

Exercising, Socialising and Thinking – an Environmental Enrichment Model in the community After Stroke (ESTEEM)

The development of an environmental enrichment model:

ESTEEM I – Phase 1

PARTICIPANT INFORMATION STATEMENT –Carers of Stroke Survivors

(V3_28/08/20 - Carers)

Introduction

You are invited to take part in a workshop at Hunter Medical Research Institute (HMRI) to help design a group for stroke survivors to exercise, socialise and take part in art-based thinking activities. The new group, ESTEEM, aims to improve recovery and the quality of life of people who have had a stroke.

Researchers at the University of Newcastle are designing a program that will be run in the community. We are looking to find out what effect further rehabilitation in the community using this group has on stroke survivor independence, emotional health and quality of life.

To make sure that this program meets the needs of those who use it, this research project will involve people who have had a stroke, their carers, health professionals, researchers and other people who deliver a variety of community programs. Together they will use their knowledge and experience to design a program that everyone can and wants to use.

This is the **first phase** of a **4 phase process** that makes up the study.

- **Phase 1** (which you are being invited to take part in) is to **help design the program. To do this you will work with people from different groups who will be involved in the program in the future.**
- Phase 2 is to test if people like the program and will they use it?
- Phase 3 will test if the program works and if it safe for stroke survivors, and
- Phase 4 will test how well the program works when it is used early after stroke as well as regular rehabilitation provided by health services.

Please read this information carefully.

Ask questions about anything that you don't understand or want to know more about.

The Principal Investigator for this project is Dr Heidi Janssen.

Where is the research being done?

The study is being conducted at Hunter Medical Research Institute (and other community venues if needed) and over online platforms such as Zoom.

Who can take part in the research?

People aged 18 years or over who are currently providing care to someone living in the community after a stroke, or have done so in the past.. Researchers are looking to include people with a broad range of knowledge and experience to help develop the ESTEEM program. There will be people in the workshops who represent a variety of carers.

What choice do you have?

Participation in this study is entirely up to you. If you do take part, you can leave at any time without having to give a reason. Whether or not you take part, your decision will not disadvantage you in any way.

What would you be asked to do if you agree to take part?

If you agree to take part in this study, you will be asked to sign the Participant Consent Form. You will then be asked to come to one workshop at the Hunter Medical Research Institute or online. We will let you know the time and date of the workshop at least 2 weeks beforehand, and we will call you to confirm the day before the workshop. The workshops will go for no longer than 2 hours.

COVID safe practices in line with government regulations will be in place. For example, providing alcohol based hand gel, physical distancing, additional cleaning, and the use of face masks where required.

During the workshop we will tell you about a program that is being developed to help people who have had a stroke to continue their rehabilitation in the community. The research team will then invite you to share your knowledge, experience and opinions. The discussion will focus on what you and others in the workshop think will be important to the program being successful.

You may be asked to complete a brief questionnaire at the beginning of the workshop. This will collect information such as your age and your prior experiences with stroke. This will take less than 5 minutes to complete.

Notes will be taken by the researchers during the workshop which will also be recorded. All notes, questionnaires and audio recordings are confidential and will only be used by members of the research team.

Following this workshop, you may be invited to attend future workshops, up to a maximum of 4 in total, to continue the development of this program.

What are the risks and benefits of taking part?

There are no known risks related to taking part in this research project. It may be inconvenient to travel to and spend time at the workshops.

This research is unlikely to directly benefit you at this stage. We hope this project will improve programs available to people who have had a stroke, and may help other stroke survivors to decrease their risk of more strokes.

Will the study cost you anything?

You will not be paid for taking part in this study. You will need to provide your own transport to and from the workshop. Parking will be provided.

How will your privacy be protected?

Researchers will collect personal information, and your answers to interviews and focus group discussions. All information collected will be treated confidentially. The study results may be presented at conferences or in a scientific publication, but individual participants will not be able to be identified unless they provide written consent for this to take place.

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 pull out of the study the information already collected from you will still be used in the research as it cannot be separated from the group discussions. If you pull out, we will not contact you for further information.

All information collected will be kept at Hunter Medical Research Institute, stored on a password-protected file or in a secure filing cabinet. All information will be held for a minimum of 7 years and destroyed prior to disposal to make sure it remains confidential.

Further Information

If you have **any questions** or would like more information about this project, you can contact us on **02 4042 0417** or **email Dr Heidi Janssen** at Heidi.Janssen@health.nsw.gov.au.

Researchers involved in this research project are:

<p>Dr Heidi Janssen, Conjoint Lecturer, University of Newcastle, Hunter Medical Research Institute. Heidi.Janssen@newcastle.edu.au</p>	<p>Dr Kirsti Haracz – Senior Lecturer, University of Newcastle. Kirsti.Haracz@newcastle.edu.au</p>
<p>Dr Marie-Louise Bird - University of Tasmania. marie-louise.bird@utas.edu.au</p>	<p>Ms Alexandra Denham – University of Newcastle. alexandra.denham@newcastle.edu.au</p>
<p>Ms Diana Colvin - Hunter Medical Research Institute. Diana.Colvin@health.nsw.gov.au</p>	

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 research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District; **Reference 2020/ETH01723**.

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 Nicole Gerrand, Manager, Research Ethics and Governance Office, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, HMRI Building Level 3 POD HMRI Lot 1 Kookaburra Circuit New Lambton NSW 2305, telephone (02) 49214950, email HNELHD-HREC@health.nsw.gov.au