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

Phase II (Feasibility)

INFORMATION FOR PARTICIPANTS
CONTROL + INTERVENTION

V1_08/05/2023

Introduction

You are invited to take part in **this research project** to help **researchers understand the benefits for stroke survivors of participation in the ESTEEM Program.**

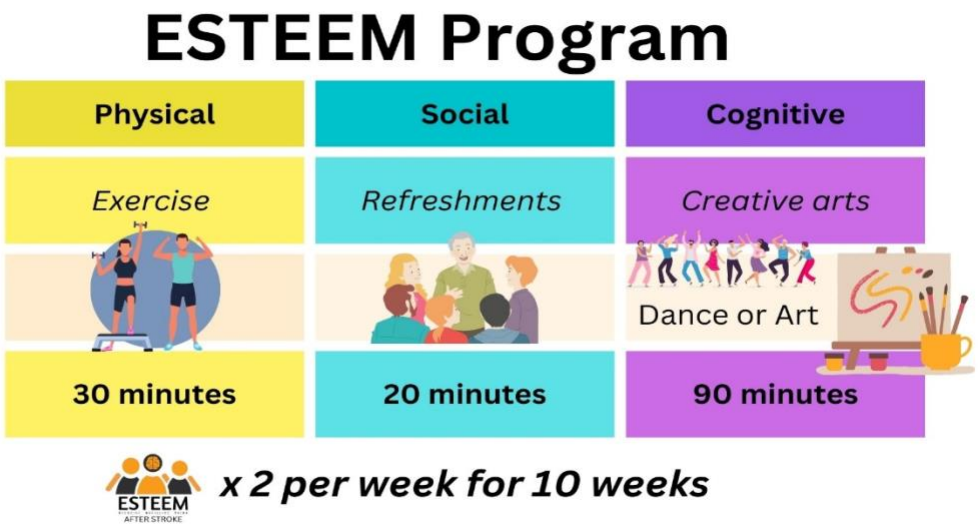
Please **read this information carefully. Ask questions** about anything that you don't understand or want to know more about.

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.

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 part of the ESTEEM project which you are being invited to take part in, aims to determine 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.**

Who can participate in the research?

People who are:

- **18 years and over** who have **had a stroke in the last 5 years**
- **living in the community**
- **willing to participate in the program** (exercising, socialising, and engaging in creative arts)
- **able to stand independently or with the assistance of one person**
- **able to follow instructions safely**

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.**

If you agree to participate in this project, **your involvement will be approximately 8 months long. We will meet with you 3-5 times at a location of your choice.**

This location can be in any of the below locations:

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 the visit will involve answering some questions about your health and activity in the community, completing some surveys and participating in some physical movement tests.

The 4 times we will meet with you are explained below.

Time 1: The start of the **Waiting Phase (baseline, 0 weeks)**

Time 2: The end of the **Waiting Phase (10 weeks)**

Time 3: The end of the **ESTEEM Program Phase (20-24 weeks)**, and

Time 4: 3 months after the end of the **ESTEEM Program Phase (32-36 weeks)**.

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 take time out of your busy days to participate in these visits and to attend the ESTEEM program twice weekly for 10 weeks.

We hope this research project will help stroke survivors to recover as well as 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 study.

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

How will your privacy be protected?

All the **information** collected from you for the study will be **treated confidentially**. To keep your records confidential, they will be identified by a code instead of your name, and all study records will be kept in a secure place to which no one but the researchers has 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 study results may be presented at conferences or in health research publications. Individual participants will not be identifiable in such presentations or publications unless they provide written consent for this to occur.

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.

What do you need to do to take part?

Please read this Information Statement and be sure you understand its content before you consent to take part. If you would like to take part, please complete the consent form and return it to Dr Heidi Janssen at Hunter Medical Research Institute, Locked Bag 1000, New Lambton Heights, NSW 2305 or alternatively it can be sent back to the clinician who invited you to participate.

Further Information

You may wish to consult 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 (02) 4042 0417 or email

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-ResearchOffice@health.nsw.gov.au

Participant Consent Form

Project Title: Exercising, Socialising and Thinking: an Environmental Enrichment Model (ESTEEM) After Stroke
HREC Reference No:
Principal Investigator: Dr Heidi Janssen

Consent

I_____(Your name), have read and I understand this Participant Information Sheet.

- I have had the opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to take part in the research project named above, according to the conditions in the Information sheet, and that I am free to withdraw from the trial at any time, without giving a reason, and without my medical care or legal rights being affected.
- I understand that the consequences of my withdrawal will be that no new information will be collected, but that already collected data will be used.
- I will be given a copy of the Participant Information and Consent Form to keep.
- I am happy for study staff to notify my GP about me being in this study.

  o Yes o No (Please tick the appropriate box)

- I consent to the storage and use of my data, as described in this document for use in:

Tick ONLY ONE box:

- ☐ research for this project
- ☐ research for this project, and research into Stroke and other related illnesses
- ☐ research for this project, research into Stroke and other related illnesses, and for future unspecified research into other unrelated illnesses

Signatures (after the Participant Information sheet has been read and explained to the Participant)

Participant's name (printed) ……

Signature Date…….

Interpreter (Required when this document is read to the participant in a language other than English.)

Name of Interpreter (printed) ……

Signature Date……..

Declaration by Principal or Associate Investigator: I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible has understood that explanation.

Investigator's name (printed) ……

Signature Date……

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