Tailoring the ESTEEM Program for delivery in the community setting

ESTEEM After Stroke: ESTEEM - Phase 2b (Feasibility and Acceptabilty)

INFORMATION FOR PARTICIPANTS
Carers

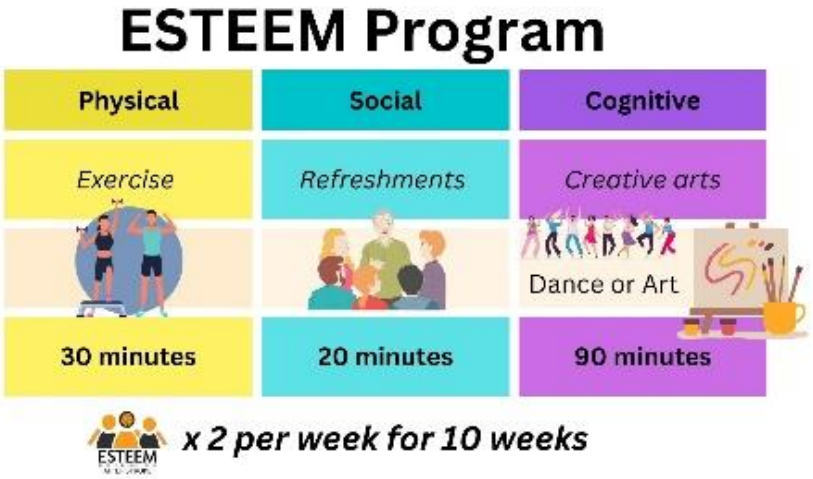
V1_080523

Introduction

You are invited to take part in a **workshop** to help **researchers understand how a group for stroke survivors, the ESTEEM Program, one which enables people** to **exercise, socialise and participate in art-based thinking activities, could work when delivered by community-based care providers**. The ESTEEM Program aims to provide people living with stroke easier access to **further rehabilitation after their discharge from the hospital and other health- based services. We seek to test what effect the** ESTEEM Program has on stroke survivor **independence, emotional health** and **quality of life**.

The parts of the ESTEEM Program are outlined in Figure 1 below: 30minutes of exercise, 20-30 minutes of socialisation and 90 minutes of engaging in creative activities which make you think (i.e., art, dancing, singing etc), twice a week for 10 weeks.

Figure 1. Parts of the ESTEEM Program



Please **read this information carefully. Ask questions** about anything that you don't understand or want to know more about.

The Coordinating Principal Investigator for this project is Dr Heidi Janssen.

What is the research about?

Researchers at the University of Newcastle have worked with stroke survivors, carers, health professionals and artists in the community to design the ESTEEM Program. We listened to their wants, needs and ideas on how to design a program that everyone after stroke can use.

It can be challenging to get more active when living with the effects of stroke. It is very important that this **program meets the needs** of those who use it. The ESTEEM Program is a group-based program for **stroke survivors where they can go twice a week to exercise, socialise and participate in creative thinking activities. The ESTEEM Program is designed to** provide **further opportunities for rehabilitation in the community.**

This is the **second phase** of a **3-phase process** that makes up the overall project

- Phase 1, which has been completed involved working with people representing different groups or organisations to design the program;

- **Phase 2*, which you are being invited to take part in,* is to test the feasibility of the program – do people like it and will they use it?**

- Phase 3, will test how effective the program is and if it is safe for people to use.

Where is the research being done?

The study is a partnership project between **Hunter Medical Research Institute (HMRI), the University of Newcastle** and **Hunter New England Local Health District. There is the option** for people to participate in this study virtually through an online platform such as Zoom and in-person (on-site).

Who can participate in the research?

People **aged 18 years or over** who are **providing care for someone who has previously had a stroke and is waiting to participate or has participated in the ESTEEM Program. You are invited to contribute knowledge and experience** to support the development of a community-based program that will provide physical, cognitive and social enrichment for people who have had a stroke.

There may be other people joining in at the workshops who represent **other important stakeholders** including stroke survivors and people that work for community-based care providers similar to those which you may use.

What choice do you have?

Participation in this study is **entirely voluntary.** You do not have to take part in it. If you do take part, you can **withdraw at any time** without having to give a reason. Whether or not you decide to take part, your decision will not disadvantage you in any way.

What would you be asked to do if you agree to participate?

If you **agree** to participate in this study, you will be asked to **sign the Participant Consent Form.**

You may be asked to complete a **brief survey** to understand your perceived quality of life and perception of your role as a carer four times. The four times will be as follows:

(i) At the beginning when you are waiting for your family/friend with stroke to entering the ESTEEM Program (Week 0);
(ii) Just prior to family/friend with stroke to entering the ESTEEM Program (Week 10);

(iii) At the end of their participation of the ESTEEM Program (Week 20); and
(iv) 3 months after they have finished the ESTEEM Program (Week 32).

These two surveys will be the same each time. We will also ask have questions at the beginning (Week 0) to collect information about yourself so that we can describe the different characteristics of people caring for those with stroke. This and the other surveys and will approximately 15-20 minutes to complete and can be done online.

You will also be asked to participate in a group or one-on-one interview to understand your experience of being a carer of a person living with stroke who participated in the ESTEEM Program research project.

Notes will be taken by the researchers throughout the interview which will also be **audio recorded, either on a digital recorder or zoom recording**. All notes, surveys and audio recordings are **confidential** and will only be accessed by members of the research team.

What are the risks and benefits of participating?

There are **no known risks** related to participation in this research project. It may be inconvenient to travel to and spend time at the workshops or take time out of your busy days.

This research is unlikely to be of direct benefit to you. We hope this research project will improve the development and delivery of the ESTEEM program to people who have had a stroke and may help other stroke survivors to reduce their risk of more strokes.

Will the study cost you anything?

You **will not be paid** for your participation in this study. You will be required to provide your **own transport** to and from the workshop. **Parking** will be **provided**.

How will your privacy be protected?

All the **information** collected from you for the study will be treated **confidentially**. The study results may be presented at conferences or in a scientific publication, but individual participants will not be identifiable in such presentations unless they provide written consent for this to occur.

Your personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

If you decide to withdraw from the study the information you have contributed to the study already will still be used in the research as it cannot be separated from other participants' contributions. If you withdraw, we will not contact you for further information.

All data including questionnaires, audio recordings and the notes from the workshops will be kept by the site at which the workshop occurred, stored on a password-protected file or in a secure filing cabinet. **All data will be held for a minimum of 7 years** and destroyed prior to disposal to ensure confidentiality is maintained.

Further Information

If you have **any questions** or would like further information concerning this project, you can contact the study team on **02 4042 0417** or **email Dr Heidi Janssen** at Heidi.Janssen@health.nsw.gov.au. Hunter New England Health HREC number: 2020/ETH01723.

This information statement is for you to keep.

Thank you for considering the invitation to take part.

Yours sincerely,

Dr Heidi Janssen

Principal Coordinating Investigator

Complaints about this research

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007), produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Should you have **concerns about your rights** as a participant in this research, or you have a **complaint** about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Sarah Moberley, Manager, Research Ethics and

Governance Office, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHD-HREC@health.nsw.gov.au