Participant Information Sheet

Title	The effect of an omega-3-rich food on markers of inflammation and severity of Achilles tendinopathy
Principal Investigator	Dr David Musson 09 9235714
Co-Investigators	Associate Professor Richard Ellis Dr Andrea Braakhuis Dr Dorit Naot
Locations	University of Auckland Auckland University of Technology

Introduction

You are invited to take part in a study on omega-3-rich food and its effects on inflammation, Achilles tendinopathy, and wellbeing. 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 will not affect the care you receive. If you decide to take part now but change your mind later, you can pull out of the study at any time.

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.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the purpose of this research?

This study will explore a novel omega-3-rich food product and its effects on inflammation, Achilles tendinopathy, and wellbeing.

Inflammation is fundamental in maintaining health and in many healing processes. However, inflammation that persists for too long can have severe health consequences. Such unresolved inflammation plays a key role in several chronic diseases, including cardiovascular disease and rheumatoid arthritis. Thus, the ability to regulate inflammatory processes is fundamental to maintaining wellbeing. Based on this, the concept of therapeutically targeting inflammation to improve health outcomes is a growing and promising area of research that is targeted to improve the wellbeing of people with chronic health conditions.

Supplementation with omega-3 has demonstrable effects on lowering inflammation. This trial builds on existing scientific literature demonstrating a role for omega-3 supplementation in improving inflammation by studying the effect of an omega-3-rich food product.

How many people will participate in this study?

Sixty (60) people will be recruited from across the Auckland region. Thirty will be randomised into the treatment group and thirty to the placebo control group.

What will happen in the study?

If you are interested in participating in this study, please respond to the invitation email, and a member of our research team will contact you by phone. In the phone conversation, we will discuss the study, and you will have the opportunity to ask any questions you may have. You will then have another week to make a final decision on whether you want to participate. If you do, we will arrange for your first visit to the Whenua Pupuke Waitemata Clinical Skills Centre at North Shore Hospital. Here you will sign the consent form, and your participation in the study begins.

During your visit:

1. Blood samples will be collected to measure inflammatory markers. Blood samples will be drawn by a qualified phlebotomist. Only 15 ml of blood will be drawn at each visit. This is equivalent to a standard blood test at your medical centre.

2. A physiotherapist will examine your affected Achilles tendon using ultrasound with shear wave elastography. This is a non-invasive way of measuring the structure and properties of the tendon. For this you will lie prone on a bed, have gel applied to your ankle and a probe will be run over the top of the skin.

3. Our research team will then take you through a questionnaire about the severity of your Achilles tendon symptoms and your mood and wellbeing. Overall, the questionnaire should take approximately 20 minutes of your time.

4. You will be provided with an activity tracking watch which you will wear for the length of the study. This will provide us with information on your heart rate, activity levels, and sleep.

You will receive a tube of sauce containing an active omega-3 ingredient derived from algal and NZ Hoki oil, or a colour and taste-matched placebo. You will be asked to consume one dessertspoon of the sauce daily for a period of 12 weeks. Compliance will be self-monitored, and we will contact you regularly to record this.

After 6 weeks, and at the end of the study, you will be invited back into the clinic for a repeat of the previous measures.

You will receive a $100 fuel voucher to contribute to your travel to and from the clinic: $50 on the first visit and $50 on the second visit.

What will happen to my blood samples?

All your blood samples will be stored at -80°C until analysis. The tubes they are stored in will not have your name on them or any other way of identifying you personally. Numbers will be allocated to the tubes, and only the researchers involved in the study will know which tubes are yours. All samples will remain in New Zealand and be analysed at the University of Auckland's Nutrition and Dietetics lab in the Faculty of Medical and Health Sciences. Your samples will only be kept until the analysis has been completed, and destroyed after that. You have the right to request your samples be returned to you or request your samples be withdrawn from the study and any analysis.

Rights to your blood samples

You may hold beliefs about a sacred and shared value of any tissue samples removed. The cultural issues associated with storing your blood samples should be discussed with your family/ whānau as appropriate. There is a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.

Your samples will be kept until the end of the analysis. At this time, a medical waste contractor will dispose of your tissue. If you would like a karakia said at this time, please indicate so in the consent portion of this form. Cremation and karakia ceremonies take place through the Auckland District Health Board and occur every 2 months during the year.

What are the possible benefits of taking part?
There are some potential direct benefits to you participating in the study. You will receive a detailed ultrasound assessment of your Achilles tendon. If you wish, the ultrasound images can be sent to your physiotherapist to track your recovery progress.

The benefits to the community and population are that the findings may help identify a natural, NZ-sourced food product that reduces inflammation and may provide benefits to tendon healing and wellbeing.

What are the possible risks of taking part?
This study involves minimal risks. Blood samples will be drawn from the arm by a phlebotomist, and there may be a small level of discomfort associated with this.

There will be questions asked related to wellbeing, stress, and anxiety. For some people discussing these issues 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.

There are very stringent safety protocols in place to ensure your health and safety throughout the entire study process. If any new adverse effects related to the study that may impact your health are found, you will be immediately and fully informed of these. We will contact you each week to ensure you are in good health.

What happens if something goes wrong?
If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

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 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. Identifiable information is any data that could identify you (e.g., your name, date of birth, or address).

Before the information is stored, any identifiable details will be removed, and a code will be generated and used instead. There will be only one 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. 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 your results 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.

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.

Right to Withdraw from Participation
You have the right to withdraw from the study at any time. This can be done by contacting the principal investigator. Once you have let us know, we will stop collecting data from you. Your collected data will continue to be anonymous, and with your permission, be included in the data for the study.

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.

Who is funding the study?
This study is being conducted by the University of Auckland and Auckland University of Technology, with funding from High Value Nutrition (HVN). HVN is a New Zealand government agency that supports scientific projects that examine the benefits of foods on health.

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.

Further information and who to contact
If you require Māori cultural support, talk to your whānau in the first instance. For further Māori cultural support, you may also contact:

The administrator for He Kamaka Waiora (Māori Health Team)
Phone: 09 486 8324 ext 2324.

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 ETHICS
Email: hdecs@moh.govt.nz

You may also contact the research team who will endeavour to connect you with the relevant support.

Further information from the research team
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-Investigators: Associate Professor Richard Ellis
Email: richard.ellis@aut.ac.nz

Dr Andrea Braakhuis
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Dr Dorit Naot
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APPROVED BY THE HEALTH AND DISABILITY ETHICS COMMITTEE ON 22 July, 2022
FOR 3 YEARS
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