Enhancing the effects of post-stroke memory rehabilitation: A feasibility trial of two e-Health interventions to sustain the benefits of a memory skills group.

TRIAL PROTOCOL

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STATEMENT OF COMPLIANCE

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

PROJECT TEAM

Coordinating Principal Investigator and Lead Researcher

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STUDY SYNOPSIS

Title:	Enhancing the effects of post-stroke memory rehabilitation: A feasibility trial of two e-Health interventions to sustain the benefits of a memory skills group
Short Title:	Memory-SuSTAIN (Memory Strategy Skills Training Applied IN the long term)
Trial registry:	Intended registry: ANZCTR
Design:	Phase II pilot single-blind randomised controlled trial (RCT) with three arms (Booster Sessions, SMS Reminders, and No Active Maintenance)
Study Centres:	**Primary centre:** Monash Health (Cranbourne Community Rehabilitation Centre) **Participating health services:** Austin Health (Austin Hospital) Barwon Health (McKellar Centre) Melbourne Health (Royal Melbourne Hospital) Western Health (Sunshine Hospital) **Academic partners**: La Trobe University Monash University University of Nottingham
Primary Objective:	Aim 1: To assess the feasibility of two eHealth interventions for maintaining levels of self-reported everyday memory functioning achieved by survivors of stroke after participating in a group-based memory skills training program.
Secondary Objectives	Aim 2: To determine whether the trial design and procedures are feasible.

	Aim 3: To assess the potential effectiveness of maintenance intervention options (a) booster sessions, or b) SMS reminders) compared with no active ongoing support after completion of a group-based memory skills training program. Aim 4: To estimate the potential costs and cost-effectiveness of delivering the maintenance intervention options compared with no active maintenance.
Inclusion Criteria:	Adults aged >18 years with post-stroke memory complaints
Exclusion Criteria:	Neurodegenerative conditions (e.g. dementia), severe mental health conditions, major illness and unlikely to survive up to final follow-up assessment. Current participation in other individual rehabilitation sessions focusing on memory or other cognitive functions.
Planned Participants:	45 (15 per group; 1:1:1 randomisation)
Safety considerations:	Possible risk of participant distress related to assessment and discussion of memory concerns
Funding	Seed grant from the Stroke Foundation awarded to Dr Dana Wong, date of acceptance 15 January 2019.

GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation/Term	Description (using lay language)
Health service sites	The health services participating in the study by referring participants and collecting baseline data from participants. Sites include: Monash Health; Austin Health; Barwon Health; Melbourne Health; Western Health
iVERVE	An electronic automated messaging system designed and developed by Cadilhac et al. (2018) for message-based e-health interventions.
REDCap	A secure web-based database management system.

STUDY SITES

Site	Contact Person	Address	Phone and Email
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INTRODUCTION/BACKGROUND INFORMATION

Lay Summary

Addressing memory problems after stroke is a research priority due to significant unmet needs reported by survivors of stroke. Memory rehabilitation, including group programs based on teaching people strategies to compensate for their memory problems (such as using diaries or calendars), has been shown to produce significant short-term improvements in memory after a stroke. However, difficulties establishing new strategies into everyday routines can mean that effects are inconsistently maintained over time.

In this project, we seek to evaluate the following two eHealth maintenance intervention programs that are designed to sustain the improvements in everyday memory made following six weeks of group-based memory skills training:

1) Booster sessions delivered via telehealth (videoconferencing), and
2) SMS or email reminders prompting use of memory strategies taught.

As well as evaluating whether these eHealth interventions are effective in maintaining the use of strategies that enhance memory function, we are seeking to assess whether these interventions are appropriate, practical, and potentially cost-effective. In order to evaluate whether these intervention strategies are effective in helping people maintain their benefits, we will compare the results that we find from the two treatment options against results from having no maintenance support (which is the current practice).

Identifying effective strategies for maintaining the benefits of memory rehabilitation could help reduce the long-term impact of these problems after a stroke. These benefits could include increased independence and employment opportunities, as well as better quality of life for those recovering from a stroke and their families.

Background information

Addressing memory problems post-stroke has been identified by consumers and clinicians as a priority research area (Pollock, St George, Fenton, & Firkins, 2014) due to high unmet needs

among survivors of stroke (Andrew et al., 2014). Post-stroke memory impairment is common even after successful recovery (Jokinen et al., 2015), and compromises several functional outcomes including work capacity, independence in daily activities, and quality of life. A Cochrane review (das Nair, Cogger, Worthington, & Lincoln, 2016) of post-stroke memory rehabilitation (i.e., memory strategy training) reported significant improvement in everyday memory immediately post-treatment. However, these effects are not consistently sustained over time. This "relapse" effect is unsurprising given the well-established difficulties in maintaining healthy behaviour change experienced even by neurologically intact individuals. These difficulties may be exacerbated by post-stroke impairments in memory and executive functions, which can act as a barrier to remembering and consistently implementing new strategies. Consistent with this idea, Ponsford & colleagues (2016) found that booster sessions delivered 9-18 weeks after treatment completion were essential for maintaining gains made from psychological therapy for depression and anxiety after brain injury.

Our recent randomised controlled trial (RCT) (Withiel et al., in press) was used to evaluate the efficacy of a memory skills group that incorporated compensatory memory strategy training, psychoeducation and lifestyle improvements. Improvements were demonstrated in subjective everyday memory immediately post-treatment that were not maintained at follow-up. Our other recent study of telehealth-delivered memory rehabilitation indicated that a single booster session delivered between 6-12 weeks post-intervention resulted in superior gains during the post-intervention period compared with participants not receiving a booster (Lawson et al., under review). The findings highlight the potential of telehealth delivery of sessions to the participant in their home, minimising consumer and caregiver burden and enabling strategies to be applied in the participant's everyday context.

Provision of additional intervention sessions over the long term is, however, associated with additional costs. A potentially cheaper alternative method for boosting long-term behaviour change is the use of regular reminder text messages, which have been used successfully by Goodwin, Lincoln, das Nair, and Bateman (2018) as memory aids in a multiple sclerosis cohort. The iVERVE platform, developed by Cadilhac and colleagues (2008), uses a bank of SMS/email messages to encourage self-management after discharge from hospital following stroke to

support recovery and secondary prevention, but this has not yet been tested specifically for post-stroke memory rehabilitation. The iVERVE system includes a bank of messages for memory skills development consistent with strategies taught during group training.

This is the first study to evaluate the potential advantages of eHealth maintenance interventions following post-stroke memory rehabilitation. It will deliver new knowledge about whether relatively low-cost methods such as SMS/email reminders could feasibly enhance long-term gains by consolidating use of helpful strategies, so they become more routine and automatic. A subsequent Phase III trial could also address questions of clinical and cost-effectiveness of such interventions, and to establish the ideal "dose" of boosters required to automatise strategy use so that lifelong benefits can be realised. Identification of clinically relevant and cost-effective maintenance strategies has the potential to significantly reduce the long-term impact of memory problems on community participation, independence, employment, caregiver burden, health service utilisation, and quality of life.

STUDY OBJECTIVES

Aims

We aim to compare the potential of two eHealth interventions for maintaining improvements after participating in a memory skills group against no active maintenance (i.e. usual care). These interventions are:

a. Booster sessions delivered by a clinician via telehealth (videoconference); and

b. SMS/email reminders prompting use of key memory strategies, delivered using iVERVE.

Specifically, we aim to:

1. Determine the feasibility (i.e. acceptability of, adherence to, and satisfaction with) the eHealth interventions for survivors of stroke;
2. Determine whether the trial design and procedures are feasible, including:
    a. The willingness of clinicians to recruit participants
    b. The number of available and eligible potential participants and rates of recruitment

c. The willingness of participants to be randomised
d. The appropriateness of the proposed set of outcome measures
e. Rates of adherence and compliance to follow-up assessments
f. The time required to collect and analyse data

3. Provide an initial estimate of the extent to which the two eHealth interventions maintain benefits from memory rehabilitation compared with no active maintenance, measured over an 18-week period; and
4. Estimate the potential cost and cost-effectiveness of delivering the proposed maintenance intervention program (i.e. booster sessions and SMS reminders) compared with no active maintenance.

Ultimately, we will use the information from all four of these aims to estimate the parameters for a Phase III trial.

Hypotheses

We hypothesise that the level of everyday memory function at the end of the study, from largest to smallest effect, will be: eHealth booster sessions > SMS/Email reminders > no active maintenance.

STUDY DESIGN

Research Design

We will conduct a multi-site, single-blind, Phase II pilot randomised controlled trial (RCT) with three arms to evaluate two eHealth interventions designed to sustain the effects of memory skills training (booster sessions delivered via videoconferencing, and SMS/email reminders) compared to no active maintenance. We will use an intention to treat method of analysis, as well evaluate the maintenance interventions as per protocol in terms of:

1) Feasibility;
2) Effectiveness in prolonging intervention-related gains; and
3) Estimated cost.

PARTICIPANTS

Recruitment Procedure

Potential participants will be identified from survivors of stroke enrolled to participate in a memory skills group program at one of the health service sites participating in the study (please see Study Sites section). These sites are already running, or are planning to run, memory skills groups as part of usual care.

Recruitment will follow a two-step process:

1. Prior to commencing the memory skills group program, willingness to participate in the Memory-SuSTAIN study will be established. Health service staff will obtain verbal consent for identified potential Memory-SuSTAIN participants to be contacted by study staff to discuss participation.
2. At the conclusion of the memory skills group program, interested participants will be re-contacted by study staff to be formally enrolled in the Memory-SuSTAIN study. The initial outcome assessment data (T1) will then be collected within three weeks of completion of the memory group program (completion is defined as minimum attendance of four out of the six total weekly group sessions). Randomisation (1:1:1) will occur once participants are formally enrolled in the study.

A flyer will also be distributed to memory group participants inviting expressions of interest.

Inclusion Criteria

Participants will satisfy the following criteria:

1. Adults (age at least 18 years);
2. Primary diagnosis of stroke as determined by medical records;
3. At least 3 months post-stroke;
4. Everyday memory complaints, reported by self or other;
5. Sufficient cognitive and English language skills to participate in a memory skills group;
6. Completion of a memory skills group program at any of the participating clinical sites (defined as attending at least 4 of the 6 memory group sessions);
7. Access to a computer with a webcam and internet connection; and

8. Access to either SMS text messaging via a mobile phone with active service, or an active email service.

Exclusion Criteria

1. Severe psychiatric illness
2. Known presence of a neurodegenerative conditions (e.g. dementia), severe mental health conditions, or other known neurological disorder impacting cognition
3. Major illness and unlikely to survive up to final follow-up assessment
4. Current participation in other individual rehabilitation sessions focusing on memory or other cognitive functions.

Consent

Eligible participants will be provided with a verbal explanation of the study requirements and a participant information statement. Participants will be required to provide written consent before enrolment to the study. Consent forms will be stored securely at La Trobe University in individual client paper files (please see Data Handling and Security section below). The Participant Information and Consent Form (see attachment) will explain the following:

- What information is being collected
- Voluntary participation and withdrawal rights
- The purposes for which the information is being collected
- The period for which the records relating to the participant will be kept
- The form in which the data will be stored (i.e. whether identifiable or not)
- The steps taken to ensure confidentiality and secure storage of data
- How privacy and confidentiality will be protected in any publication of the information
- The fact that the individual may access that information
- Any risks and benefits from participation

Group Randomisation and Blinding

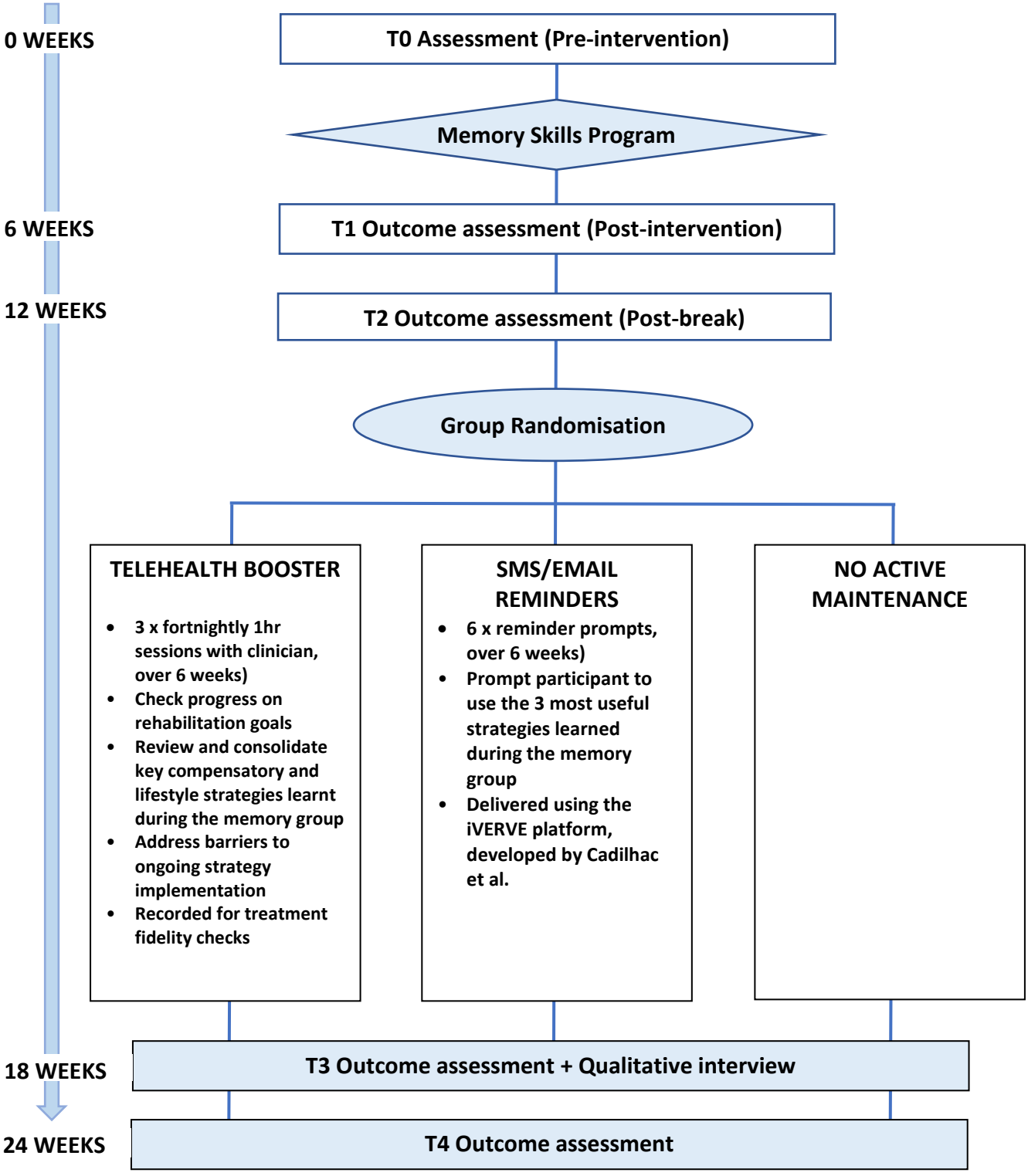
Participants will be randomised into one of three groups:

1) Receiving 3 x 1-hour booster sessions over a period of 6 weeks
2) Receiving a minimum of 6 x SMS/email strategy reminders over a period of 6 weeks

3) No active maintenance.

The randomisation sequence will be generated by the Research Officer using Stata Version 15 (StataCorp, 2017). The sequence will be generated using random block sizes with 6 allocations per block (2 per condition), stratified by health service site to ensure equal distribution across sites. The randomisation schedule will then be uploaded to REDCap, which will ensure allocation concealment. As participants complete their post-break assessment (i.e. the T2/12-week outcome assessment, see flowchart below), the Memory-SuSTAIN study Research Officer will trigger randomisation within REDCap and inform both participants and the relevant team members delivering the maintenance interventions (i.e. those arranging SMS/Email reminders or conducting booster sessions) of the participant allocations.

PARTICIPANT FLOWCHART



MAINTENANCE INTERVENTION

Participants will be contacted following the 12-week assessment by the Memory-SuSTAIN research officer and informed of their random group allocation.

Maintenance Program option 1: Telehealth booster sessions

Participants in the Booster Sessions condition will receive three fortnightly sessions of one-hour duration each, with a trained clinician. Sessions comprise:

- Checking the progress of rehabilitation goals (previously negotiated with memory group clinicians);
- Reviewing and consolidating key compensatory and lifestyle strategies covered during the memory group program;
- Expanding the number and range of everyday situations to which these memory strategies could be applied; and
- Addressing any barriers to ongoing implementation of strategies.

Booster sessions will occur remotely via videoconferencing using Zoom, a freely available software program facilitating Internet-enabled videoconferencing. Booster sessions will also be video recorded and treatment fidelity checks conducted by an independent expert.

Maintenance Program option 2: SMS/Email Reminders

Participants in the SMS/Email Reminder condition will receive one strategy message per week for six weeks, sent either to their mobile phone as a text message or to a nominated email address, depending on each participant's preference. Reminder messages will prompt participants to use their three most relevant strategies learned during the memory group program.

Following group allocation, participants in the SMS/Email Reminders condition will be asked to nominate their three most useful personally salient strategies from a list of all strategies

taught in the memory skills group. These strategies will inform the range of reminder prompts that they receive. Strategies will be identified from a list covering the following areas:

- Internal Strategies:
    - Using repetition to enhance encoding (mental rehearsal, asking others to repeat, re-reading text);
    - Using association to enhance retrieval;
    - Route-finding strategies: Paying attention to key features to enhance encoding;
    - Using context to assist recall;
    - Word-finding and conversations: focusing on meaning, using association, and descriptions;
    - Learning and recalling names: using alphabet search, association, and elaboration;
- External Strategies:
    - Optimising the home environment: decreasing distractions, reducing clutter;
    - Using note-taking, diaries, calendars, physical reminders, and alarms;
    - Using smartphones and electronic devices;
    - Using checklists for complex tasks.

Messages will be delivered using the iVERVE platform, an electronic automated messaging system designed and developed by Cadilhac et al. (2018) for message-based e-health interventions. iVERVE will store a bank of strategy reminder messages and securely extract de-identified participant data (selected strategies matched with each relevant participant's nominated phone number or email address) from a secure web-based database management system (REDCap; Harris et al., 2009). Study data will be collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted and managed by Helix (Monash University; Harris et al., 2009). REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages;

and 4) procedures for importing data from external sources. Automated messages will be sent to participants at designated times, once per week for six weeks.

No Active Maintenance

Participants in the No Active Maintenance condition will not be contacted during the T2-T3 maintenance intervention phase, apart from the reminder messages for the follow-up (T4) outcome assessment as described below.

All groups

All group will also receive up to two reminder messages via email or SMS for their follow-up outcome assessment.

MEASURES

Sample characterisation measures

- Age (years and months)
- Sex
- Socioeconomic status
- Date of stroke and Time post-stroke
- Stroke characteristics, including:
    - Hemisphere affected
    - Stroke type (ischaemic or haemorrhagic)
    - Level of stroke severity using the National Institutes of Health Stroke Scale (NIHSS) and Functional Independence Measure (FIM)
- Montreal Cognitive Assessment, as a cognitive screen
- Premorbid intellectual functioning, using the Test of Premorbid Functioning (TOPF).

Measures for Aim 1 (*Determining acceptability of the two eHealth interventions*):

1) An acceptability rating (usefulness score out of 10), rated by participants about each maintenance condition.

2) All participants will also be interviewed about their experiences in each condition, including questions regarding the following:
    a. Experiences receiving the maintenance intervention (i.e. booster sessions, SMS/email, or no active maintenance);
    b. The appropriateness of the maintenance intervention dose (6 weeks);
    c. Safety (i.e., any adverse events)
    d. Experiences of the outcome assessments; and

    Follow-up prompting questions will be asked to elicit further details as required.

Measures for Aim 2 (*Determining whether the trial design is feasible*)

Indicators of feasibility will include:

- Willingness of clinicians to recruit participants
- Number of eligible and available participants
- Recruitment rate;
- Willingness of participants to be randomised
- Rates of adherence/study completion rates, defined as:
    - For the booster session condition: participating in all three booster sessions;
    - For the SMS/Email Reminders condition: Receiving all six reminder messages (i.e. not opting to discontinue receiving messages)
    - For all conditions: completing all outcome assessments across all time points;
- Number of intervention and assessment sessions requiring rescheduling and reasons for these.
- Frequency of technical issues (e.g., message send failures, internet dropouts during telehealth sessions).
- The time required to collect data.
- The feasibility of data collection related to costs will be assessed by accessing the amount of missing data and participants opting out of providing these data.

Measures for Aim 3 (*Determining an initial estimate of intervention effectiveness*):

1) **Goal Attainment Scaling (GAS; Turner-Stokes, Williams, & Johnson, 2009)**

GAS is a person-centred measure of rehabilitation progress commonly used with clinical populations, to define and assess attainment of therapy goals. Participants will be invited to nominate two problematic types of memory lapses in everyday activities, in which improvements would represent realistic participation goals.

2) **Everyday Memory Questionnaire-Revised (EMQ-R; Royle & Lincoln, 2008)**

   Self-reported lapses in memory will be assessed using the Everyday Memory Questionnaire-Revised, a 13-item item scale measure of memory failures in everyday activities.

3) **Strategy Use Checklist**

   A self-report Strategy Use Checklist will record participant use of external strategies (e.g., lists, smartphone applications) and internal strategies (e.g., mental rehearsal, face-name association) from "*Daily*" to "*Not at all*".

4) **Rivermead Behavioural Memory Test – Third edition (RBMT-3; Malec, Zweber, & Depompolo, 1990)**

   Everyday memory will be assessed via the RBMT, an ecologically valid measure of functional performance in everyday tasks. 14 subtests cover verbal, visual, recognition, recall, immediate, and delayed memory performance. Items include demonstrating recall of a route around a room, recalling the locations of objects in the room, and recognising a series of faces.

5) **The Valued Living Questionnaire (VLQ; Wilson, Sandoz, Kitchens, & Roberts, 2010)**

   As a brief self-report measure of quality of life from a behavioural perspective, the VLQ captures the extent to which participants' actions are consistent with their values or the areas during the previous week.

6) **Community Integration Questionnaire (CIQ; Willer, Ottenbacher, & Coad, 1994)**

   The CIQ is a 15-item self-report measure of social role limitation and community participation. Items include "approximately how many times do you participate in leisure activities such as movies, sports, restaurants, etc".

Measures for Aim 4 (*Estimating and comparing the potential cost-effectiveness of booster sessions or SMS reminders compared with no active maintenance*):

- Resource use and costs will be captured to determine the feasibility of conducting an economic evaluation and providing preliminary data as part of this Phase II study.
- Participant-level data will be obtained using the Adapted Resource Use Questionnaire for Stroke (developed by CI Cadilhac) and
- Program delivery costs for each intervention arm e.g. costs of staff time to do telehealth or setup SMS program, costs of equipment, SMS service costs, etc. Costs of data collection for research are not counted.

Memory Skills Group Sites

Prior to randomisation for this trial, participants will first complete a 6-week memory skills group program which will be facilitated by trained neuropsychologists at multiple sites:

1. Monash Health - Cranbourne Integrated Health Centre (the primary site)
2. Austin Health – Heidelberg Repatriation Centre
3. Barwon Health – McKellar Centre
4. Melbourne Health - Royal Melbourne Hospital
5. Western Health – Sunshine Hospital

*(*Note: additional sites may be added, including Epworth Hospital).*

Clinicians at all sites will have undergone comprehensive training in delivering the memory skills group program by Dr Dana Wong before the trial commences. This training includes didactic instruction, watching videos of a previous memory group sessions, and supervision based on video recordings of the first group they facilitate. All memory skills group sessions will be video recorded throughout the study period, for treatment fidelity checks of a random selection of sessions by an independent expert. Treatment fidelity monitoring will include measures of adherence (using a session content checklist) and competence (using the eNACT Group Facilitation Competency Checklist; Wong, Grace, Baker, & McMahon, in press).

The flowchart below shows the design and flow of participants through the trial, and the timing of baseline and outcome assessments. Baseline (pre-memory skills group intervention) assessment (T0) will be conducted by neuropsychologists at the health service site. This will be a brief assessment of the first three outcome measures for Aim 3 only: Goal Attainment Scaling, the EMQ-R, and the Strategy Use Checklist (as an indication of the extent of the gains

made during the memory skills group). Outcome assessments (T1 6-week, T2 12-week, T3 18-week and T4 24-week assessments) will be conducted by an independent assessor masked to group allocation. The trial will be conducted and reported according to best practice guidelines.

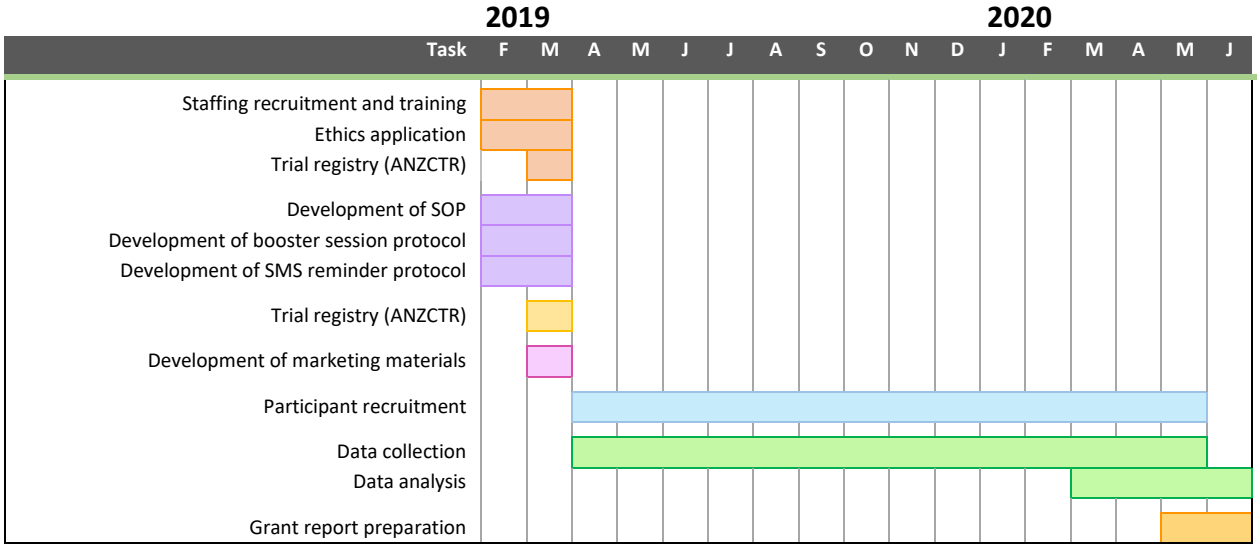
Study Coordination

Study coordination, including administration and management, will occur at La Trobe University, Bundoora campus.

Sample size

Based on other similar studies, we believe that recruiting 45 participants is possible in the 12-month study period given that memory groups are conducted in parallel across the multiple health service sites. This sample size would be sufficient to detect a small-medium effect size (*d*=0.33), calculated using G-Power, which compares with medium-large effect sizes of booster sessions in previous literature (Lawson et al., under review; Ponsford et al., 2016).

TIMEFRAMES



PARTICIPANT SAFETY AND WITHDRAWAL

Risk Management and Safety

It is possible that some booster condition participants may become distressed when discussing their memory issues and the changes in their life that have occurred as a result of their stroke. Booster sessions will be conducted by highly experienced clinicians in a sensitive and supportive manner and it will be emphasised that no participant is required to share information that they do not wish to disclose. Any distressed participants will be offered separate counselling and support by qualified clinical staff within the relevant health service who are not members of the research team.

Adverse Events and Serious Adverse Events

Consistent with the Statement of Compliance, this study adopts the policies and guidelines for safety monitoring and reporting as per the NHMRC statement on Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods (NHMRC, 2016).

Handling of Withdrawals and Replacements

Information collected prior to a participants' withdrawal will be retained, but no further information will be collected. In cases of participant withdrawing before the conclusion of the booster program, or participants being lost to follow-up, recruitment will continue until target sample size is achieved, within the restrictions of the recruitment period.

STATISTICAL ANALYSES

Aim 1 (*Determining acceptability and safety of the two eHealth interventions*):

- Pairwise comparisons and linear mixed models will be used to explore between-group differences at T3 and T4 in acceptability ratings. Qualitative data will be thematically analysed to extract themes relating to intervention acceptability from participant interviews, using Braun and Clarke's (2006) approach to thematic analysis.

Aim 2 (*Determining whether the trial design is feasible*)

- Descriptive statistics will be calculated for feasibility measures, including rates of recruitment, study completion, and technological issues.

Aim 3 (*Determining an initial estimate of intervention-effectiveness*):

- Pairwise comparisons and linear mixed models will be used to explore between-group differences at each time point in clinical outcomes. The effect size of each maintenance condition, defined as the magnitude of change from T1-T4, will be estimated with Cohen's *d* based on output from regression models.

Aim 4 (*Estimating and comparing costs of booster sessions, SMS/email reminders, and no active maintenance*):

- Resource use data will be converted to costs and the average costs per participant for each intervention arm described and compared. The costs of each program will be accounted for in the determination of total costs and the average cost per participant. The reference year for costs will be 2019. The net cost per participant achieving the maintenance outcome will be estimated against the control group as a measure of potential cost-effectiveness. Various sensitivity analyses will be performed. If effectiveness information is able to be used for health benefit modeling relative to costs, then these will also be described to inform the business case and budget needed for a larger, fully powered Phase III study.

REPORTING OF RESULTS

Study results will be prepared for publishing at the completion of data collection and analysis. Results will be reported according to guidelines outlined by the Consolidated Standards of Reporting Trials (CONSORT) extension for randomised pilot and feasibility trials checklist, and the Template for Interventional Description and Replication (TIDieR) Checklist for describing an intervention. A final report will also be prepared for The Stroke Foundation in compliance with funding requirements.

DATA SECURITY AND HANDLING

All data will be stored according to the NHMRC guidelines for conduct of research (http://www.nhmrc.gov.au/publications/synopses/e72syn.htm). Participant informed consent will be obtained to transfer a copy of participants' data from the baseline (T0) assessments from each health service site to Dana Wong's research lab at La Trobe University. In all instances, data (both hard-copy and electronic versions) will protect the privacy of participants and clinicians. Electronic study data will be securely stored and managed using the REDCap electronic data capture system (Harris et al., 2009) hosted on a secure drive at Monash University. Hard copy data will be de-identified and stored separately from any identified data, in a secure locked filing cabinet in the lab, which is locked when not attended. Electronic data, including video recordings, will be stored on a password-protected secure server only accessible by the researchers. Only study staff, including chief investigators, project coordinator and research assistants will have access to the data and all results of the data analyses. No research data will be stored on personal equipment. All data will be de-identified prior to analysis and only aggregate data will be reported. Research data, including identified participant data, will be securely retained for a period of seven years.

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