

Participant Information Sheet

Title	The modification of challenge in the rehabilitation of walking after stroke.
Short Title	Challenge modification in walking rehabilitation after stroke.
Protocol Number	124502
Project Sponsor	The University of Queensland
Principal Investigator	Dr. Niruthikha Mahendran
Lead Investigator	Andrea Saverymuthapulle
Associate Investigator	Professor Sandra Brauer
Location	Surgical Treatment and Rehabilitation Service (STARS), Herston. QLD. Australia.

Thank you for your interest in participating in this research project. Please read the following information about the project so that you can decide whether you would like to take part in this research. Please feel free to ask any questions you might have about our involvement in the project.

If you decide to participate in this research, please keep in mind that your participation is voluntary. 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 stop at any time, and you would not need to give any explanation for your decision to stop participating. If you choose to stop participating, your data will not be used in the research.

You will be given the Participant Information and Consent Form to sign, and you will be given a copy to keep. Your decision whether you take part, or not to take part, or to take part and then withdraw, will not affect your relationship with the University of Queensland.

What is this research about?

Physiotherapy rehabilitation improves walking after a stroke. However, we are still unsure how challenging therapy tasks need to be to improve walking after a stroke. We also do not know how differences between people with stroke affect how they recover and how difficult therapy might be to the person with stroke.

This research is looking at changing the level of difficulty during walking to understand how difficult therapy is for the person with stroke and which therapy modifications are the most effective to improve walking.

What does participation in this research involve?

A member of the research team will talk to you to check if you are suitable to take part in the study. If you are eligible to take part, you will be asked to sign the consent forms at the end of this document.

If you consent to take part, this research involves attending one 2-hour, face-to face session where you will be asked to (i) complete questionnaires / surveys and (ii) walk at a pace that is comfortable for you, while receiving feedback or information from a physiotherapist about your walking. A family member or support person can be present with you during the session. You will also receive a \$20 gift card as an honorarium for your participation.

You will not be paid for your participation in this research project. All equipment required as part of the research project will be provided to you free of charge. While there is no cost to participate in this study, please note that you will be responsible for any parking costs associated with the visit. Parking on site at STARS is limited (450 spaces). There are 30 disabled and short term parking bays and a dedicated drop-off/ pick up zone at the entrance to the hospital. Privately owned carparks that offer parking for visitors to STARS include Wilson Parking (\$8/hour), Bramston Point Parking (\$13.20/hour) and Cornerstone Parking (\$12/hour) . If you have a local doctor, you may choose to inform them of your participation in this research project.

What will I have to do?

The session will take place at the Research laboratory, which is located on level 1 of STARS hospital, Herston. Details about what you do in the session are provided below:

When you first arrive at the research laboratory, you will be asked some questions about yourself and your health by a member of the research team. A family member or support person can be present with you during this survey. You will have your blood pressure and heart rate taken and a heart rate monitor will be placed on your chest. You will have your blood pressure and heart rate taken and a heart rate monitor will be placed on your chest

Next, you will complete walking tasks of approximately two minutes each, at a pace that is comfortable for you, with rest periods provided between each task.

You will be asked to walk around the laboratory on the floor and over a thin mat. Each of the walking tasks may differ slightly but you will be provided instructions before you begin each task. You will be allowed to use your usual walking aid and will be supervised closely during each of the walking tasks. There will be a display screen in front of you to show you how far

to step when you walk. After the walking tasks are completed, you will be given a few minutes to rest.

What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. We hope that these results will benefit people in the future who have had a stroke. You will receive one walking session with a physiotherapist. It is possible that your walking performance may improve during the session, but this may be temporary. You will receive an assessment of your walking ability.

What are the possible risks and disadvantages of taking part?

The test session is not expected to be more demanding than walking in daily life. You will be walking at your pace that is comfortable for you, with your typical aids (if needed) with frequent rest periods scheduled after walking for short periods. Although it is unexpected, during the session, you may experience some fatigue or physical discomfort answering questions or doing the walking tasks. If you have any of these side effects, or are worried about them, talk with a member of the research team. The research team will also be looking out for signs of fatigue or discomfort. Any fatigue and physical discomfort that you may experience, expected to go away during rest or shortly after treatment ends. There is a slight risk that you may overbalance while walking. Your walking will be supervised by a physiotherapist walking alongside you.

Tell your research team immediately about any new or unusual symptoms such as chest pain, dizziness, feeling faint, nausea or vomiting. If any incidents occur, they will be managed in accordance with usual occupational health and safety protocols employed by the University of Queensland. The research team may need to stop the session and refer you to the medical team on site or emergency services.

Sometimes during a research project, new information becomes available about the participant. If this happens, a member of the research team will tell you about it and discuss with you. If the investigative team, consider it is in your best interests to withdraw you from the research project. If this happens, they will explain the reasons, discuss with you and notify appropriate health care professionals as for follow up, if you agree to this. Some questionnaires may ask about mood, motivation or emotions. These may be upsetting for some people. If this happens, we will take a break and provide support. You can skip questions or stop the study at any time. If you become upset or distressed because of your participation in the research, the research team may refer you for counselling or other appropriate support, if you provide consent for this.

What will happen to the information about me?

All information collected about you will remain confidential. This will be done by de-identifying the information (this means, taking any identifiable details such as your name out of the data and storing your information under a unique ID code). Any deidentified data collected during this project will be stored in the University of Queensland's secure data storage service (UQRDM). Only de-identified data will be used for the purpose of this research project.

With your permission, de-identified information may be stored securely and used for future research. Only approved researchers will have access to this data, and it will not have any information that clearly identified you. Your decision to allow or not allow the storage of your information will not affect your participation in this study. Information will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forms. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your expressed permission.

What will happen if I decide to withdraw?

Your participation in this research is voluntary, and you are free to withdraw from the research anytime without needing to provide any explanation, and you would not receive any penalty or bias because of your withdrawal. Should you decide to withdraw, all the information collected from/about you will be destroyed and will not be used in the research.

Can I hear about the results of this research?

When the research project ends, you will be provided with a summary of the results which can be emailed or posted out to you (if you agree to this). The results of the study may also be published or presented in academic settings or conferences. We will not disclose any information that might identify you during any presentations, ~~or~~ publications or reports arising from this study.

Could this research project be stopped unexpectedly?

Although unexpected, this research project may be stopped unexpectedly if decisions are made in the commercial interests of the sponsor or by local regulatory/health authorities.

Who has reviewed the research project?

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 approved by the HREC of Metro North Health and The University of Queensland, Australia.

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

Who can I contact if I have any concerns about the project?

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with the researcher contactable on andrea.savermuthapulle@student.uq.edu.au or 0481 388 042. If you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on +617 3365 3924 / +617 3443 1656 or email humanethics@research.uq.edu.au

This research Ethics ID number: 2025/HE002459

Consent form

Research Title:	The modification of challenge in the rehabilitation of walking after stroke.
Lead investigator:	Andrea Saverymuthapulle (BPhty, MRehab (Neurological), PhD student, The University of Queensland)
Other researchers:	Dr. Niru Mahendran (BPhty (Hons), PhD), Conjoint Research Fellow STARS Alliance and The University of Queensland. Professor Sandy Brauer (BPhty (Hons), PhD), Co-Director of Centre for Neurorehabilitation, Ageing and Balance Research.
Ethics approval number:	2025/HE002459

Declaration by Participant

- I have read the Participant Information Sheet (version number 1), or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research.
- I have had an opportunity to ask questions, and I am satisfied with the answers I have received.
- I consent to the storage and use of any **de-identified**, personal or sensitive information taken from me for use, as described in Part 2, section 14 of the Participant Information Sheet, for: (please circle)
 - This specific research project. (yes/no)
 - Other research that is closely related to this research project (yes/no)
 - Any future research. (yes/no)
- I freely agree to participate in this research project and understand that I am free to withdraw at any time. I understand what will happen to the data and information if I decide to withdraw.
- I understand that I will be given a signed copy of this document to keep.

Participant name (please print):

Participant Signature:

Date:

Declaration by Researcher

I have answered any questions about the research project, and I believe that the participant has understood the purpose, procedures and risks involved.

Researcher name (please print):

Date:

Researcher signature:

Participant Withdrawal Form

Research Title: The modification of challenge in the rehabilitation of walking after stroke.

Lead researcher: Andrea Saverymuthapulle (BPhty, MRehab (Neurological), PhD student, The University of Queensland)

Other researchers: Dr. Niru Mahendran (BPhty (Hons), PhD), Conjoint Research Fellow STARS Alliance and The University of Queensland.
Professor Sandy Brauer (BPhty (Hons), PhD), Co-Director of Centre for Neurorehabilitation, Ageing and Balance Research.

Ethics approval number: 2025/HE002459

Declaration by Participant

- I wish to withdraw from participation in the research project.
- I understand that I do not need to provide a reason for my decision to withdraw and that withdrawal will not affect my health care or relationship with the University or researchers.
- I understand that the Participant Information Sheet (version number 1) explains what happens if I withdraw, and I have had any questions answered to my satisfaction.

Participant name (please print):

Date:

Participant signature:

Declaration by Researcher

I have answered any questions about withdrawal, and I believe that the participant has understood any implications of withdrawal.

Researcher name (please print):

Date:

Researcher signature: