

Participant Information Sheet

Title	Correlating BMI, waist circumference and eating patterns with severity of Achilles tendinopathy
Principal Investigator	Dr David Musson 09 9235714
Co-Investigators	Professor Clare Wall Miss Lauren Vodanovich
Locations	University of Auckland

Introduction

You are invited to take part in a study to better understand the factors which contribute to the severity of tendon disease. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive.

This participant information sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the consent form on the last page of this document. You will be given a copy of the participant information sheet to keep.

What is the purpose of this research?

This study aims to increase our understanding of the link between increased BMI and/or waist circumference and tendon disease, by determining whether increased BMI and/or waist circumference are also linked to the severity of Achilles tendon disorders. We will also further assess whether the intake of specific foods affects severity of disease.

There is a well known link between increased BMI or increased waist circumference with risk of developing Achilles tendon disorders. However, to date no study has looked at the association between BMI and/or waist circumference with severity of tendon disease. Given the effect of specific foods on BMI and waist circumference we will also study the correlation between the intake of specific foods with severity of Achilles tendon disorders. This will be the first time this has been explored.

The data obtained from this study will form part of a Masters research thesis for Miss Lauren Vodanovich.

How many people will participate in this study?

One hundred (100) people are expected to participate across the Auckland region

What will happen in the study?

If you have an interest in taking part in this study, a member of our research team will contact you to discuss the study and what is involved. A time will then be arranged over the following week between yourself and our research team to discuss your involvement. If you are happy to be involved, then please sign the participant consent form provided with this document, scan it and return it to us by email, or we can send you an electronic version which you can sign and return to us by email. At this point, your participation in the study begins.

Our research team will then organise a time to take you through a questionnaire about the foods you eat and the severity of your Achilles tendon symptoms. We will also ask for some background information, including your weight, height, and your waist circumference. This will be discussed with you during the initial conversation with our research team to ensure you are comfortable with measuring these and providing the relevant information during the questionnaire itself. Overall, the questionnaire should take approximately 20 minutes of your time.

Do I have to take part in this research study?

Your participation in the study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the medical care you receive or are entitled to receive. Whatever your decision, it will not affect your relationship with the staff caring for you.

What are the possible benefits of taking part?

Participation in this study may not result in any direct benefits to you.

This study aims to better understand the links between dietary patterns and body shape with severity of Achille tendinopathy. In future this information will hopefully be used to better inform clinical practice and improve outcomes for people who have Achilles tendinopathy

What are the possible risks of taking part?

The information provided as part of this project is complementary to your physiotherapist's standard of care treatment approach and hence pose no additional risks to the treatment procedure.

For some people discussing body shape and food intake can be uncomfortable and/or distressing. If you feel you may be triggered by such discussions, please talk to your family, whānau, friends, or healthcare providers beforehand to decide whether being involved in this study is right for you. If at any time during the questionnaire you feel uncomfortable, please discuss this with the research member taking the questionnaire and we will cease any further questions.

What will happen to my information?

During this study, the researchers will record information about you and your study participation. This includes the results of any study assessments. Before the information is stored, any identifiable details will be removed, and a code will be generated and used instead. Identifiable information is any data that could identify you (e.g., your name, date of birth, or address). There will be a master file linking the list of codes to identifiable information. Only the research team will be able to access this file, which will be stored in secure, password-protected University of Auckland servers for 10 years. Identifiable information will only be used by the research team should you request access to your results, should you wish to withdraw at a later date, or if you indicate on the consent form that you are happy to be contacted about future research. If you do not consent to being contacted about future research, your identifiable data will be stored on a separate master sheet and only used for your requests for results or withdrawal from the the study. To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researchers.

Security and Storage of Your Information.

Your identifiable information is held at the University of Auckland during the study. After the study, it is transferred to a secure archiving site. All information is stored for a period of 10 years, then destroyed.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g., making it harder for you to get or keep a job or health insurance) is currently very small but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. Please ask if you would like to access the results of your screening during the study. If you have any questions about the collection and use of information about you, you should ask Dr David Musson.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time by informing the researcher. 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.

If you decide to take part and later change your mind, you are free to withdraw from the study without prejudice, and this will not affect your clinical care.

Can I find out the results of the study?

We are happy to give you information about the progress of the project if you ask us to at any time. This can be done by emailing the principal investigator at d.musson@auckland.ac.nz.

If you wish to receive a summary of the results upon completion of the study, please indicate this by ticking the relevant box on the consent form provided.

The data from this study will be stored for 10 years from the date of collection and accessible only to members of the research team. After 10 years all files will be destroyed.

Further information

If you require Māori cultural support, talk to your whānau in the first instance. You may also contact the research team who will endeavor to connect you with the relevant support.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 x 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Further information and who to contact

If you have any further questions about your participation in this study, you should contact the lead investigator, Dr David Musson. You can reach the investigators at:

Lead Investigator: Dr David Musson
Telephone: 09 9235714
Email: d.musson@auckland.ac.nz

Co- Investigator: Miss Lauren Vodanovich
Email: lvod124@aucklanduni.ac.nz

APPROVED BY THE AUCKLAND HEALTH RESEARCH ETHICS COMMITTEE ON [29/06/2022]
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