Exercising, Socialising and Thinking: an Environmental Enrichment Model (ESTEEM) After Stroke

Phase III (Effectiveness)

PARTICIPANT INFORMATION STATEMENT

(Stroke Survivor)

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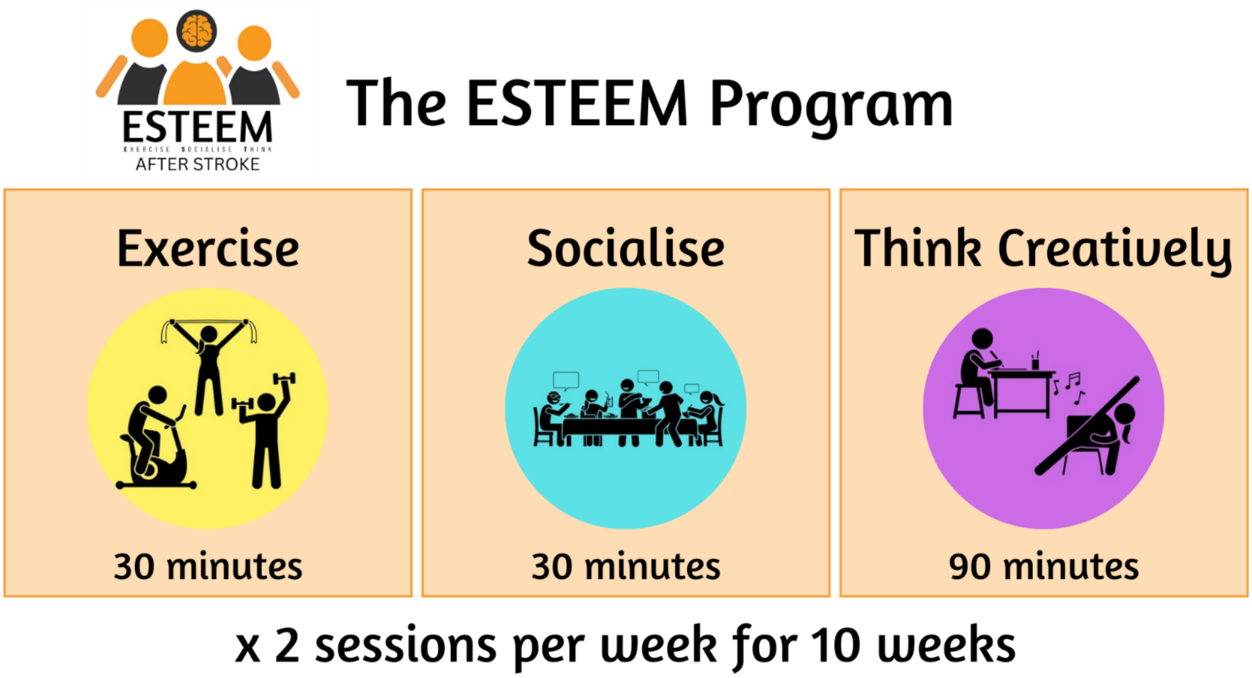

Introduction

You are invited to take part in **this research project** to help **researchers understand the benefits of the ESTEEM Program for people who have had a stroke.**

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

The Chief 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.

The ESTEEM Program is a community-based group program where people living with stroke come together twice a week to exercise, socialise and engage in arts-based activities such as visual arts and dancing. The ESTEEM Program is designed to provide further opportunities for rehabilitation in the community.

This aim of theESTEEM project is to find out if:

- people like it and would recommend the program to others, and
- participating in the ESTEEM Program helps people recover after stroke.

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.**

The program is available at **Newcastle** and **Maitland**. A third location will likely be available in the future.

Who can participate in the research?

People who:

- Are **18 years** or over
- Have had a **stroke**
- Are **living in the community**, not in a residential aged care facility
- Have the **cognitive ability** to provide informed consent and follow instructions
- Can **communicate** to provide informed consent and follow instructions
- Are **willing to participate in all aspects of the program** (exercising, socialising, and engaging in creative arts)
- Are **able to stand independently or with the assistance of one person**
- Are **able to use the bathroom independently or with the assistance of their support person (who can attend all sessions)**

- Are **medically fit to attend and able to engage in physical activity twice per week** (as determined by the ESTEEM physiotherapist, or a medical clearance from a GP if required)
- Are **able to follow instructions safely.**

What choice do you have?

Participation in this study is **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 WILL YOU BE ASKED TO DO IF YOU PARTICIPATE?

Participation in ESTEEM will involve attending the ESTEEM program twice a week for 10 weeks.

If you agree to participate in this project, **your overall involvement will be approximately 6-8 months long.**

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

- **Medical Records Access:** researchers accessing your Hunter New England Health medical records

- **Randomisation:** being randomly allocated to either starting ESTEEM within 2-3 weeks (referred to as “ESTEEM Now”) OR waiting 10 weeks to start (referred to as “ESTEEM Wait”)
- **Research Appointments to Collect Health Information:** researchers meeting with you 3 times (if you are allocated to ESTEEM Now) or 4 times (if you are allocated to ESTEEM Wait). This will include a short (approx. 10mins) physical test and several health surveys (approx. 30mins).

Once the Participant Consent Form is signed, and you are ready to commence, data collection will begin. Then you will be **randomly allocated** to either:

1. **Control Group (ESTEEM Wait)**

If allocated to the control group, you will receive fortnightly newsletters with information about stroke topics for a period of 10 weeks, whilst you wait to start the ESTEEM program. After a 10 week wait, you will be able to attend ESTEEM.

2. **Intervention group (ESTEEM Now)**

You will be asked to start attending the ESTEEM Program on the agreed starting date.

DATA COLLECTION:

The researchers will meet with you 3 or 4 different times at a location of your choice from the following:

1. in your own home, or
2. the Hunter Medical Research Institute (HMRI),
3. or another location of your choice.

When we meet with you we will ask some simple questions about your life after stroke and ask you to do some basic movement tests. Each meeting will take about 1 hour and is explained below:

Pre-waiting time ESTEEM Wait group only (-10 weeks): at the start of the waiting phase

Beginning: at the start of the ESTEEM Program (0 weeks)

End: at the end of the ESTEEM Program (10 weeks), and

Post: 3 months after the end of the ESTEEM Program (20-24 weeks).

What are the risks and benefits of participating?

Consenting to this research project enables you to participate in the ESTEEM program.

There are **no known risks** related to participation in this research project.

We hope this research project will help people who have had a stroke to recover and to improve the development and delivery of the ESTEEM Program to people who have had a stroke.

Will the study cost you anything?

You **will not be paid** for your participation in this research project.

You will need to provide your **own transport** to and from the ESTEEM program or we may be able to assist you with community transport at your own cost. **Parking** will be **provided.**

HOW WILL YOUR PRIVACY BE PROTECTED?

Information collected about you during the ESTEEM program will be **shared** between the referrer, the project research team, and the provider of the program. This may include sharing of information from your Hunter New England Local Health District Medical record and your GP regarding your medical history and suitability for the program. **Once you have completed the consent form, researchers employed by Hunter New England Local Health District will access your medical record to gain information** about:

- your stroke and its effects.
- your background medical information.
- your use of Hunter New England Local Health District health services during the period 3 months prior to consenting to the research project until the conclusion of your involvement in the project.

This will allow the research team to gather health information about your stroke and to better understand your use of HNELHD health services.

All the **information** collected about you for the project will be **confidential**. To keep your records confidential, they will be identified by a code instead of your name, and all project records will be kept in a secure place and only the researchers will have access.

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.

The project results may be presented at conferences or in health research publications. Individual participants will not be identifiable in any presentations or publications unless they provide written consent for this to occur.

If you decide to withdraw from the project, the information you have contributed to the project already will still be used in the research. If you withdraw, we will not contact you for further information.

What do you need to do to take part?

Please read this Information Statement and ask any questions you may have before you consent to take part. If you would like to take part, please follow the instructions provided to complete the consent form.

Further Information

You may wish to talk with your doctor, a relative or friend before agreeing to take part in this study. If you have **any questions** or would like further information concerning this project, you can contact **Dr Heidi Janssen** via phone 0473 434 389 or email Heidi.Janssen@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

Chief Investigator

Complaints about this research

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023), 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, please contact the HNE Research Office, Hunter New England Local Health District, Level 4 West, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305, telephone (02) 49214140, email HNELHD-ResearchOffice@health.nsw.gov.au and quote reference 2020/ETH01723.