaire]		
Validated questionnaire [TOPF assessment cover page]		
Validated questionnaire [DKEFS assessment cover page]		
Validated questionnaire [WMS Older Adult assessment cover page]		

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

IRAS Project ID: 286103	Please quote this number on all correspondence

Yours sincerely

Ms Sarah Lorick Assistant Ethics Co-ordinator Appendix 2.5. Participant information sheet.





# **PARTICIPATION INFORMATION SHEET V1.2**

Title of Project: ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application With Community-Dwelling Adults Who Have Sustained A Stroke

IRAS ID: 286103

Date: 05/10/2020

Participant

Principal Investigator: Prof Jon Evans Chief Investigator: Mr John Wilson

You are being invited to take part in a research study. Before you decide whether you would like to take part, it's important for you to understand what the research will involve and why it is being done. Please take time to read the below information regarding the study. You can ask the researcher any questions you may wish before you decide to take part.

## PURPOSE OF THIS RESEARCH STUDY

We are asking you to take part in a study to investigate the usefulness of a smartphone application (or 'app') that you can use to remind you about things you intend to do. To do this, we will ask you about things you need to do (e.g. take medication, attend appointments, everyday tasks). We will ask you to record how often you forget to do things each week, and then see if using the app helps you remember to do things. We will also ask you about how easy it was using the app.

To be eligible to take part in this study, you must be aged 18 years or over (we are looking to recruit both younger adults (18-65s) and older adults (over 65s) in this study), be fluent in English, have difficulties remembering things, own and be able to use a smartphone and have someone who is willing to help by completing weekly forms (a nominated person). For instance, you could nominate your significant other or a carer to take on this role. Your participation in this research is contingent on both you and your nominated person participating throughout the study.

# PROCEDURES

If you decide to take part in this study, we will ask you to tell us about any memory difficulties you are experiencing, whether you use memory aids currently or in the past, and tell us about what tasks that you would like to be reminded of using a smartphone application. We will ask you to complete some brief tests of your thinking skills, including memory.

We will ask your nominated person to complete a form with you which lists the memory events that you would like to be reminded of using the smartphone application. They will do so by placing a tick/cross beside each task to indicate whether you remembered to complete it. This part of the study will last either 5, 6 or 7 weeks.

We will then provide you with an illustrated, step by step guide on the use of the smartphone application and a video tutorial to help you download and use it. We will ask you to set reminders using the application for the tasks that you would like to be reminded about. After this training, we will ask your nominated person to continue to complete the checklist of whether you completed the memory events, by placing a tick or a cross beside each task on the form. This will last 5 weeks. Your nominated person will receive a daily reminder text message to complete this form.

After this 5-week period is finished, we will ask you to complete a brief questionnaire regarding how useful you found the application, which will be emailed or posted to you. We will also ask you about your thoughts on the strengths, weaknesses and usefulness of the application over the telephone.

At the end of the study you can continue to use the app free of charge. Because the app is still being researched, we cannot guarantee how long it will be available to use. However, if the app is shown to be useful, our intention is to keep the app maintained to so that it continues to work beyond the time period of the study. If the app is not going to be continued after the study, we will let you know when it will stop working. We will also provide you with information about alternative apps that you may find useful.

# POSSIBLE RISKS OF DISCOMFORT

There is very little risk to taking part in this study. The use of the smartphone application does not pose any risk. The methods used in this study have been used before. Arranging a convenient time to complete the cognitive assessments over video conference may be inconvenient. We will do everything we can to accommodate your preferred time and date which to complete these. The findings of the memory assessments may reveal that your memory ability has changed since your stroke. Researchers will be able to discuss the findings of these assessments with you and sign post you to relevant organisations and services who will be able to provide you with support and information.

# **POSSIBLE BENEFITS**

The use of the application may benefit you directly by increasing the likelihood of you remembering to complete tasks that you intend to do (but sometimes forget). Other people may also benefit from you taking part in this study. For example, if the study finds that the use of the smartphone application increases the number of tasks that you complete, it may be recommended as a clinical intervention for other people who are experiencing memory difficulties.

If you would like to receive a report of the results of this study when they are available, you can initial your response to this on the consent form later.

# FINANICAL CONSIDERATIONS

The smartphone application is free to use. However, you will require the use of your own smartphone and have access to the internet in your home. No aspect of taking part in this study is expected to result in any additional cost to you.

# CONFIDENTIALITY

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules. Universities, NHS organisations and companies may use patient data to do research to make health and care better. Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'. If they could do the research without using patient data, they would not be allowed to get your data. Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

To protect your confidentiality, we will assign you a unique number or code that will be used to label your information and sample that you provide. Any personal information that you provide, such as your name and contact details, will be kept separately and locked away. Only the researchers will have access to the information you provide. None of your personal information will be on the assessments or questionnaires you completed unless you request these to be added to your medical file.

The results of this study may be published for scientific purposes as well as direct quotes from you. Direct quotes from you may be published. Pseudonyms will be assigned to you so that you will not be identifiable in these reports.

Further information on how your information may be used is available at <a href="https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/">https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/</a>

# **TERMINATION OF RESEARCH STUDY**

You do not have to take part in this study. Even if you do decide to take part but in future decide that you no longer wish to take part, you are free to withdraw from the study. You will not be penalised in any way if you decide that you do not want to take part or no longer wish to take part. You can choose to stop participating at any point during the study. If you would like to withdraw your consent, you can do so by contacting the Principal Investigator. If you should lose capacity to continue to take part in the study, your participation will be stopped and you will be informed of this. Any data gathered up to the point of your withdrawal will be analysed and used in the final write-up and publication of the study findings, but no further data will be collected.

# **ETHICS REVIEW**

This study has been approved by North of Scotland Research Ethics Committee 1 (Project Reference Number: 20/NS/0108).

# AVAILABLE SOURCES OF INFORMATION

All participants will be given a copy of this information sheet and of their signed consent form. If you have any questions later on or would like any additional information about the study and your rights as a participant, please feel free to contact the Chief Investigator (John Wilson) by email at john.wilson17@nhs.scot

# COMMENTS OR CONCERNS DURING THE STUDY

If you have any comments or concerns you should discuss these with the Principal Researcher. If you wish to complain about any aspect of the way that you have been approached or treated during the course of this study, you should email jonathan.evans@glasgow.ac.uk who will take the complaint forward as necessary.

Appendix 2.6. Nominated person information sheet.





# NOMINATED PERSON INFORMATION SHEET V1.1

Title of Project: ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application With Community-Dwelling Adults Who Have Sustained A Stroke

IRAS ID: 286103

Date: 05/10/2020

Participant

Principal Investigator: Prof Jon Evans Chief Investigator: Mr John Wilson

You are being invited to take part in a research study. Before you decide whether you would like to take part, it's important for you to understand what the research will involve and why it is being done. Please take time to read the below information regarding the study. You can ask the researcher any questions you may wish before you decide to take part.

# PURPOSE OF THIS RESEARCH STUDY

We are asking you to take part in a study to investigate the usefulness of a smartphone application (or 'app') that the person who nominated you can use to remind them about things they intend to do. To do this, we will ask the person who nominated you about things they need to do (e.g. take medication, attend appointments, everyday tasks). We will ask you to record when the person who nominated you remembers to do the things that they intended to do each week, and then investigate whether using the application helps the person who nominated you to remember to do more things.

To be eligible to take part in this study, you must be fluent in English, live with the person who nominated you and be able to record when the person who nominated you remembers to complete the tasks they choose to be reminded of at the end of each day. The participation of the person who nominated you in this study is only possible with your participation in the study.

# PROCEDURES

If you decide to take part in this study, we will also ask you to place a tick/cross beside each task that the person who nominated you has chosen to be reminded of, on a monitoring form. This is to indicate whether the person who nominated you successfully remembered to complete the task/activity. This part of the study will last either 5, 6 or 7 weeks. We will send you a daily reminder text message to complete this form at a time agreed by you.

We will then start the second part of the study by using the ApplTree application. We will ask you to continue to complete the monitoring form to record whether the person who nominated you completed the memory events, by placing a tick or a cross beside each task on the form. This will last 5 weeks. We will send you a daily reminder text message to complete this form at a time agreed by you.

# POSSIBLE RISKS OF DISCOMFORT

There is very little risk of discomfort in taking part in this study. The findings of the memory assessments may reveal that the memory ability of the person who nominated you has changed since their stroke. Researchers will be able to discuss the findings of these assessments with you and the person who nominated you, and will be able to sign post relevant organisations and services who will be able to provide support and information about this. Should you have any concerns, please don't hesitate to contact either the Chief or Principle Investigator (see point 10, overleaf for contact information).

# **POSSIBLE BENEFITS**

The use of the application may benefit the person who nominated you directly by increasing the likelihood of them remembering to complete the tasks that they intend to do (but sometimes forget). Other people may also benefit from you taking part in this study. For example, if the study finds that the use of the smartphone application increases the number of tasks that the person who nominated you completes, it may be recommended as a clinical intervention for other people who are experiencing memory difficulties.

If you would like to receive a report of the results of this study when they are available, you can initial your response to this on the consent form later.

# FINANICAL CONSIDERATIONS

The smartphone application is free to use. However, the person who nominated you will require the use of their own smartphone and have access to the internet in your home. No aspect of taking part in this study is expected to result in any additional cost to you.

# CONFIDENTIALITY

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules. Universities, NHS organisations and companies may use patient data to do research to make health and care better. Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'. If they could do the research without using patient data, they would not be allowed to get your data. Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

To protect your confidentiality, we will assign you a unique number or code that will be used to label you information. Any personal information that you provide, such as your name and contact details, will be kept separately and locked away. Only the researchers will have access to the information you provide. None of your personal information will be on the questionnaires you complete.

The results of this study may be published for scientific purposes as well as direct quotes from you. Direct quotes from you may be published. Pseudonyms will be assigned to you so that you will not be identifiable in these reports.

Further information on how your information may be used is available at <a href="https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/">https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/</a>

# **TERMINATION OF RESEARCH STUDY**

You do not have to take part in this study. Even if you do decide to take part but in future decide that you no longer wish to take part, you are free to withdraw from the study. You will not be penalised in any way if you decide that you do not want to take part or no longer wish to take part. You can choose to stop participating at any point during the study. If you would like to withdraw your consent, you can do so by contacting the Principal Investigator. If the person who nominated you should lose capacity to continue to take part in the study, both yours and their participation will be stopped and both of you will be informed of this. Any data gathered up to the point of your withdrawal will be analysed and used in the final write-up and publication of the study findings, but no further data will be collected.

# **ETHICS REVIEW**

This study has been approved by North of Scotland Research Ethics Committee 1 (Project Reference Number: 20/NS/0108

# **AVAILABLE SOURCES OF INFORMATION**

All participants will be given a copy of this information sheet and of their signed consent form to keep. If you have any questions later on or would like any additional information about the study and your rights as a participant, please feel free to contact the Chief Investigator (John Wilson) by email at john.wilson17@nhs.scot

# COMMENTS OR CONCERNS DURING THE STUDY

If you have any comments or concerns you should discuss these with the Principal Researcher. If you wish to complain about any aspect of the way that you have been approached or treated during the course of this study, you should email <u>jonathan.evans@glasgow.ac.uk</u> who will take the complaint forward as necessary.

Appendix 2.7. Participant consent form.





PARTICIPANT INFORMED CONSENT FORM V1.2

Title of Project: ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application With Community-Dwelling Adults Who Have Sustained A Stroke

IRAS ID: 286103

Date: 05/10/2020

Participant Identification

Please initial boxes on the right. Initial either the yes or the no box to numbers 5-8.

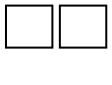
- I confirm that I have read the information sheet dated <u>05.10.2020 (Version1.2)</u> for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected, and that data collected up until the time that I withdraw will be analysed and used.
- 3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the NHS Highland Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 4. I understand that a copy of this consent form will be added to my medical notes.





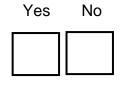


- 5. I would like to be informed of the results of the cognitive assessments.
- 6. I would like a copy of the cognitive assessments added to my medical notes.
- I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.
- 8. I agree to be contacted in future by the study researchers about this and other studies I may be interested in.
- I agree to my General Practitioner being informed of my participation in the study including any necessary exchange of information about me between my GP and the research team.
- 10. I agree that if I disclose information that suggests that I am or someone else is at risk of harm to myself or others, they will need to pass this on to relevant agencies and services in order to minimise the harm.
- 11. I agree to take part in the above study.



No

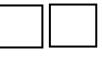
Yes



Yes



No







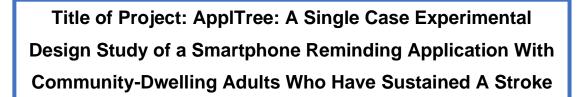
Name of the nominated person	Date	Signature
Name of person taking consent (Chief Researcher)	Date	Signature

Appendix 2.8. Nominated person consent form.





# NOMINATED PERSON INFORMED CONSENT FORM V1.1



IRAS ID: 286103

Date: 05/10/2020

Participant

Please initial boxes on the right. Initial either the yes or the no box to numbers 3 and 5.

- I confirm that I have read the information sheet dated <u>05/10/2020 (Version 1.1)</u> for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected, and that data collected up until the time that I withdraw will be analysed and used.
- 3. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.



Yes No



- 4. I agree that if I disclose information that suggests that I, or someone else, is at risk of harm, the researchers will need to pass this information on to the relevant service.
- 5. I wish to receive a report of the results of this study when they are available.
- 6. I agree to take part in the above study.

# Comments or concerns during the study

If you have any comments or concerns you should discuss these with the Principal Researcher. If you wish to complain about any aspect of the way that you have been approached or treated during the course of this study, you should email jonathan.evans@glasgow.ac.uk who will take the complaint forward as necessary.

Name of the nominated person	Date	Signature
Name of person taking consent (Chief Researcher)	Date	Signature



Yes	No

Appendix 2.9. Telephone interview questions.





# **INTERVIEW QUESTIONS V1.0**

# Title of Project: ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application With Community-Dwelling Older Adults Who Have Sustained A Stroke

Have you read through the information sheets that were sent to you?

Do you have any questions about this or from the informed consent form that you would like to ask me?

Have you experienced any psychological difficulties or difficulties with your mood since the stroke?

Have you received any support for any psychological or mood difficulties, if so?

Are you currently taking medication for this?

Have you experienced any memory difficulties since you had a stroke?

Has anyone you know commented on any memory difficulties since you had a stroke?

Have you been diagnosed with any other medical or neurological conditions?

Have you ever used a memory aid before?

If so, what memory aids have you used previously?

What type of tasks do you complete each week or would like to complete each week that you may wish to be reminded to do, by ApplTree?

On what days and at what time would you like ApplTree to send a reminder to your phone in order to complete each of these tasks?

Appendix 2.10. Weekly memory log.

# Week Beginning Monday: / /2021

Please enter week commencing date above. If you would like to add any further memory tasks to be completed as the week goes by, simply enter them on the day which they are due to be completed below. You do not need to fill in all the lines in each box for each day.

Activity	Was it completed Yes/No?

	Activity	Was it completed Yes/No?
Thursday		
Friday		
Saturday		
Sunday		

The Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire

# Date:

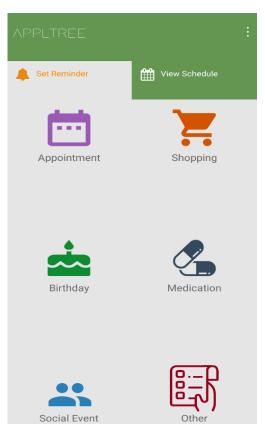
Below is a list of the statements regarding the ApplTree application. Please indicate by placing an 'X' in the most appropriate column, how you would feel using AppITree. Please complete all questions, on all four pages of this form.

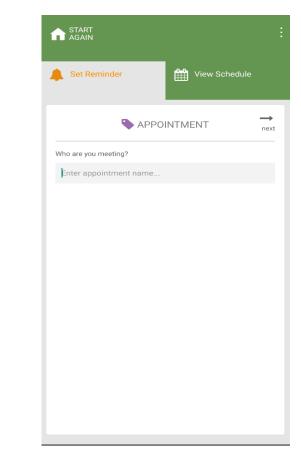
	Strongly Disagree	Disagree	Slightly Disagree	Strongly Disagree Slightly Neither Slightly Disagree Disagree Agree or Agree Disagree	Slightly Agree	Agree	Strongly Agree
Performance expectancy							
U6: I would find AppITree useful in completing daily tasks.							
RA1: Using AppITree enables me to accomplish tasks when I intend to complete them.							
RA5: Using AppITree increases my chances of doing the things I intend to do.							
Effort expectancy							
EOU3: ApplTree is clear and understandable.							
EOU5: It would be easy for me to become <u>skillful</u> at using AppITree.							
EOU6: I would find ApplTree easy to use.							
EU4: Learning to use AppITree is achievable for me.							

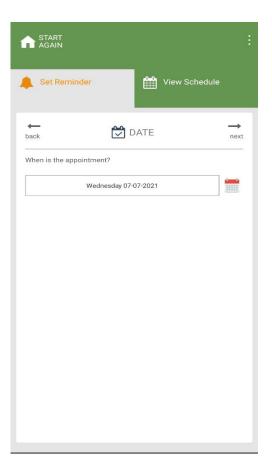
	Strongly Disagree	Disagree	Slightly Disagree	Neither Agree or Disagree	Slightly Agree	Agree	Strongly Agree
Attitude toward using technology							
Al: Using ApplTree is a good idea.							
AF2: Working with ApplTree is fun.							
Affect1: I like working with AppITree.							
Social influence							
SN2: People who are important to me think that I should use AppITree.							
Facilitating conditions							
PBC3: I have the knowledge necessary to use ApplTree.							
PBC5: AppITree is not compatible with other memory aids that I use.							

	Strongly Disagree	Disagree	Slightly Disagree	Neither Agree or Disagree	Slightly Agree	Agree	Strongly Agree
Self-efficacy I could complete a job or task using ApplTree							
SE1: If there was no one around to tell me what to do as I go.							
SE4: If I could call someone for help if I got stuck.							
SEO: If I had a lot of time to complete the task that ApplTree reminded me to do.							
SE7: If I had just the built-in help facility for assistance.							
Anxiety							
ANX1: I feel apprehensive about using ApplTree.							
ANX2: It worries me to think that I could lose a							
lot of information using AppITree by hitting the wrong key.							
ANX3: I hesitate to use AppITree for fear of making mistakes I cannot correct.							
ANX4: ApplTree is somewhat intimidating to me.							
Behavioural intention to use ApplTree							
BI1: I intend to use AppITree in the next 3							
months.							

	Strongly Disagree	strongly Disagree Disagree	Slightly Disagree	Neither Agree or Disagree	Slightly Agree	Agree	Strongly Agree
B12: I predict I would use AppITree in the next 3 months							
B12: I plan to use AppITree in the next 3 months							



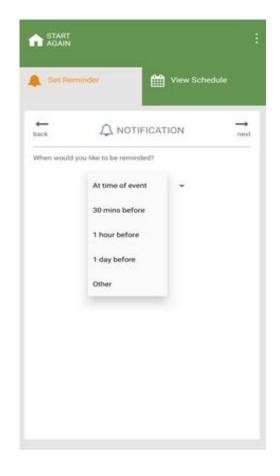


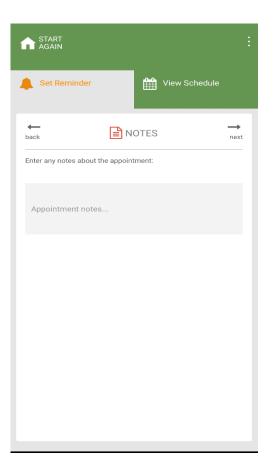


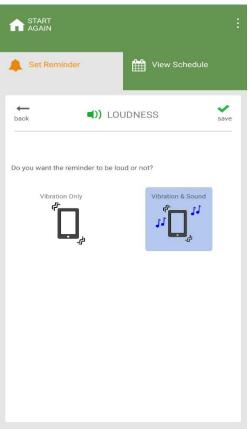
AGAIN		:
Let Reminder	View Schedule	
back		next
Time of the appointment?		
C	06:24 PM	
Set for t	he afternoon / evening	

# Appendix 2.12. ApplTree menus and navigation

START AGAIN		
🔔 Set Reminder	View Schedule	
←     back Will this happen again? Choose days to repeat     Mon     Thurs     Sun How long would you like	C REPEAT	→ next





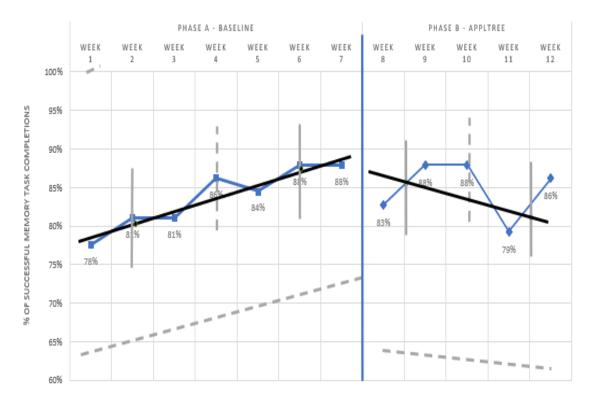


AGAIN	
🔔 Set Reminder	1 View Schedule
back	JDNESS save
New Appointn	nent Reminder
When: 07/07/21 at 18:24 Notification: Event Time before Repeat:	
← Back	Save

APF						
•	Set Remind	er	Ê	🖞 View 🗄	Schedule	2
<		Sep	tember 2	021		>
SUN	MON	TUE	WED	THU	FRI	SAT
			1	2	3	4
				(+3)	-	
		Medica	ation - 08	:00 AM		
		Medica	ation - 09	:35 AM		
		Appoint	tment - 1	5:09 PM		
		Medica	ation - 17	:00 PM		
		Medica	ation - 18	:00 PM		
		Medica	ation - 18	:00 PM		
5	6	7	8	9	10	11
12	13	14	15	16	17	18

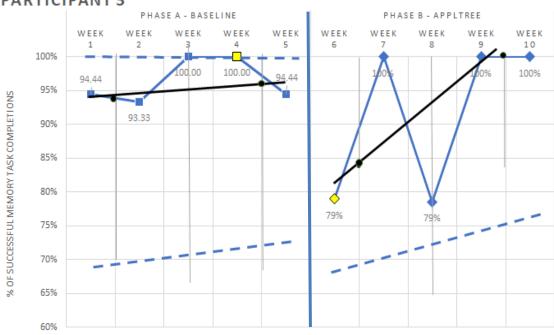


# PARTICIPANT 1



# **PARTICIPANT 2**

				PHASE A -	BASELINE				PHAS	E B - APPL	TREE	
	100%	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	W E E K 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10	WEEK 11
NS	10070	100%	100%	100%	100%	1009		100%	100%	100%	100%	100%
TASK COMPLETIONS					1		$\setminus$			I		
ASK COI	90%				1		90%					
MORY T												
% OF SUCCESSFUL MEMORY	80%											
UCCESS												
% OF SI										_		
%	70%											



#### PARTICIPANT 3

Appendix 2.14. Submitted major research project proposal.



# ApplTree: A Single Case Experimental Design Study of a Smartphone Reminding Application With Community-Dwelling Older Adults Who Have Sustained A Stroke

Name of Assessment:	Major Research Project Proposal Outline
Matriculation Number:	
University Supervisor:	Professor Jonathon Evans
Field Supervisor:	Dr. Jim Law
Date of Submission:	29 <sup>th</sup> of May 2020
Version:	5
Actual Word Count:	2994
Maximum Word Count:	3000

\*Secondary Covid-19 social distancing protocol with an alternative assessment procedure

#### Abstract

Prospective memory (PM) difficulties are common in survivors of stroke. Assistive Technologies (AT) have been used in various populations to aid performance on tasks of PM by prompting the user to complete scheduled tasks. However, research into the effectiveness of AT interventions in PM impairment post-stroke are limited. This study aims to investigate whether a smartphone AT application 'ApplTree' improves successful completion of PM tasks by recruiting three to six community-dwelling, older adult stroke survivors, with PM impairment in this multiple baseline, single case experimental design study. The completion of personally-meaningful tasks will be recorded against a weekly monitoring form completed by the participant's carers throughout phase A (5-7 weeks) and phase B (5 weeks). During phase B, ApplTree will prompt participants to complete their everyday tasks. This study aims to add to the literature on the use of AT in the rehabilitation of PM impairment following stroke in community-dwelling OAs.

#### Introduction

Stroke is a life-threatening, cerebrovascular accident which results in cerebral dysfunction (Zhelev et al., 2019). More than 100,000 strokes are recorded each year in the United Kingdom (NICE: Impact Stroke, 2019). Stroke disproportionally affects older adults (OAs); around 50% of strokes occur in adults aged 45-74 years (Scottish Stroke Statistics, 2019). Stroke is the third most prevalent source of mortality and the most prevalent cause of disability in Scotland; two thirds of stroke patients are discharged from hospital with some form of impairment (Adamson et al., 2004).

Post-stroke memory impairment can affect a person's ability to recall past events (retrospective memory) and their ability to remember to carry out intended actions in the future (prospective memory) (Kvavilashvili, 1992). Rehabilitation of prospective memory (PM) impairment can employ either a restorative approach; aiming to restore cognitive function through the use of memory strategies, such as repetition, or a compensatory approach; using environmental adaptations, internal memory strategies and external memory aids, to augment memory performance (Spreij et al., 2014). For post-stroke OAs a consensus has not been reached as to which approach is the most effective (das Nair et al., 2016).

Memory strategies can either be 'internal' such as using mnemonic devices and rehearsal or 'external' such as using diaries and calendars; which are recommended for post-stroke memory problems (Cicerone et al., 2011). Electronic memory aids, such as alarms and calendars, have increased but the use of these aids remains relatively low with people living with acquired brain injury (ABI) (Jamieson et al., 2017). Several assistive technologies (AT) have been developed to improve everyday memory performance following ABI, for instance the pager-based reminder system, NeuroPage (Wilson, Emslie, Quirk & Evans, 2001).

More recently, smartphone applications (apps) have been designed as reminder systems, sending prompts to the user's phone to remind them to complete a prespecified task at a prespecified time (Gillespie et al., 2011). One app, MindMate, has been found to increase memory performance in OAs with memory impairment due to Alzheimer's dementia (McGoldrick et al., 2019). ApplTree is another smartphone reminder app developed for people with memory difficulties following acquired brain injury (Jamieson, 2015).

ApplTree prompts users about events which they have scheduled into the app. It can be programmed to send unsolicited prompts to remind the user to add any additional events on to the app schedule. The app allows users to enter fully customisable, repeat reminders for reoccurring events. ApplTree has two user interface options for entering reminders. One is referred to as 'narrow-deep' and involves the user having small amounts of information on several screens as they work through the process of entering a reminder. The other interface is 'broad-shallow' and is more typical of smartphone calendar apps where data entry is done on one screen and scrolling is required. The idea is that the narrow-deep interface reduces attentional demand on the user and is easier to use. A pilot feasibility randomised controlled trial of ApplTree, concerned primarily with efficacy, is currently collecting outcomes on memory performance and gathering feedback regarding how best to implement a mobile reminder app intervention (Jamieson, 2019).

#### **Plan of Investigation**

#### Aims and hypotheses

This study aims to investigate the usefulness and efficacy of ApplTree in increasing PM performance in OAs who have post-stroke, PM difficulties.

The primary hypothesis is:

A significant increase in frequency of successful target memory event (TME) completion will be found after the introduction of the ApplTree application

The secondary hypothesis is:

Participants will rate ApplTree as an acceptable and useable AT

#### Participants

Three to six community-dwelling OA's (≥ 65 years), stroke survivors will be approached by the Chest Heart and Stroke Team (CHST) in NHS Highland. Participants will have self or other-reported PM difficulties and share accommodation with a person willing to complete weekly monitoring forms (WMFs) and support the participant in using the ApplTree application.

Exclusion criteria:

- Non-fluent English speakers
- Aged ≤ 64 years
- Index stroke ≤ 6 months prior to recruitment
- Diagnosed, pre-existing neurological condition
- Severe psychiatric diagnosis (e.g. psychosis, clinical depression)
- Pre-existing dementia or ABI diagnosis
- Diagnosed or suspected learning disability
- Current cognitive impairment of sufficient severity that would prevent the participant using the app
- Don't have a smartphone
- Physical, visual or auditory impairments which, if uncorrected with assistive aids, prevent the operation of a smartphone

#### **Recruitment Procedures**

Potential participants who satisfy the inclusion/exclusion criteria, will be approached by the CHST and provided with an invitation letter and participant information sheet. Interested potential participants will be contacted by the researcher who will answer any study-related questions, prior to obtaining their consent.

#### Materials

Cognitive impairment will be determined using neuropsychological assessment at the participant's home or the older adult department (OAD) at New Craig's Hospital using:

- ✓ Test of Pre-Morbid Functioning (TOPF, Wechsler, 2011)
- ✓ Prospective and Retrospective Memory Questionnaire (Smith et al., 2000)

- Rivermead Behavioural Memory Test -3<sup>rd</sup> version (RBMT-3; Wilson et al., 2008)
- ✓ Trails, verbal fluency and the colour-word interference subtests of the Delis–
   Kaplan Executive Function System (D-KEFS; Delis et al., 2001)
- ✓ Modified Six Elements Test from the Behavioural Assessment of the Dysexecutive Syndrome (BADS: Wilson et al., 1996)
- ✓ Centre for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977)

ApplTree will be programmed by participants to send reminder prompts to their phone for upcoming events and unsolicited prompts to set any additional reminders. The participant's carer will be asked to complete WMFs regarding the completion of TMEs.

Participants will be asked to complete the Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire (Venkatesh et al., 2003) to assess the usability, usefulness and intention to use the ApplTree app, at the onset and completion of the study.

#### Design

This study will utilise a multiple baseline single case experimental design (SCED). Participants will be randomly allocated to either a 5, 6 or 7 week baseline, in each group of three participants, using the Social Psychology Network's electronic randomiser programme (<u>http://www.randomizer.org</u>). After the baseline phase, each participant will be given the use of the ApplTree application for 6 weeks; inclusive of a training week. Carers will complete WMFs throughout the baseline and intervention phases.

#### Procedure

Ethical approval will be obtained from the NHS Highland Ethics Committee. Informed consent will be obtained from potential participants. In the event that Scottish Government social distancing measures remain in place during the study, a secondary protocol will supersede the primary protocol, making use of video technology to deliver the study (See Appendix 1). Scottish Government guidance on social distancing will be consulted prior to any appointment.

#### Protocol

At the initial interview potential participants will be provided with a study information sheet and asked to provide their consent to take part in the study. Information regarding previous use of memory aids and the identification of TME will be collected. Subjective reports of the participant's cognitive and psychological difficulties will be gathered. A two-hour appointment will be arranged to complete the neuropsychological assessments. Data will be gathered from weekly monitoring forms which list the week's target memory events. The participant's carer will place a tick or a cross beside each target memory event to signify its successful or non-successful completion, throughout baseline and intervention phases

Participants and carers will receive training regarding the study process and in using the ApplTree application. An illustrated, step by step guide on the use of ApplTree and a video tutorial on downloading, navigating and programming ApplTree, will be emailed to the participant. Carers will receive orientation and training in the completion of WMFs via telephone. Personally-meaningful TMEs for which reminders will be set and the number of 'reminder' prompts the participant would like to receive for these will then be discussed. Participants will input reminders and receive unsolicited prompts to add any additional events. After this training week, the intervention phase will begin and last 5 consecutive weeks.

During the intervention phase, participants will enter events on ApplTree with the assistance of their carer, if required. ApplTree will provide prompts at the predetermined times. Carers will receive a daily reminder text message to complete the monitoring form (every evening). Following completion of the intervention phase, participants will be asked to complete the Unified Theory of Acceptance and Use of Technology (UTAUT) which will be emailed or posted to them. Qualitative information will be gathered from participants regarding the strengths, weaknesses and usefulness of ApplTree and whether they would wish to use it in future.

#### **Data Analysis**

To answer the primary hypothesis, visual analysis of WMF data will be completed. Visual analysis is the most commonly used method of analysing frequency data in SCED studies, allowing for the analysis of the degree and variability of change in data (Barton, Lloyd, Spriggs & Gast, 2016).

Comparison of percentage of successful TME completions between baseline and intervention phases will be analysed using Tau-U. This non-parametric data analysis method, uses pairwise comparisons of data points to statistically analyse non-overlapping data (Parker & Vannest, 2009) allowing for the comparison of individual participant performance between phase A and phase B, and the computation of effect size (Cliff, 1993).

SCED standards published by Kratochwill et al., (2012) stipulate a minimum of three data points in each phase and three opportunities to demonstrate the experimental effect. The current study design satisfies these criteria.

#### Power

Tau-U has demonstrated statistical power of 91-115 percent of parametric equivalents (Vannest et al., 2011) and reliably detects medium effect sizes in small sample sizes (Parker et al., 2014). A recent meta-analysis of SCED studies of AT interventions, using non-overlapping pairs methodology, found several large effect sizes (Jamieson et al., 2013). Large effect sizes have also been found in similar SCED studies with a N=3 sample size (McGoldrick et al., 2019). It is expected that the current study will find similar levels of effect and, therefore, Tau-U will have sufficient power to detect a large effect size.

#### **Ethical Issues**

Feedback regarding this proposal will be gathered from the NHS Research Ethics Committee and be submitted to University of Glasgow for review prior to study commencement. Potential participants may have significant cognitive impairment which may negatively affect their capacity to consent to participate in the study. The Stroke Co-ordinator of the CHST will raise any concerns regarding capacity following their initial contact with potential participants, who will be checked for capacity to consent to the study by the primary researcher before informed consent is gained. Any doubt relating to capacity to consent to the study will be referred to the field supervisor before the potential participant is enrolled.

All participants will receive the intervention which will not be withdrawn due to the multiple baseline study design. A low risk of psychological distress may arise through the completion of cognitive assessments. Participants will be asked whether they would like to receive their assessment results and whether they would like their results added to their medical file. Reassurance and advice will be offered by the primary researcher in light of any emotional difficulties during their participation. Adverse events will be recorded in the local site file and the patient's medical folder, and reported to both the field and research supervisor.

At the end of the study participants will be able to continue to use ApplTree if they wish. However, ApplTree is currently a research tool and whilst the aim is for ApplTree to be maintained in the longer term, how long it will continue to operate after the end of the study cannot be guaranteed. Participants will be provided with information on other reminding apps that may be useful.

Participant data will be stored on an encrypted, password protected NHS laptop, in password protected files. Hard copies of assessments will be stored within NHS Highland premises in line with local and national data protection guidelines. Hard copies of participant personal information will be securely destroyed when the study has concluded. The Chief Investigator, based in the Institute of Mental Health and Wellbeing at the University of Glasgow, will have access to, and will securely store, study data for a duration of ten years.

#### **Financial Issues**

ApplTree is a free app, however, participants must have a smart phone and access to the internet from home. All neuropsychological assessment stimuli will be borrowed from the OAD at New Craigs Hospital at no cost. However, response forms for each assessment will require purchasing. See Appendix 2 Costs for costs for protocol one, and Appendix 3 for costs for protocol two.

### Health and Safety Procedures

See Appendix 4 for protocol one and Appendix 5 for protocol two.

#### Timetable

Ethics Submission	June-July 2020
Information to CHST	September 2020
Recruitment	September-November 2020
Data collection	January-March 2021
Analysis and write up	April-May 2021
Final write-up and viva preparation	June-July 2021

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#### **Secondary Protocol**

At the initial telephone interview, the potential participant will be provided with an information sheet about the study and will be asked to provide their consent to take part in the study. Information regarding the participant's previous use of memory aids and the identification of target events will be collected on the telephone. Subjective reports of the participant's cognitive and psychological difficulties will also be gathered at the telephone interview. Copies of questionnaires, will be posted to the participant with a stamped, return envelope. The researcher will then post the Prospective and Retrospective Memory Questionnaire (PRMQ) to the carer for their completion and return the completed questionnaire in the prepaid envelope. A date and time will then be arranged with the participant in order to complete neuropsychological assessments of cognitive function via video call.

Roughly 1 hour of neuropsychological assessments will then be completed with the participant in order to obtain objective, quantitative evidence of participant cognitive function. The following assessments will be delivered remotely with the participant via video call:

- Test of Pre-Morbid Functioning (TOPF)
- Auditory Memory Index (AMI) of the Older adult version of the Wechsler Memory Scale (WMS-IV)
- Verbal Fluency subtest of the Delis–Kaplan Executive Function System (DKEFS)

Data will be gathered from weekly monitoring forms which list the week's target memory events. The participant's carer will place a tick or a cross beside each target memory event to signify its successful or non-successful completion throughout baseline and intervention phases. The carer/ significant other will receive a daily reminder from the study team, via text message at a predetermined time of day, to complete the weekly monitoring form for that day. Participants and their carers will receive training regarding the study process, as well as on the use of the ApplTree application. A video tutorial on downloading the ApplTree application and navigating and programming it, will be sent to the participant's email address. Participants will also be provided with an illustrated, step by step guide, on the use of the application (via email or post) including; creating, naming, editing, setting and deleting events, as well as setting repeat reminders events, and also how to access and navigate the calendar function. Participants and their carers will also receive orientation and training in the completion of weekly monitoring forms during this week, via telephone/video call.

Following this training, the personally-meaningful events for which reminders will be set as well as the number of 'reminder' prompts the participant would like to receive about the event, will be discussed. Participants will enter their reminders themselves and they will also be sent the agreed unsolicited prompts, to their device, at the time and dates agreed upon. After this training week, the intervention phase will begin and last for 5 consecutive weeks

During the intervention phase, the participant will enter the events to be remembered on to the ApplTree app with the assistance of their participant's carer/significant other, if required. The application will send the reminder prompts at the predetermined times to the participant via their phone. Carers will receive a text message from the researcher to remind them to complete the monitoring form (every evening). At the end of the intervention phase, participants will be asked to complete the Unified Theory of Acceptance and Use of Technology (UTAUT) which will be either emailed or posted to them. Additionally, qualitative information will be gathered from participants regarding the strengths, weaknesses and usefulness of the ApplTree application, and whether they would wish to continue to use the app.

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