Participant Information Sheet and Consent Form

Adult providing own consent

Title	Transforming care using a transdisciplinary assessment: a multi-site study
Short Title	Transdisciplinary Translation Study
Protocol Number	108414
Coordinating Principal Investigator	Aleysha Martin
Associate Investigator(s)	Liisa Laakso, Cassidy Hall, Tina Tran, Tegan Scott, Steven Wityk
Location	Online, research is based at the Mater Hospital Brisbane

1 Introduction

You are invited to take part in this research project because you have experienced or care for someone who has experienced a transient ischaemic attack (TIA) or a stroke. The research survey is designed to understand the experience of being assessed with a single, comprehensive stroke assessment by one allied health professional. Allied health professionals include people like occupational therapists, physiotherapists, speech pathologists and social workers.

This document tells you about the research project. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand, or you want to know more about. Before deciding if you would like to take part, you might want to talk about it with a trusted support person.

You will be given a copy of this Participant Information and Consent Form to keep. If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatment that are described, and
- Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

The research aims to study the experience of using a different allied health assessment approach for people who experience TIA/stroke. Some acute stroke units are moving away from separate assessments completed by the occupational therapist, physiotherapist, speech pathologist, and social worker. We have combined the most important aspects of the assessments to create a single, comprehensive assessment. This means that one allied health professional can ask you all the important questions to help identify your needs and streamline your hospital care.

3 What does participation in this research involve?

The survey is designed to understand the experience of being assessed with a single, comprehensive stroke assessment by one allied health professional. Participation will occur during 2 sessions.

In session 1, you will be asked to:

1. Watch a video of an allied health professional completing the assessment with a person who experienced a stroke. The assessment would normally take up to 1 hour, the video is 40 minutes long. You are welcome to view the whole video or stop/start at your convenience.
2. Answer online survey questions based on your experience of the video

In session 2 (in about 13 months after we have finished our clinical study) we will contact you again, to ask you to:

1. Review our study results
2. Answer online survey questions based on what the results mean to you and how we should share them

4 Other relevant information about the research project

As part of the online survey, you will see a video of an allied health professional completing the assessment with a person who experienced a stroke. The video is the confidential intellectual property of the Mater Hospital Brisbane, and you are not granted permission to download, record, save, or share the video. You have permission to view the video only while completing the survey.

5 Do I have to take part in this research project? What if I decide to withdraw?

Participation in any research project is voluntary. If you decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you decide to withdraw later, please notify a member of the research team. We will discuss any health risks or special requirements linked to withdrawing and ask you to sign a Withdrawal of Consent Form. We will not collect additional personal information from you although personal information already collected will be retained (with your permission) to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you request to remove your data from the study record at the time of withdrawal, then this request will be honoured if your data can be identified and therefore removed. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the hospital.

6 What are the alternatives to participation?

If you choose not to partake in this research project you do not have to. No other options to participate are available.

7 What are the possible benefits of taking part?

By completing the survey, you will provide healthcare professionals with valuable information that could improve the stroke assessment experience for future people who experience stroke as well as their support persons. You will be reimbursed for your time at $40/hour (as per Queensland Clinical Guidelines). We have funding for up to 5 participants for each session. The survey is expected to take you 1 hour to complete (40 minutes to watch the video 10-20 minutes to answer the questions). At the end of the survey, you will be asked if you would like to receive reimbursement. If you select “yes” the Principal Investigator will contact you to organise the reimbursement.

8 What are the possible risks and disadvantages of taking part?

There are no expected physical risks or disadvantages to you from your participation in this research. Participating may prompt you to reflect on your own experience, which could bring up positive or negative memories. We encourage you to complete this survey with a trusted support person, who could provide assistance to read, understand and/or respond to questions as needed. A trusted support person could also help you if answering questions about stroke assessment and reflecting on your personal experience might cause you distress.
You may also stop and withdraw participation at any point and for any reason.

9 Could this research project be stopped unexpectedly?

This research project could be stopped unexpectedly if we are unable to recruit enough participants at session 1.

10 What happens when the research project ends?

You will be provided with the contact details the Principal Investigator (listed on this document). When your involvement in the research project ends, you can initiate follow-up or request results using these details. Results will be available on the completion of the study (approximately 2026).

11 What will happen to information about me?

By signing the consent form, you consent to the research staff collecting and using de-identified personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential, recorded using your personal study code number, and will be deleted at the end of the project (estimated 2026). Your contact information (i.e., email address) will be kept confidential and separate from your survey answers. We will only use your email to share survey information

(now and in about 13 months), answer your questions, and organise reimbursement. Your contact information will be deleted when the study concludes. Only the Principal Investigator can access your information.

Your unidentifiable survey responses will be accessible from the survey platform and will be transferred to a password-protected Microsoft Word or Excel document, which will be stored in a password-protected folder on a secure Mater Research Institute drive during the study. At the end of the study, final unidentifiable datasets will be saved on the University of Queensland's Research Data Manager system and may be published online via UQ eSpace to allow for transparent research and assist future research. To protect your privacy, no information will be published that could identify you as a participant in this study. Your unidentifiable information will be used for the purpose of this research project and to help modify the assessment at other hospitals and healthcare sites and, if published, may be used in future studies. Participant information will only be disclosed with your permission, except as required by law. Any other information related to your admission will be kept secure in your medical notes as is usual practice.

12 Complaints

For complaints regarding your involvement in this research, you can contact the approving Human Research Ethics Committee (telephone (07) 3163 1585 or email research.ethics@mater.uq.edu.au).

13 Who is organising and funding the research?

This research project is being conducted by Principal Investigator Aleysha Martin. There are no conflicts of interest, although the research is expected to form part of the postdoctoral studies of the Principal Investigator (Aleysha Martin). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than ordinary wages).

14 Who has reviewed the research project?

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007, updated 2018).* This statement has been developed to protect the interests of people who agree to participate in human research studies. All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been reviewed and approved by the *Mater Misericordiae Limited Human Research Ethics Committee (EC00332*), which is the institution responsible for supervising the standard of care where the research will be carried out. Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you can contact the HREC Liaison Officer or HREC Chairperson, Human Research Ethics Committee, Mater Misericordiae Ltd, Raymond Terrace South Brisbane 4101, or telephone (07) 3163 1585, email: research.ethics@mater.uq.edu.au.

15 Further information and who to contact

The person you need to contact will depend on the nature of your query. For questions about the research, you can contact the approving Human Research Ethics Committee (telephone (07) 3163 1585 email research.ethics@mater.uq.edu.au) or the Principal Investigator (aleysha.martin@mater.org.au). For complaints, contact the Research Governance Office (telephone (07) 3163 3769 or email research.governance@mater.uq.edu.au.

Consent Form

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

Declaration by Participant

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my information to be used for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future healthcare.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

Withdrawal of Participation Form

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

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my relationship with the Mater Hospital Brisbane and Investigators.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Researcher must provide a description of the circumstances:

Declaration by Researcher

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____