

School of Psychological Sciences

Faculty of Medicine, Health and Human Sciences

MACQUARIE UNIVERSITY NSW 2109

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**INFORMATION STATEMENT AND CONSENT FORM**

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| **HREC Project Number:** | <insert after submission> *The ethics secretariat will advise you of this number after you have completed and submitted an ethics application.* |
| **Research Project Title:** | Navigating Recovery after Stroke: A Co-Design Approach | |
| **Enhanced Chief Investigator:** | Dr Vincent Oxenham, Senior Clinical Neuropsychologist and Clinical Discipline Head of MQ Health Neuropsychology | | |

1. **What is the purpose of this research?**

Being discharged from the hospital after a stroke can be a challenging time as people adjust to managing post-stroke symptoms and navigating their daily routines. Mood (e.g., anxiety, depression) and cognitive difficulties (e.g., attention difficulties, memory problems) are common during this time and can negatively impact day-to-day functioning and independence. However, many stroke patients report that they feel unsupported navigating these mood and cognitive difficulties after hospital discharge. This research aims to bridge these gaps to improve long-term outcomes for stroke survivors.

The purpose of this study is to understand the perspectives of stroke survivors, their caregivers/support people, and multidisciplinary clinicians involved in stroke care regarding what they believe helps support common mood and cognitive difficulties following stroke. These findings will inform the development of an educational resource (psychoeducation) to better support stroke survivors and their carers after their discharge from the hospital.

This study is being conducted by Alyssa Sher to meet the requirements for a combined Doctor of Philosophy Master of Clinical Neuropsychology degree through Macquarie University. This project is under the supervision of Dr Vincent Oxenham ([vincent.oxenham@mq.edu.au](mailto:vincent.oxenham@mq.edu.au)) and supervisors A/Prof. Heather Francis and A/Prof. Milena Gandy of the School of Psychological Sciences.

1. **Who can take part?**

If you choose to participate, you will be asked to consent to participate by selecting the ‘yes’ box at the end.

To take part, you must fit one of the following three categories:

* 1. Have had at least one stroke diagnosis as an adult
  2. Are a caregiver or support person to a stroke survivor
  3. A practicing and certified allied/medical health professional (e.g., nurse, occupational therapist, psychologist, medical doctor etc.) with at least three years of working experience in stroke care

To be eligible to participate, you must:

* Be over the age of 18 years old
* Not experience severe cognitive difficulties (e.g., dementia) that limit your ability to participate in effective discussion of the topic
* Be proficient in English and able to communicate with support tools/aids
* Be living in Australia

1. **What does participation in this research involve?**

* You will be asked to complete a brief online expression of interest form asking for contact details and demographic and/or medical information.
* You may then be invited to attend an online focus group via Zoom to explore post-stroke mood and cognitive difficulties. A copy of the focus group aims and some likely questions will be given to you a few days before the focus group is scheduled. The main aim of the focus groups is to understand common needs, preferences and priorities for developing an educational (psychoeducation) resource to support common mood and cognitive difficulties people who have had a stroke face when they are discharged from hospital. Questions about the potential content, structure and delivery will be asked. Each focus group will be approximately 90 to 120 minutes, with 5 to 8 participants, and will be led by co-facilitators. Separate focus groups will be run for each participant group (i.e., only stroke survivors or caregivers/support people or health professionals involved in stroke care will be included in each focus group).
* The researchers will set up the focus groups to be recorded and transcribed in real-time using an automated transcription tool (i.e., Otter.ai or Zoom transcription function) and stored securely on SharePoint (see below for more details).

There are no costs associated with participating in this research project. You will be given a gift card worth AUD$50 for your time and contribution to the focus group.

1. **Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to participate, you do not have to. If you decide to take part and change your mind, you can withdraw from the project at any stage. If you decide to participate, you will be asked to sign this Participant Information and Consent Form online and given a digital copy to keep.

1. **What are the possible benefits of taking part?**

Taking part in this study may not be of direct benefit to you, but the knowledge gained from this study will help inform the development of effective stroke care that is relevant and sustainable.

1. **What are the possible risks and disadvantages of taking part?**

As discussions within the focus groups will require you to reflect on your experiences, feelings, behaviours and thoughts, there is a risk that some of the content may cause you to feel distressed. If you do not wish to participate in a topic, you may skip it or withdraw from the group immediately. If you become upset or distressed as a result of your participation in the research project, you will be provided immediate support where necessary and a mental health resources pack to help you seek further assistance. There may be other associated risks that are presently unknown or unforeseeable. If participation raises any concerns, you can contact the Principal Coordinating Investigate, your GP, StrokeLine (1800 787 653; a free service available Monday to Friday 9am-5pm), or Lifeline (13 11 14; a free service available 24 hours/day).

1. **What if I withdraw from this research project?**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a research team member before you withdraw. There is no consequence should you decide to withdraw from the study at any time.

1. **What will happen to information about me?**

By signing the consent form, you consent to the research team collecting and using information about you for the research project. The research team will store the data collected for at least 7 years and may be destroyed at the end of the period. It will be ensured that the disposal process will involve an irreversible method that renders that data unreadable.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored and only accessible to the researchers. Your personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

* Your personal information will be collected and stored using a code to identify you in REDCap (Macquarie University server), a secure web application for building and managing online surveys and databases. Access to REDCap is password protected and will be directly and permanently stored on infrastructure located in Australia.
* Focus groups will be recorded and transcribed using pseudonyms and securely stored separately from any identifying information on Macquarie University SharePoint (password protected).

It is anticipated that the results of this research project will be published and/or presented at meetings, conferences, scientific publications and/or project reports. In such cases, information will be provided so that you cannot be identified except with your express permission.Confidentiality will be maintained using pseudonym codes.

Following relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information you disagree with be corrected. Please inform the research team member named at the end of this document if you would like to access your information. Upon request, a summary of the results can be made available to you by contacting the investigators.

You may be contacted and invited by the research team in the future to participate in related projects.

1. **Who is organising and funding the research?**

This research project is being conducted by Principal Investigator Dr Vincent Oxenham, associated with Macquarie University.

No research team member will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

1. **Who has reviewed the research project?**

The ethical aspects of this research project have been approved by the Human Research Ethics Committee (HREC) at Macquarie University.

This project will be carried out according to the *National Statement on Ethical Conduction in Human Research (2007).* This statement has been developed to protect the interests of people who agree to participate in human research studies.

1. **Further information and who to contact**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the Principal Investigator at (02) 9463 1826 or any of the following people:

**Research contact person**

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| Name | Alyssa Sher |
| Position | School of Psychological Sciences, Macquarie University |
| Telephone | 0452 471 307 |
| Email | alyssa.sher@students.mq.edu.au |

1. **Complaints contact person:**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

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| Reviewing HREC name | Macquarie University Human Research Ethics Committee |
| Telephone | +61 2 9850 7854 |
| Email | ethics@mq.edu.au |

**Declaration by the participant:**

I have read and understand the Participant Information Sheet above. I understand the purposes, procedure and risks of the research described in this project. I agree to be video and audio recorded if I participate in the focus group. I understand that the researchers may contact me about future research related to this project, including evaluating an educational resource. I freely agree to participate in this research project as described and understand that I can withdraw at any time.

Yes (checkbox)

No (checkbox)