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Participant Information and Consent Form

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)
Principal Investigators	Dr Dana Wong (Coordinating Principal Investigator) Prof Dominique Cadilhac Prof Roshan das Nair Dr Rene Stolwyk
Clinical Site Investigators	Sandy Grayson Dr Jennifer Bradshaw Jenny Todd Dr Toni Withiel Dr Katharine Baker
Research Officers	David Lawson Dr Joosup Kim Garveeta Sookram
Location	La Trobe University

Part 1: What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have been experiencing memory difficulties since your stroke, and you are participating in a memory skills group program to learn strategies to better manage these problems. In this project we want to know how to best help people maintain any improvement they have made during the memory skills group, over a longer period of time after the group program has finished.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent form at the end of this letter. By signing it you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to have the treatments and assessments that are described below; and
- Consent for us to use your personal and health information as described below.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Problems with memory after a stroke can affect ability to work, independence in daily activities, and quality of life. Subsequently, memory problems following a stroke have been identified by stroke survivors and clinicians as a top priority research area.

Memory skills groups can help with these problems. The program involves learning memory strategies and lifestyle improvements to help manage memory difficulties. For many people, this program has resulted in immediate significant improvement in everyday memory. However, these effects have not always been maintained over time.

There are some eHealth methods that could help maintain the effects of memory skills group programs over a longer period of time. Here, eHealth means using communications technology such as internet videoconferencing, email, or mobile phone SMS (text messages) to connect clinicians and stroke survivors, and to provide health services. This project aims to find out how acceptable different eHealth methods are for you, and whether these methods are effective.

3 What does participation in this research involve?

Participation involves either receiving your usual care, or receiving one of two types of support. Which type of support you receive will be determined at random (that is, everyone has an equal chance of

receiving one of the three conditions, and neither you nor us will have a say in which condition you get). Six weeks after completing the memory skills group program, you will receive:

- three "booster sessions", one-on-one with a clinician. These sessions will occur over the internet, using a program called "Zoom", which is similar to Skype. There will be one session every two weeks, for six weeks. Sessions will review and refresh the information and strategies that were covered in the memory skills group program. With consent, these sessions will be videotaped for quality assurance purposes.

OR…..

- one electronic message prompt per week for six weeks, to remind you to use the strategies you found most useful in the memory group program. If you are allocated to receive these electronic reminders, you will be invited to nominate the three most useful strategies that were learned during the memory skills program. Reminders will be sent either as text messages to a mobile phone, or as emails to a personal email address (whichever you preferr).

OR…..

- no reminders or booster sessions during the maintenance period. This is the usual care people receive after participating in memory skills groups.

In addition, you will also complete four outcome assessments. These will occur at the end of the memory group program, and then three more times, each 6 weeks apart. The purpose of these assessments is to see if the memory group and eHealth support resulted in any change in memory and its impact on your daily life. At each assessment you will be asked to complete some paper and pencil type tasks, and to answer questions about your memory problems in everyday life. Each of these assessments will take approximately one hour, and you will need access to a computer that has Internet connection and a camera (a webcam). A videoconferencing software program called Zoom (similar to Skype) will be used to remotely connect to your assessment clinician. You will be given all necessary assistance to download and operate the free Zoom software.

Prior to participating in the memory skills group, you will have completed a brief assessment with a clinician at the health service where you attended the memory group. With your permission, we will also use the results of that assessment for this research study. That is so we can understand what, if any, changes in memory function occurred during the memory group.

There are no additional costs associated with participating in this research project. The memory skills program will be provided to you at the usual fee charged by **[SITE]**. The eHealth maintenance interventions (booster sessions or reminder messages) will be provided free of charge. It will not be possible to pay you for your participation in the study.

4 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, or your relationship with anyone treating you. You can still attend the memory skills group without participating in this study.

5 What are the possible benefits of taking part?

We don't know if there is any benefit in taking part in this study, however, some people may find it useful to have routine memory assessments. Other benefits include contributing to research about what helps stroke survivors with memory difficulties, which may benefit other stroke survivors.

6 What are the possible risks and disadvantages of taking part?

It is possible that participating in the memory group may trigger uncomfortable feelings that you may have about your memory problems and/or your stroke.

If you become upset or distressed as a result of your participation in the research, the researchers will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

7 Can I have other treatments during this research project?

Yes, you can continue to take all of the medications you would usually take while participating in this project. You can also continue any community rehabilitation, with the exception of individual rehabilitation sessions focusing on memory or other cognitive functions (e.g., with a neuropsychologist or occupational therapist). The memory skills group program will replace individual memory/cognitive rehabilitation whilst you participate in this project. However, if needed, individual memory/cognitive rehabilitation sessions can resume after you complete your participation in the project. We also ask that

you refrain from any brain-training games (e.g. Lumosity) during your participation in the study. Speak to a member of the research team if you have any questions about this.

8 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team. If you do withdraw your consent during the research project, the researchers will not collect any additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

9 What happens when the research project ends?

After completing all of the outcome assessments, you will receive individual feedback by a member of the research team and you will also receive a written summary describing any changes in your memory function. We are also happy to provide a summary of the overall results of the study. Please let us know if you are interested in this.

Part 2: How is the research project being conducted?

10 What will happen to information about me?

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Participants will be given a study number or code and this information will be kept separate from the data so that only the study investigators will be able to re-identify participants.

We anticipate that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with Australian privacy laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project or for related research in the future that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

All hard copy data will be securely stored at La Trobe University. A copy of your consent form will be retained in the medical file at your health service. Electronic data will be stored on a secure drive hosted by Monash University. Access to the drive will be password-protected and only the research team members will have access to the password. Hard copy and electronic data will be retained for seven years, consistent with the Australian Code for the Responsible Conduct of Research (2007). Data will then be destroyed by deleting electronic records and any video recordings, and shredding all paper records.

11 Who is organising and funding the research?

This research project is being organised by a team of researchers. The Chief Investigator for this project is Dr Dana Wong at La Trobe University, with Associate Investigators Professor Roshan das Nair at the University of Nottingham (UK), Professor Dominique Cadilhac at Monash University, and Dr Rene Stolwyk at Monash University.

The project is being funded by the Australian Stroke Foundation.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

12 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Austin Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

13 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the following person:

Research Officer: La Trobe University

Name	David Lawson
Telephone	03 9479 1679
Email	d.lawson@latrobe.edu.au

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Consent Form - *Adult providing own consent*

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
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Research Officers	David Lawson Dr Joosup Kim Garveeta Sookram
Location	La Trobe University

Declaration by Participant

I have read the Participant Information Sheet or it has been read to me in a language I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories to release information to **La Trobe University** concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

If I am to receive booster sessions. I give permission to be videotaped in order for researchers to assess the quality and consistency of the sessions.

I understand that my data may be used in related research projects in the future.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

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Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

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Form for Withdrawal of Participation - *Adult providing own consent*

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Location	La Trobe University

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, or my relationship with those treating me.

Name of Participant (please print) _____

Signature _____ Date _____

[†] A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Declaration by Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Senior Researcher†
(please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.