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 –Stroke Survivors

(V3_28/08/20 Stroke Survivors)

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**. This 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 group** which will be run in the community. We are looking to find out what **effect a group like this** has on stroke survivor **independence, emotional health** and **quality of life**.

To make sure that this **group 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 are involved in the delivery of a variety of community programs. Together they will use their knowledge and experience to design a program that everyone can and wants to use.

You are being invited to take part in 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 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, community venues (ie. council hall/church halls)** and over **online platforms** such as Zoom.

Who can participate in the research?

People aged **18 years or over** who have **previously had a stroke** and are **living in the community.**

Researchers who are looking to include people with a broad range of experience. There will be **many different people in the workshops**.

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 **attend one workshop** at the Hunter Medical Research Institute (or another community based venue) in person or online. The choice of workshop, or in person or online interview will be yours. Carers or partners are welcome to attend.

We will let you know the time and date of the workshop no later than 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 will be in place, including appropriate hand hygiene, 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. We 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 participation 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 for 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 your participation 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?

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 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 concerning 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:

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

This information statement is for you to keep.

Thank you for considering the invitation to take part.

Yours sincerely,

Dr Heidi Janssen

Principal 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 Nicole Gerrand, Manager, Research Ethics and Governance Office, Hunter New England Human Research Ethics Committee (HNE HREC), Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHD-HREC@health.nsw.gov.au. The HNE HREC number to quote is 2020/ETH01723