

Project Title: Acceptability of balance-enhancing outdoor shoes compared to minimalist outdoor shoes in older women: a randomised crossover trial		
The research is being carried out in partial fulfilment of a Doctor of Philosophy (PhD) under the supervision of Professor Hylton Menz (Principal Investigator and student supervisor). The following researchers will be conducting the study:		
Role	Name	Organisation
Lead investigator	Professor Hylton Menz	Discipline of Podiatry, School of Allied Health, Human Services and Sport, La Trobe University
Co-investigators/co-supervisors	Professor Shannon Munteanu Dr Shan Bergin	
Student investigator	Ameer Nor Azhar	
Research funder	This research is partially supported by ecnalabs, pty, ltd as part of La Trobe University's Industry PhD program. Ameer Nor Azhar is supported by an Australian Government Research Training Program Scholarship 2024.	

1. What is the study about?

You are invited to participate in a study investigating the effect of two different types of outdoor shoes on acceptability, balance performance and perceived risk of falls in older women. There has been little research to evaluate what type of outdoor shoe is most acceptable in older women, and what type of outdoor shoe is most beneficial for balance performance and reducing perceived risk of falling. We hope to learn if balance-enhancing outdoor shoes or minimalist outdoor shoes is more acceptable in older women and if either outdoor shoe type is more beneficial for balance performance and perceived risk of falling.

Your contact details were obtained from a database of people who have been attending the La Trobe University Health Sciences Clinic for treatment of foot care or from your response to an advertisement about this research.

2. Do I have to participate?

Being part of this study is voluntary and you can withdraw your consent to participate at any time up until 4 weeks after you have participated in the study. If you want to be part of the study, we ask that you read the information below carefully and ask us any questions. You may also like to discuss participation in the study with friends or family before deciding.

You can read the information below and decide at the end if you do not want to participate. If you decide not to participate this won't affect your relationship with La Trobe University, including the student led podiatry clinic, or any other listed organisation.

3. Who is being asked to participate?

You have been asked to participate because:

- You identify as a woman and are aged 65 years or older

To be eligible to participate in this study, you must:

- identify as a woman
- be aged 65 years or older
- be able to walk household distances (>50 metres) without walking aids
- be free of any disease or condition which interferes with balance or walking (e.g. Parkinson's disease)
- be free of any lower limb or partial foot amputation
- be free of any surgery to the foot or ankle in the past 12 months
- be willing to wear two different types of shoes across two different six-week periods
- have the capacity to provide informed consent to participate in the study

- be able to understand and communicate in English (verbally and in written form)
- have capacity to attend the four different sessions at La Trobe University (Bundoora).

4. What will I be asked to do?

If you want to take part in this study, we will ask you to attend four sessions (in-person) at La Trobe University (Bundoora) over three months, wear two different types of outdoor shoes (six weeks in both pairs of shoes each) and complete surveys and complete balance performance testing.

You will be given one of two types of outdoor shoes before crossing over to the alternate type of outdoor shoe. This type of study is known as a "randomised crossover trial". To ensure the two groups in the study are similar to start with, participants are randomly put into one of the two groups by a computer program, like the flip of a coin. Neither the researchers nor the study participant can decide which shoe type you will be given for the first six-week period. As this is study is a crossover trial, you will receive both types of outdoor shoes, however the order you receive them (first or second) will be random.

It will take approximately 8 hours (up to 2 hours for each session) of your time to participate in this study.

Enrolment: Appointment 1 (2 hours):

This session will be held at the Podiatry Clinic Research Room at La Trobe University, Melbourne (Bundoora) Campus. This session will take approximately 2 hours of your time. You will be asked to complete a series of questionnaires, perform balance testing measures and your foot sized will be assessed by a podiatrist. Please wear comfortable clothing and bring the shoes you wear most often.

This session will involve a series of assessments such as the following:

Anthropometric measurements: We will measure your height and weight and calculate your body mass index.

Questionnaires: We will ask you to provide information about your education level, culture and ethnicity, medical history and medication information and complete some health questionnaires related to your foot and overall health (e.g., Manchester-Oxford Foot Questionnaire [MOXFQ] and 5-level EQ-5D version [EQ-5D-5L]). Other questionnaires will also be used to determine shoe acceptability (modified Monitor Orthopaedic Shoes Questionnaire [MOSQ] and perceived risk of falling (Falling Efficacy Scale International [FES-I]).

Balance performance testing: We will ask you to walk across an uneven grass-like surface (10 metres long) a number of times. Whilst doing so, you will wear a chest harness with a sensor attached. This will be completed in the shoes you present in.

Shoe sizing assessment: Your shoe size will be assessed by a podiatrist. You will also have the opportunity to try on both types of shoes you will wear during the study to ensure that the size you nominate for each shoe is appropriate for you.

Foot scanning: 3D foot photographs / scans will be taken using the using a 3D scanner (INFOOT, I-Ware Laboratory, Japan). This will create a stereolithography (STL) file of each foot that will be allocated a participant ID number. The INFOOT software automatically generates a comprehensive suite of foot dimensions, including foot length, width, forefoot girth, arch height and first and fifth toe angles. The scan is a surface image and is non-identifiable and non-invasive.

Appointment 2: (2 hours)

This session will be held at the Podiatry Clinic Research Room at La Trobe University, Melbourne (Bundoora) Campus. This session will take approximately 2 hours of your time. You will be issued shoes and asked to complete a questionnaire.

This session will involve a series of assessments such as the following:

Issuing shoes: You will receive your first pair of outdoor shoes (balance-enhancing or minimalist). A podiatrist will ensure that the shoes fit appropriately. You will be asked to wear these newly issued shoes as much as possible for the next six weeks.

Questionnaire: You will be asked to complete a questionnaire to determine shoe credibility and expectancy. These will be in relation to the shoes you have been allocated within this session.

Appointment 3: (2 hours)

This session will be held at the Podiatry Clinic Research Room at La Trobe University, Melbourne (Bundoora) Campus approximately six weeks after "Appointment 2". This session will take approximately 2 hours of your time. You will be asked to complete a series of questionnaires and complete balance performance tasks. You will also be issued your second pair of outdoor shoes.

This session will involve a series of assessments including:

Questionnaires: You will be asked to complete questionnaires to determine shoe acceptability and perceived risk of falling. There will also be an additional survey which will allow you to report any adverse events from wearing the shoes (e.g. discomfort).

Balance performance testing: We will ask you to walk across an uneven grass-like surface (10 metres long) a number of times. Whilst doing so, you will wear a chest harness with a sensor attached.

Issuing shoes: You will receive your second pair of outdoor shoes; they will be the alternate type of shoe compared to what you were allocated in "Appointment 2" (balance-enhancing or minimalist). A podiatrist will ensure that the shoes fit appropriately. You will be asked to wear the newly issued shoes as much as possible for the next six weeks.

Questionnaire: You will be asked to complete a questionnaire will also be used to determine shoe credibility and expectancy.

Appointment 4: (2 hours)

This session will be held at Podiatry Clinic Research Room at La Trobe University, Melbourne (Bundoora) Campus approximately six weeks after "Session 2". This session will take approximately 2 hours of your time. You will be asked to complete a series of questionnaires and complete balance performance tasks.

This session will involve a series of assessments such as the following:

Questionnaires: You will be asked to complete questionnaires will also be used to determine shoe acceptability and perceived risk of falling. There will also be an additional survey which will allow you to report any adverse effects from wearing the shoes (e.g. discomfort).

Balance performance testing: We will ask you to walk across an uneven grass-like surface (10 metres long) a number of times. Whilst doing so, you will wear a chest harness with a sensor attached.

Questionnaire: You will be asked to complete a questionnaire which will detail your preference over the two types of shoes you were issued during the study.

5. What are the benefits?

The benefit of you taking part in this study is that you will receive two free pairs of outdoor shoes. The expected benefits to society in general are that it will help to inform clinical guidelines which has the potential to improve the management falls in older women.

6. What are the risks?

With any study there are (1) risks we know about, (2) risks we don't know about and (3) risks we don't expect. If you experience something that you aren't sure about, please contact us immediately so we can discuss the best way to manage your concerns. In the first instance please contact Professor Hylton Menz.

Name/Organisation	Position	Telephone	Email
Professor Hylton Menz	Principal Investigator	(03) 9479 5801	h.menz@latrobe.edu.au

We have listed the risks we know about below. This will help you decide if you want to be part of the study.

- There is a low risk that you may experience minor transient discomfort from either shoe type. You may discontinue wearing the shoes at any stage during the study if the discomfort is too burdensome. You will need to contact Professor Hylton Menz or any other of the study investigators if you need to discontinue wearing the shoes. You may discontinue wearing the shoes at any stage during the study if the discomfort is too burdensome.
- There is a risk of inconvenience to you as you will need to attend the La Trobe University, Bundoora campus four times to take part in the study. However, the sessions will be scheduled at a time that is convenient for you.

7. Will I be paid to be part of this study?

It will not cost you to be part of this study. As mentioned previously, you will receive two free pairs of outdoor shoes. However, any travel costs associated with attending the sessions will not be covered by the study.

8. What will happen to information about me?

We will **collect** information about you in ways that may reveal who you are.

We will **store** information about you in ways that that will not reveal who you are.

We will **publish** information about you in ways that you will not be identified in any type of publication from this study.

We will **keep** your information for 15 years after the project is completed. After this time we will destroy all of your data.

The storage, transfer and destruction of your data will be undertaken in accordance with the [Research Data Management Policy](https://policies.latrobe.edu.au/document/view.php?id=106/) <https://policies.latrobe.edu.au/document/view.php?id=106/>.

The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

9. Will I hear about the results of the study?

We will let you know about the results of the study by sending you a lay personal summary and a summary of the overall results on completion of the project. The investigators may also present results of this study at professional conferences and may also publish this work in a peer reviewed journal. You will not be identifiable in either conference presentations or publications.

10. What if I change my mind?

You can choose to no longer be part of the study at any time until four weeks following the collection of your data. You can even withdraw your consent during the focus group discussion. You can let us know by:

1. Completing the 'Withdrawal of Consent Form' (provided at the end of this document);
2. Calling us; or
3. Emailing us

Your decision to withdraw at any point will **not** affect your relationship with La Trobe University or any other organisation listed.

When you withdraw we will stop asking you for information. Any identifiable information about you will be withdrawn from the research study. However, once the results have been analysed we can only withdraw information, such as your name and contact details. If results haven't been analysed you can choose if we use those results or not.

11. Who can I contact for questions or want more information?

If you would like to speak to us, please use the contact details below:

Name/Organisation	Position	Telephone	Email
Professor Hylton Menz, La Trobe University	Principal Investigator	(03) 9479 5801	h.menz@latrobe.edu.au

12. What if I have a complaint?

If you have a complaint about any part of this study, please contact:

Ethics Reference Number	Position	Telephone	Email
[INSERT - Ethics Number]	Senior Research Ethics Officer	(03) 9479 1443	humanethics@latrobe.edu.au

Consent Form – Declaration by Participant

I (the participant) have read (or, where appropriate, have had read to me) and understood the participant information statement, and any questions have been answered to my satisfaction. I agree to participate in the study, I know I can withdraw at any time until four weeks following the collection of my data. I agree information provided by me or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that I cannot be identified.

I would like my information collected for this research study to be:

- Only used for this specific study;
 Used for any future studies
 I consent to be contacted for any future studies

I would like to receive a copy of the results via email or post. I have provided my details below and ask that they only be used for this purpose and not stored with my information or for future contact.

Name	Email (optional)	Postal address (optional)

Participant Signature

I have received a signed copy of the Participant Information Statement and Consent Form to keep

Participant's printed name	
Participant's signature	
Date	

Declaration by Researcher

- I have given a verbal explanation of the study, what it involves, and the risks and I believe the participant has understood;
 I am a person qualified to explain the study, the risks and answer questions

Researcher's printed name	
Researcher's signature	
Date	

* All parties must sign and date their own signature

Withdrawal of Consent

I wish to withdraw my consent to participate in this study. I understand withdrawal will not affect my relationship with La Trobe University of any other organisation or professionals listed in the Participant Information Statement. I understand the researchers cannot withdraw my information once it has been analysed.

I understand my information will be withdrawn as outlined below:

- ✓ Any identifiable information about me will be withdrawn from the study
- ✓ The researchers will withdraw my contact details so I cannot be contacted by them in the future studies unless I have given separate consent for my details to be kept in a participant registry

I would like my already collected and unanalysed data

- Destroyed and not used for any analysis
 Used for analysis

Participant Signature

Participant's printed name	
Participant's signature	
Date	

Please forward this form to:

CI Name	Professor Hylton Menz
Email	h.menz@latrobe.edu.au
Phone	(03) 9479 5801
Postal Address	Discipline of Podiatry, School of Allied Health, Human Services and Sport, La Trobe University, Kingsbury Dve, Bundoora, 3086