Participant Information Sheet

Date Information Sheet Produced:

07 September 2022

Project Title

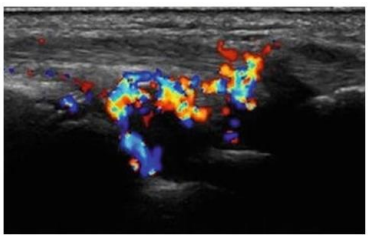
The association between dynamic plantar pressure and sonographic evidence of metatarsophalangeal joint synovitis in people with rheumatoid arthritis

Kia ora Tātou, Ko Kakepuku te maunga, Ko Waikato te awa, Nō Tāmaki Ahau, Ko Anderson Tōko Whānau

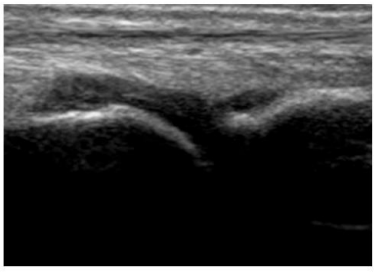
My name is Libby Anderson. I am a second-year podiatry student at AUT. I am doing a research project over summer which is supervised by Dr Sarah Stewart and Belinda Ihaka from the AUT School of Podiatry, and Professor Catherine Bowen from the University of Southampton. We would like to invite you to participate.

What is the purpose of this research?

Rheumatoid arthritis (mate rumatiki) causes inflammation of joints. The joints of the feet are commonly affected by inflammation in people who have rheumatoid arthritis, even though they may not have any pain. Joint inflammation can be easily measured by using ultrasound imaging where it shows up as a colour signal called the 'Power Doppler' signal (see images to right). Joint inflammation can affect the structure of the joints and the amount of pressure under the foot when walking. The aim of this project is to look at how inflammation in joints of the foot (measured by the ultrasound Power Doppler signal) affects the amount of pressure under the foot during walking. The findings from this research may be used for academic publications and presentations.



Joint inflammation present (seen by the colourful ultrasound Power Doppler signal)



No joint inflammation (no ultrasound Power Doppler signal)

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 responded to an advertisement about the study or been told about the study by your doctor. To be eligible to participate, you must have rheumatoid arthritis diagnosed by a doctor, be aged 20 years or older, and be able to walk 10 meters barefoot. Unfortunately, we are unable to include people with rheumatoid arthritis who also have other inflammatory conditions (including lupus, spondyloarthritis, gout).

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether or not 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 are able to 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, Libby will ask you your date of birth, gender, ethnicity, and some questions about your rheumatoid arthritis. We also ask that you bring in a list of your current medications so Libby can record these too. Libby will also measure your weight and height and ask you to complete three short questionnaires related to foot pain. Libby will then scan the joints in your feet using an ultrasound machine. Ultrasound scans involve no radiation exposure. Ultrasound scanning is safe and painless and involves soundwaves to obtain images of your joints. This technology is the same as that used to scan a pregnant woman and has no known side effects. After your ultrasound scan, Libby will then measure the pressure underneath your feet. This will involve walking back and forth across a thin pressure mat. 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?

Libby will explain each test to you before performing it so you are comfortable and know what to expect.

Ultrasound is an extremely safe imaging tool. Libby will apply some gel to your feet which may feel cool and a little odd, but it is essential in providing a clear and detailed ultrasound image. She will apply gentle pressure with the ultrasound probe to the joints on top of your feet and underneath your feet, which should not cause any discomfort. If you do feel any discomfort, please let Libby know and she will stop.

During the pressure assessment you will be asked to walk back and forth barefoot over a thin mat about 6 times. You will be given plenty of time to rest in between if you need it. If at any time you feel any discomfort or pain while walking, please let Libby know. You will not be asked to perform any thing you do not feel comfortable doing.

What are the benefits?

The findings from this research study will provide us with an increased understanding of the way people who have rheumatoid arthritis walk and how joint inflammation affects their walking. This knowledge may contribute to further work that will help us manage joint inflammation in people who have rheumatoid arthritis, including the use of footwear, orthotics (insoles), padding, and walking programmes.

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 receive a $50 supermarket voucher (koha) at the end of your study visit. You will also be offered one free AUT Podiatric Rheumatology Clinic appointment to be used within one year of your study visit.

What opportunity do I have to consider this invitation?

You will have two 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 Sarah Stewart, sarah.stewart@aut.ac.nz, (09) 921 9999 ext 5451*.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, *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. You are also able to contact the research team if you have any questions about the study or would like to participate/

Project Supervisor Contact Details:

Dr Sarah Stewart; Email: sarah.stewart@aut.ac.nz; Phone: (09) 921 9999 ext 5451.

Approved by the Auckland University of Technology Ethics Committee on *3 Oct 2022*, AUTEC Reference number *22/261*.

Consent Form

Project title: ***The association between dynamic plantar pressure and sonographic evidence of metatarsophalangeal joint synovitis in people with rheumatoid arthritis***

Student researcher: ***Libby Anderson***

Supervisors: ***Dr Sarah Stewart, Belinda Ihaka, Professor Catherine Bowen***

- ○ I have read and understood the information provided about this research project in the Information Sheet dated 7 September 2022.
- ○ 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 barefoot. Other than rheumatoid arthritis, I do not have any other inflammatory conditions.
- ○ 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○

Participant's signature: .....

Participant's name: .....

Participant's Contact Details (if appropriate):

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Date : .....

Approved by the Auckland University of Technology Ethics Committee on *3 Oct 2022*, AUTEC Reference number *22/261*.

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