# Participant Information Sheet

## Hip and knee osteoarthritis trial

***He Oranga mō te Whānau***

Formal Study title: He Oranga mō te Whānau: Improving outcomes for people with hip and knee osteoarthritis and co-morbidities

Sponsor: Centre for Musculoskeletal Outcomes Research, University of Otago Medical School, Dunedin.

Lead: Prof. Haxby Abbott and Assoc. Prof Kirsten Coppell

Study Site: Hawkes Bay

Contact phone number: 027 767 1599

Ethics committee ref.: 2023 EXP 15077

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You are invited to take part in a study on whether a new 6-month programme of exercise therapy and healthy food choice education and goal setting improves hip and knee pain and physical function for people with hip or knee osteoarthritis and at least one other chronic health problem. 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 health care you receive. If you do want 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 both the Participant Information Sheet and the Consent Form to keep.

This document is 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## Voluntary Participation and Withdrawal From This Study

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. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

## WHAT IS THE PURPOSE OF THE STUDY?

This study will test whether a 6-month programme of exercise therapy and healthy food choice education and goal setting improves hip and knee pain and physical function for people with hip or knee osteoarthritis and at least one other chronic health problem.

## HOW IS THE STUDY DESIGNED?

This study is designed in a way that will allow the researchers to compare usual current treatment for hip and knee pain with a new structured programme. To do this, every person in the study will first be put on a waiting list for at least 3 months and up to 9 months before starting the new programme. During the time on the waiting list everyone will be asked to continue with their usual treatment for their hip and knee pain. How long you wait before starting the new treatment programme will be by chance, but everyone will be offered the new treatment programme.

Up to 200 people will take part in this study. You will have the opportunity to have whānau, family or friends with hip or knee pain and at least one other chronic health problem take part in the study with you.

## WHO CAN TAKE PART IN THE STUDY?

*You have been invited to participate in this study because you are having pain or problems with your hip(s) or knee(s) of both,* ***and*** *at least one other chronic health condition (māuiuitanga taumaha) such as diabetes or pre-diabetes, heart health problems, or low mood).*

- You may be eligible if you are aged 35-70 years and have activity-related hip or knee pain, ***and***
- at least one of the following chronic health conditions: type 2 diabetes or prediabetes, heart disease (heart failure or coronary heart disease), hypertension, or symptoms of mild-moderate depression. Having other long-term conditions does not exclude your participation.

## WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Participation in the study will take between 15 months and two years, depending on how long you wait before starting the new treatment programme.

The new 6-month treatment programme includes 12 sessions of exercise therapy with a physiotherapist *and* up to 6 visits to your primary care nurse or health coach over a 6-month period to talk about food and healthy choices and set achievable lifestyle goals. The primary care nurses and health coaches will be those who are normally based at your primary care practice. Health coaches may or may not have had previous clinical training, but they and the primary care nurses will receive special training about healthy food choices and setting achievable lifestyle goals programme.

- The primary care nurse or health coach visit will take 30 minutes for the first visit, and about 15 minutes for subsequent visits. These visits will take place at your primary care practice.

- The exercise therapy sessions will take around an hour each time. These will take place either individually at a physiotherapy clinic or in a group at a community venue or public park.
- In addition, you will be advised to carry on doing the exercise therapy either on your own, or with whanau, friends or family between the physiotherapy sessions.

Each participant will fill in a questionnaire and have a physical assessment at the start of the study, and then every 3 months up to a year after finishing the new treatment programme. The assessments will be done by a Research Nurse and they will include tests of leg strength and walking speed, measures of your blood pressure, height and weight, and one blood test. In additional to some personal details like your age and ethnicity, the questionnaire will also ask about your health. This information will be used to assess the effectiveness of the programme.

The safety of the programme will be monitored by the physiotherapists, and by the Research Nurse who does the 3-monthly assessments. ADD Assessment with Research nurse first

The study does not involve any questions or tests that are likely to be sensitive or cause discomfort or embarrassment.

*ADD THE FOLLOWING SECTION IF APPLICABLE*

## WHAT WILL HAPPEN TO MY BLOOD SAMPLES?

If you have not had a HbA1c as part of usual care within 6 months of starting your participation in the trial, starting and finishing the intervention, you will be asked to visit a community laboratory to get this routine blood test done. The researchers get a copy of the test results from the laboratory. The researchers do not keep the samples. The test laboratory disposes of any unused sample in the same way they do for any normal blood test done by a GP or nurse.

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with storing or disposing of your blood should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; however, it is acknowledged that individuals have the right to choose.

## WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The new treatment programme only includes treatments that are known to be safe, so there are no major foreseeable risks, side-effects and discomforts of study participation, or risks to the health of a participant's family member(s).

You may experience some short-term muscle soreness or increased hip or knee pain after the exercise therapy. This is normal, and *it is important that you tell your physiotherapist about it so that the amount and difficulty of the exercises can be modified to get the best results*.

The investigators will train the nurses, health coaches and physiotherapists thoroughly, in the best practice delivery of the new treatment programme, to ensure that the best care is provided to participants during the study.

## WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The possible direct benefits of this study include reduce hip or knee pain, being better able to do the activities you like to do that have been limited by your hip or knee problems, feeling in better overall health and wellbeing and possible improvements in your other health conditions.

The possible indirect benefits of the study may include a lowering risk of your risk of other health problems worsening, for example reducing your risk of a heart attack or developing type 2 diabetes.

## WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative to taking part in this study is to continue with your usual kinds of treatments or advice in any form for your hip or knee pain, outside the study.

## WILL ANY COSTS BE REIMBURSED?

The full treatment programme will be provided no cost to study participants.

You will be offered a $25 voucher after they have completed the study assessments, to compensate for any costs incurred, up to a total of $100.

## WHAT 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 be 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.

## WHAT WILL HAPPEN TO MY INFORMATION?

During this study the researchers, doctors, nurses, health coaches, physiotherapists, and other staff will record information about you and your study participation. This includes the results of any study assessments. If needed, and with your permission, relevant information from your GP records may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

<u>Identifiable Information</u>

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only researchers, study staff, and the doctors, nurses, health coaches, physiotherapists, and their clinic staff will have access to your identifiable information.

Your GP will be notified of your participation in this study with your consent, as well as:

- laboratory staff, to process and report your blood tests
- Your usual doctor (your GP or specialist) will receive a copy of your blood test, and the researchers will additionally inform the GP if any test gives an unexpected result that

could be important for your health or well-being. This allows appropriate follow-up to be arranged.

- Rarely, it may be necessary for a study doctor 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.

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 researchers. Instead, you will be identified by a code. The researchers will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

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

Anonymised Information.

The researchers may remove the code from your de-identified information – this is called 'anonymisation'. This makes it very difficult (but not impossible) to identify the information that belongs to you.

Future Research Using Your Information.

Your anonymised information may be used for future research related to the new treatment programme or osteoarthritis. This future research may be conducted overseas. You will not be told when future research is undertaken using your anonymised information. Your information may be shared widely with other researchers. Your information may also be added to information from other studies, to form much larger sets of data to help answer new research questions. You will not get reports or other information about any other future research that is done using your information.

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 the University of Otago and Health Hawkes Bay during the study. After the study it is transferred to a secure long term storage site and stored for at least ten years, then the identifying information will be destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the researchers. Coded, anonymised study information will be kept by the researchers in secure storage indefinitely. All storage will comply with local and/or international data security guidelines.

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 tests during the study.

If you have any questions about the collection and use of information about you, you should ask the researchers or study staff.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing the researchers or study staff.

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

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Māori Data Sovereignty

During the study, data may be collected from participants identifying as Māori. *Māori data sovereignty* is about protecting information or knowledge that is about (or comes from) Māori people.

Personal and health information is a taonga (treasure) and will be treated accordingly. This study is further informed by the kairangahau Māori of this project, who will provide oversight and offer guidance to help ensure that Māori data sovereignty principles as outlined by Te Mana Raraunga[1] are adhered to. The principles of whakapapa, whanaungatanga, rangatiratanga, kōtahitanga, manaakitanga, and kaitiakitanga will be applied in the following ways:

We recognise the taonga of the data collected for this study. To help protect this taonga:

Whakapapa (Relationships): The purpose of collecting the data will be explained to Māori. Māori data collected in this study will be defined as such via linking coded participant data with the declared ethnicity. Data will be stored securely in the University of Otago high-capacity storage system.

Whanaungatanga (Obligations): Māori participants' rights, risks and benefits will be clarified to them. We will disseminate results of the study back to the individual Māori participants, as well as holding community hui in the study locations and will invite those participants and their whānau to attend.

Rangatiratanga (Authority): Māori participants will retain ownership of their data and have the authority to access, correct or withdraw it. Māori data will be stored in Aotearoa New Zealand (at the University of Otago).

Kotahitanga (Collective benefit): By supporting Māori participants with their health challenges, we also support their whānau. The research seeks to achieve both individual and collective benefit for Māori, and if there is conflict in this regard, we will be guided by the kairangahau Māori in consultation with the Māori community (Iwi/Hapū) on an appropriate way forward. Where possible, the project will be intentional with developing future kairangahau Māori and their communities to enable capacity building.

Manaakitanga (Reciprocity): We will uphold the dignity of Māori communities and will take care in the analysis of the data not to stigmatise or blame any Māori. We will seek free, prior and informed consent for data collection and use of the data. A strength-based approach will be one of the tenets of the project and every effort will be made to ensure that all processes and engagements are mana enhancing.

Kaitiakitanga (Guardianship): Māori data will be stored with data of all participants, and also be stored in a folder reserved for Māori. Access to that data will be determined following processes supported by our kairangahau Māori. Tikanga will provide the foundation from which all Māori data will be sought, accessed, interpreted, and disseminated.

- The rōpū kairangahau Māori of this project will consider reasonable requests from Māori organisations to access de-identified study data, for uses that may benefit Māori.
- We have conducted hui around the study design, and have planned consultation on interpretation / dissemination of results.

1. Te Mana Raraunga. (2016). Māori Data Sovereignty Network. (2008). Available from https://www.temanararaunga.maori.nz/, Accessed January 25, 2023.

## WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you change your mind and wish to withdraw from the study, inform the researchers or study staff. If you change your mind, this will not affect your health care and you will continue to receive health care from your usual health care providers.

After all participants have completed the study (in 2024), the data will be analysed. If it is shown that the new treatment is better, then we will provide detailed recommendations to local and national health delivery organisations to continue providing the intervention to registered patients.

The study interventions will be available to participants after the study, from the local providers who will be delivering it for the trial, at whatever current market costs apply. However we cannot guarantee that local providers will continue to make the interventions available indefinitely, as this will depend on their staff availability and training, and the business case for continuing to offer the intervention programme.

## CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants will be provided with a plain English summary of study results, if requested, from around September 2025.

The study will be registered on the Australian and New Zealand Clinical Trials Registry. This may be accessed at: www.anzctr.org.au

## WHO IS FUNDING THE STUDY?

This study is funded by the Health Research Council of New Zealand.

The investigators are affiliated with the University of Otago Medical School.

## 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 [insert Committee name] has approved this study.

## WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

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

Angeline Tangiora, Research Nurse
Telephone number: 027 767 1599
Email: angeline.tangiora@otago.ac.nz

Or: Associate Professor Kirsten Coppell
Email: kirsten.coppell@otago.ac.nz

Or: Professor Haxby Abbott
Telephone number: 027 289 0863
Email: haxby.abbott@otago.ac.nz

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/

For Māori cultural support please contact:

Angeline Tangiora, Research Nurse
Telephone number: 027 767 1599
Email: angeline.tangiora@otago.ac.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

# Consent Form

**He Oranga mō te Whānau**

*If needed, an interpreter may be available on request, subject to availability.*

**Please tick to indicate you consent to the following**

| |
|---|
| I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says. |
| I have been given sufficient time to consider whether or not to participate in this study. |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. |
| I consent to the research staff collecting and processing my information, including information about my health. |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. |
| I understand the compensation provisions in case of injury during the study. |
| I know who to contact if I have any questions about the study in general. |
| I understand my responsibilities as a study participant. |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. |

| | | |
|---|---|---|
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | | |
| I wish to receive a summary of the results from the study. | Yes ☐ | No ☐ |

**Declaration by participant:**
I hereby consent to take part in this study.

Participant's name (Ingoa):

Signature (Tohu): Date:

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name (Ingoa):

Signature (Tohu): Date: