Participant Information Sheet

PROJECT TITLE: Towards better prosthesis sockets for transtibial amputees

HUMAN RESEARCH ETHICS COMMITTEE APPROVAL NUMBER: H-2025-21383

PRINCIPAL INVESTIGATOR: Dr Ryan Quarrington

CO-INVESTIGATORS: A/Prof Boopalan Ramasamy, Prof Dominic Thewlis, Ms Angela Walls, Dr Max Nelson, Mr Peter Eaton, Ms Jane Morphett, Ms Natasha Polglase

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

Lower-limb amputees, especially those with transtibial amputations, often struggle with poorly fitting prosthetic sockets, which lead to discomfort, pressure sores, and reduced prosthesis use, impacting their mobility and quality of life. This project will identify the common issues amputees face with current prosthetics via detailed survey and group discussions, and measure residual limb geometry from CT and MRI scans, to inform an innovative, custom-fitted, and adjustable socket design. The design will integrate advanced materials, medical images, and computer-aided design to provide a responsive, comfortable fit. By addressing the core issue of socket adaptability, this design aims to enhance long-term prosthesis use, reducing complications and improving amputees' independence and well-being.

Who is undertaking the project?

This project is being conducted by University of Adelaide researcher Dr Ryan Quarrington, in collaboration with the SAHMRI Clinical and Research Imaging Centre.

Why am I being invited to participate?

You are being invited as you have indicated that you meet the selection criteria for this project and do not have any issue listed on the exclusion criteria below:

Selection criteria:

- At least 18 years of age;
- Underwent transtibial amputation at least 18-months prior;
- Have a stable residual limb condition without active infections or significant oedema;
- Have ever used a prosthetic limb for daily activities;
- Are in good general health as determined by a medical professional;
- Do not suffer from claustrophobia or other medical conditions incompatible with medical imaging;
- Are willing and able to attend all study sessions;
- Are able to give written informed consent;
- Can understand written and verbal English.

Exclusion criteria:

- have a medical condition that precludes you undergoing MRI;
- are unable to give written informed consent; or
- are unable to understand written or verbal English.

What am I being invited to do?

You are being invited to participate in a study which will inform the design process for better prosthesis sockets for transtibial amputees.

Participation includes:

1. An online survey
2. A group discussion with fellow amputees conducted at The University of Adelaide
3. Uploading of photos, video, or descriptions of significant interactions with your prosthetic socket over 5 days
4. Vital signs taken and external scan, MRI and CT scans of your residual limb at the Jones Radiology hub at the South Australian Health and Medical Research Institute (SAHMRI) Clinical Research Imaging Centre (CRIC), North Terrace.

You may also be invited to test a prototype prosthetic socket design informed by the information gained from the collective surveys, group discussions, and MRI/CT data.

Please sign the consent section included in the online survey and complete the online survey (link provided below). Your responses will determine your eligibility and you will be enrolled in the study and provided with a booking link to arrange a suitable time to attend a group discussion session.

How much time will my involvement in the project take?

The surveys, group discussion, and Jones Radiology scans could take up to 4 hours of your time, while testing of the prototype prosthetic socket will take no more than 2 hours.

Are there any risks associated with participating in this project?

There are no serious risks associated with participating in the project. This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.1mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal. There may be some discomfort experienced from the oppressive and loud MRI scanner.

If you feel the questions in the survey or group discussion make you uncomfortable, you can stop whenever you wish. For any additional support, you can use any of the mental health helplines provided below.

Helplines	
Healthdirect – 24-hour health advice	1800 022 222
Mind – Mental health support	1300 286 463
Lifeline Australia	13 11 14

What are the potential benefits of the research project?

Data collected in the current research will inform the design process for better prosthesis sockets for all transtibial amputees. This project will contribute to the advancement of evidence-based prosthetic design, improving the quality of life for amputees.

Short term and long-term benefits may include:

- Identification of problem areas in regard to current socket fit
- Better comfort and adaptability from improved socket design

Will there be any reimbursement for time or travel?

All participants will receive a $150 honorarium (Coles/Myer voucher) to reimburse them for their time and efforts. Reimbursement will be offered for parking during both the scan and group discussion sessions, although the use of public transport is encouraged due to a lack of nearby parking. Parking in the entertainment centre and catching the free tram to SAHMRI and AHMS buildings is recommended.

Reimbursement of fuel expenses ($0.88/km, per ATO) will also be offered to participants who must travel a distance greater than 50 km from the Adelaide CBD.

Can I withdraw from the project?

Participation in this project is completely voluntary. If you agree to participate, you can withdraw from the study at any time.

What will happen to my information?

Your information will only be disclosed to the researchers and their research group. The Radiologist at Jones Radiology will perform an MRI and CT safety read to check for abnormalities. Please indicate on the Consent Form if you would like to receive a copy of this report, have it sent to your GP, or both. The information will be stored on secure networks under University of Adelaide supervision, accessed only from password-protected accounts. Your name will be replaced by an alphanumeric code during data collection and analysis. Your identity will be masked in any photos and videos prior to presenting in any journal article publications, research conferences, seminars and thesis/reports. Individually identifiable materials (such as videos and photos) will be archived at the completion of the study and can be deleted at any time upon request. Other data will be stored on the research drive for at least 5 years from the date of publication (this is an Australian National Health and Medical Research Council requirement) prior to archiving.

Has this study been approved by a Human Research Ethics Committee?

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chairperson, on 7117 2229.

Who do I contact if I have questions about the project?

Name	Email	Telephone numbers
Dr Ryan Quarrington (Primary Contact)	AmpuEase@adelaide.edu.au	08 8313 2854, 0418 560 917

What if I have a complaint or any concerns?

If you have questions or problems associated with the practical aspects of your participation in the project or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator (above).

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 also contact:

Reviewing HREC approving this research, HREC Executive Officer details and Complaints contact

HREC Name	**Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)**
Contact	HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information

Your participation in this study shall not affect any other right to compensation you may have under common law.

If I want to participate, what do I do?

Complete this online survey: https://surveys.adelaide.edu.au/redcap/surveys/?s=XJA99JMR7E8JDEDA

Contact Dr Ryan Quarrington for more information.

Email: AmpuEase@adelaide.edu.au

Yours sincerely,

Dr Ryan Quarrington
A/Prof Boopalan Ramasamy
Prof Dominic Thewlis
Dr Max Nelson
Ms Angela Walls
Mr Peter Eaton
Ms Jane Morphett
Ms Natasha Polglase