

Participant Information Sheet

Date Information Sheet Produced: 18 June 2024

Project Title: The association between perceived footwear comfort and in-shoe plantar pressure in people with rheumatoid arthritis

Kia ora koutou, Ko Kakepuku te maunga, Ko Waikato te awa, Nō Tāmaki Ahau, Ko Anderson Tōku Whānau

My name is Libby Anderson. I am a postgraduate podiatry student at AUT. I am doing my honours dissertation which is supervised by Dr Belinda Ihaka, Dr Sarah Stewart and Aaron Jackson from the AUT School of Podiatry. We would like to invite you to participate.

What is the purpose of this research?

Footwear has been proven to be effective for the management of foot and leg problems in people with rheumatoid arthritis (RA) and is also highlighted in RA management guidelines. Comfort is an important determinant of footwear choice for people with RA and cushioned shoes that reduce pressure underneath the feet are often recommended; however, the relationship between patient-perceived comfort and plantar pressure (the pressure underneath the feet) has not been studied. The aim of this project is to look at perceptions of footwear comfort and pressure underneath the feet while wearing shoes in people with RA. The findings from this research may be used for academic publications and presentations.

How was I identified and why am I being invited to participate in this research?

You have been invited to participate in this research study because you have attended the AUT Podiatry Clinic, responded to an advertisement about the study, or been told about the study. To be eligible to participate, you must have RA diagnosed by a doctor, be aged 20 years or older, and be able to walk 10 meters without the use of a walking aid. Unfortunately, we are unable to include people with RA who also have other inflammatory conditions (including lupus, spondyloarthritis, gout), have had any foot or leg surgery in the past three months, and are unable to communicate in English.

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether you choose to participate will neither advantage nor disadvantage you. If you are a former or current patient of the AUT Podiatry Clinic and choose not to participate, this will not affect the care you receive currently or in the future. If you choose to participate, you will need to complete a Consent Form (attached to the end page of this document). You can complete the Consent Form and bring it with you to the study visit, or you can complete the Consent Form when you arrive before the study starts. You can withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

What will happen in this research?



If you agree to participate, you will be invited to attend a single one-off study visit at either the AUT Podiatry Clinic (located inside the Akoranga Integrated Health Clinic at 3 Akoranga, Drive, Northcote) or at the AUT South Campus (located at 640 Great South Road, Manukau). At the study visit, I will ask you your date of birth, gender, ethnicity, and some questions about your RA. We ask that you bring in a list of your current medications so I can record these too. I will also measure your weight and height and ask you to complete four short questionnaires related to foot pain and footwear. For the purpose of this study, we also ask that you wear a covered pair of shoes (i.e., not sandals) that you wear most often day-to-day. I will then measure the pressure inside your shoes using the Pedar-x System. This will involve putting elastic sensor insoles inside of your shoes that will measure the pressure underneath your feet while walking. A velcro waistband will be secured around your waist containing a Bluetooth remote that connects to the insoles via a cable. Straps will be placed around both ankles and knees to secure the cables. Once I have fitted the insoles in your shoes, you will be instructed to walk a single 10 meter length at a comfortable self-selected walking speed.

All equipment will be cleaned thoroughly between participants. The entire visit will take approximately one hour. You are welcome to bring a support person/family member/whānau with you to the study visit.

What are the discomforts and risks and how will these be alleviated?

I will explain each test to you before performing it so you are comfortable and know what to expect. The Pedar-x system is a very safe tool commonly used in clinical research to provide the best accuracy for pressure measurement on the human body. During the in-shoe pressure assessment you will be asked to walk a length of 10 meters once on a flat surface at a walking speed you feel comfortable with. You will be given plenty of time to get used to walking with the pressure sensors in your shoes and rest in between if you need it. If at any time you feel any discomfort or pain while walking, please let me know. You will not be asked to perform any thing you do not feel comfortable doing.

What are the benefits?

To our knowledge, this will be the first study that assesses the relationship between perceived footwear comfort and in-shoe pressure in people who have RA. The findings from this research study will provide us with an increased understanding of the way people who have RA walk and if perceived footwear comfort has an association. The new knowledge generated from those observations will contribute to optimizing footwear selection for people with RA.

What compensation is available for injury or negligence?

In the unlikely event of a physical injury as a result of your participation in this study, rehabilitation and compensation for injury by accident may be available from the Accident Compensation Corporation, providing the incident details satisfy the requirements of the law and the Corporation's regulations.

How will my privacy be protected?

The information collected during this research is confidential to the research team and will not be used beyond the purposes of this study. Information will be stored securely at AUT for up to ten years, after which it will be destroyed. Any reporting of this study will involve aggregated data and will not include any information that could identify you.

What are the costs of participating in this research?

The only costs to you will be related to travelling to and from AUT for the study visit. To acknowledge your time and participation, you will be offered one free AUT Podiatric Rheumatology Clinic appointment to be used within one year of your study visit. You will also go in the draw to win one of two \$100 supermarket vouchers.

What opportunity do I have to consider this invitation?

You will have three weeks to decide whether you would like to accept this invitation. Please make sure you read this information sheet and have any questions (patai) or concerns answered prior to your participation.

Will I receive feedback on the results of this research?

If you would like to receive a copy of your individual results from the assessments undertaken at the study visit, please indicate so on the Consent Form which you will be asked to sign at the start of your study visit. If you are also interested in receiving a summary of the overall findings of the research, please indicate so on the Consent Form. Any individual results or overall findings that you request will be sent to you in the form of a written summary and any academic publications resulting from this study can be provided to you upon request.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, *Dr Belinda Ihaka (Te Aupōuri)*, belinda.ihaka@aut.ac.nz, (09) 921 9999 ext 9015.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEK, ethics@aut.ac.nz, (09) 921 9999 ext 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Consent Form for your future reference.

If you have any questions about the study or would like to participate please contact the project researcher using the contact details below:

Project Researcher Contact Details:

Libby Anderson

Email: nqg0551@autuni.ac.nz

Phone: 022 308 7780

Consent Form

Project title: *The association between perceived footwear comfort and in-shoe plantar pressure in people with rheumatoid arthritis*

Student researcher: *Libby Anderson*

Supervisors: *Dr Belinda Ihaka, Dr Sarah Stewart and Aaron Jackson*

- I have read and understood the information provided about this research project in the Information Sheet dated 18 June 2024.
 - I have had an opportunity to ask questions and to have them answered.
 - I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without being disadvantaged in any way.
 - I understand that if I withdraw from the study then I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible.
 - I am aged 20 years or older and am able to walk 10 meters without the use of a walking aid. Other than rheumatoid arthritis, I do not have any other inflammatory conditions. I have not had any foot or leg surgery in the past 3 months and am able to speak English.
 - I agree to take part in this research.
 - I wish to receive a copy of my individual assessment results (please tick one): Yes No
 - I wish to receive a summary of the overall research findings (please tick one): Yes No
- I wish to be contacted for future research studies (please tick one): Yes No

Participant’s signature:

Participant’s name:

Participant’s Contact Details (if appropriate):

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Date :

Note: The Participant should retain a copy of this form.