Participant Information Sheet

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Project Title

Development of an ultrasound picture-based classification system for evaluating big toe joint osteoarthritis.

An Invitation

Thank you for considering the opportunity to participate in this imaging research for the evaluation of big toe joint osteoarthritis (OA). This study is one of five interconnected studies that will be completed in series as part of my PhD. The proposed research is funded by the Health Research Council of New Zealand. My name is Prue Molyneux, I am a podiatrist and a PhD candidate. Along with my supervision team Associate Professor Matthew Carroll, Professor Catherine Bowen, Associate Professor Richard Ellis and Professor Keith Rome, we are conducting a study to determine the reliability of a newly developed ultrasound imaging procedure for evaluating big toe joint OA. These images will then be used to develop a picture-based classification system to grade big toe joint OA. This project will advance our understanding of ultrasound for big toe joint OA. If you do choose to participate, you will be contributing to a foundation study that will inform future research and practice.

What is the purpose of this research?

The proposed study will determine the best method to take an ultrasound image of the big toe joint and determine how reliable this method is. Once developed the method of taking the ultrasound image will be used to develop a picture based classification system.

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

Via your response to our advertisement, seeking volunteers with suspected or clinical diagnosis of big toe joint OA, we invite you to participate in this research. We are looking for people between 20 to 65 years old, with no history of bunion surgery or who have had foot surgery in the past three months. However, if you have inflammatory arthritis or a neurological, metabolic, or endocrine disorder; are pregnant, regrettably we will be unable to include you in this study.

If you are unsure if you can volunteer, and would like more information, please contact Prue Molyneux, whose details are at the end of this sheet.

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. 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.

If you would like to participate in this study please contact me (Prue Molyneux) via the details given below. I will then give you a Consent Form (or send one if requested) to fill out and sign, to secure your place in the study.

What will happen in this research?

This research will be conducted at Beyond radiology (10 Grafton Road, Grafton, Auckland 1010). The session involves three components. You will process through each of these components within the same session. Your appointment and assessments are all free.

(1) The co-ordinating investigator/podiatrist (Prue Molyneux) will ask for your demographic information, e.g. height, weight and ethnicity. I will also perform some basic clinical assessments, e.g. checking your range of motion of your big toe joint.

(2) You will then be directed to your X-ray assessment, which will be performed by an experienced radiographer.

(3) Lastly, you will be directed to your ultrasound assessment. This will be performed by an experienced sonographer.

To determine how reliable the method is you may be invited to return for a second ultrasound scan one week later. If you are selected to return for a second session, this session will only involve one ultrasound assessment.

What are the discomforts and risks?

The risks associated with this study are low and the consequences of these risks are also deemed to be mild in nature and equivalent to what can be expected as possible side effects from a typical radiographic or sonographic scan. The amount of ionising radiation from one foot x-ray (<0.001 mSv) is the same as <3 days of natural background radiation that we are all exposed to as part of our daily living.

What are the benefits?

Participants: It is hoped that you will gain satisfaction in participating in a foundation study that may inform future research and practice. This will be the first study to assess the reliability of a newly developed USI acquisition procedure. You may gain insight into the function of your first MTPJ. Some participants may gain insight into the degree of osteoarthritic change in their first MTPJ. Therefore, the results of this research may contribute to reshaping your current management and/or may inform individuals of a course of action for their diagnosis.

Wider community: The research may provide a sensitive method to classify and grade the OA disease process, enabling clinicians to establish an earlier and a more specific diagnosis, allowing more precise and timely interventions. It is hoped that this will enable patients (wider community) to receive earlier conservative treatment before the point of irreversible structural damage. This research has great potential to directly impact the financial burden by reducing financial costs such as loss of productivity, time delays and number of appointments currently required for first MTPJ OA patients.

This research will assist Prue Molyneux in obtaining her Doctor of Philosophy degree.

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?

Your name, birthdate and any personal information that could identify you as an individual will not be used in this study or published in any medium. All the information that is provided by you will be confidential and strict access will only be available to the co-ordinating investigator [Prue Molyneux], sonographer, radiographer and yourself upon request. Your identity will be protected and remain confidential to all other participants at all stages of the study. All collected information will be confidential and stored securely at the researcher's office, at Auckland University of Technology for 10 years, per the Retention of Health Information Act.You will not be identified in research outputs, i.e., publications or conference presentations.

During this study the co-ordinating investigator [Prue Molyneux], sonographer and radiographer will record information about you and your study participation. This includes the results of any study assessments. You cannot take part in this study if you do not consent to the collection of this information.

<u>Privacy and Confidentiality</u>

Your privacy and confidentiality will be respected through the protection of your data. The investigators will comply with legal and regulatory requirements regarding the privacy and confidentiality of your data. You have the right to request access to your information held by the research team. You also have the right to correct personal data held by the site. In the event your privacy and confidentiality are breached during the study, you will be informed of the breach as soon as practicable and provided with support as required.

If you have any questions about the collection and use of information about you, you should ask the co-ordinating investigator.

<u>Identifiable Information</u>

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the co-ordinating investigator [Prue Molyneux] and designated study staff (Radiographer and sonographer) will have access to your identifiable information to fulfil protocol requirements and complete study assessments. Beyond Radiology is required to store your X-ray and ultrasound imaging data as part of your clinic record for 10 years. All

images will be electronically stored and password protected. The following groups may have access to your identifiable information:

Your GP will be notified if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.

Rarely, it may be necessary for the co-ordinating investigator to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.

The consent forms, containing your name, will be stored separately from other data in a locked cabinet in a locked room at Auckland University of Technology in identifiable form. All identifiable information obtained about you will be kept separate to the de-identified data, which will be held electronically on a password protected computer.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the co-ordinating investigator (Prue Molyneux). Instead, you will be identified by a code. The co-ordinating investigator will retain a log linking your code with identifiers, so that you can be identified by your coded data if needed.

All the data obtained by the co-ordinating investigator (Prue Molyneux), radiographer and sonographer will be de-identified. All data generated by these parties will be in de-identified form. All ultrasound images obtained to be included in the USI atlas development will be de-identified.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

[If you have provided consent], your coded information may be used for future research related to osteoarthritic research. This is an optional statement on the consent form.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Security and Storage of Your Information.

Your identifiable information is held at Auckland University of Technology during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Coded study information will be kept by the co-ordinating investigator in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines. The de-identified data will be stored for at least 10 years, per the Retention of Health Information Act.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded information, there is no guarantee that you cannot be identified.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing the co-ordinating investigator.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Commercial Use of Data

Study data analysis may lead to discoveries and inventions or development of a commercial product or producers. You will not receive any financial benefits or compensation from, nor have any rights to, any developments, inventions, or other discoveries arising from this analysis.

What are the costs of participating in this research?

There will be no financial cost to you if you decide to participate in this research. It will only take approximately 60 minutes of your time. We would like to provide you with $50-voucher for the visit to Beyond Radiology.

What opportunity do I have to consider this invitation?

You have until the end of 2022 to decide whether or not you would like to accept this invitation. I would like to arrange an appointment time with you at least two weeks beforehand so that I can secure the equipment needed for this study. Please make sure you thoroughly read this Information Sheet and have any concerns answered before you participate.

Will I receive feedback on the results of this research?

If you are interested to see the outcomes of this research please indicate so on the applicable section of the consent form. The results will be sent to you in the form of a written summary and any papers that may be published as a result of this study can be accessed upon request. The final results of the study will be published in a peer-reviewed journal.

Who has approved the study

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Southern Health and Disability Ethics Committee has approved this study. HDEC Ethics Reference: 2022 FULL 12721.

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

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Project Supervisor: Associate Professor Matthew Carroll
Email: (matthew.carroll@aut.ac.nz) or phone 09 9219999 x7305.
Telephone number: 0212458796

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:
Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

You can also contact the health and disability ethics committee (HDEC) that approved this study on:
Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Researcher Contact Details:

Prue Molyneux (prue.susan.molyneux@aut.ac.nz) or phone **021 0294 2970**