Participant Information Sheet

THE UNIVERSITY OF AUCKLAND
Te Whare Wānanga o Tāmaki Makaurau
NEW ZEALAND

SCIENCE
DEPARTMENT OF EXERCISE SCIENCES

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Study title: **Modifying Activity Behaviours in Osteoarthritis**

Locality: University of Auckland

Ethics committee ref.:20/CEN/200

Sponsor (if applicable): Office of Research Strategy and Integrity, The University of Auckland

Lead investigator: Rebecca Meiring

Contact phone number: **09 923 4815**

My name is Rebecca Meiring and I am a researcher in the Health and Rehabilitation Clinic in the Department of Exercise Science at the University of Auckland. I am conducting this research along with my co-investigators, collaborators and student researchers in the Health and Rehabilitation Clinic. We would like to invite you to participate in this study that aims to change activity behaviours in people with knee or hip osteoarthritis. You are eligible to participate in this study as you have been diagnosed with knee or hip osteoarthritis by an orthopaedic surgeon or a general practitioner. 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.

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. Please 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.

WHAT IS THE PURPOSE OF THE STUDY?

Being more physically active and less sedentary is associated with improvements in pain and physical function. Given that most osteoarthritis patients are older adults whose activities in the waking day constitute mainly light physical activity and sedentary behaviour, this study aims to offset sedentary behaviour with light physical activity using an integrated motivational interviewing and cognitive behaviour change intervention together with an exercise programme, and will determine the effects thereof on joint pain, physical function and quality of life. We anticipate that this study will result in greater adherence to physical activity in the long-term and this will have beneficial knock-on effects on overall well-being and quality of life in patients with OA. This study involves measuring how much physical activity people with osteoarthritis engage in and whether that amount changes following an 8-week exercise and behaviour intervention. This study is a randomized trial meaning that you will either be assigned to a group that receives the behaviour intervention or one that receives usual care. Both groups however will receive an exercise program. The group to which you are assigned is randomly decided. This is to ensure that we can be certain whether our intervention works or it doesn't.

The study has been funded internally by The University of Auckland.

If you want any further information concerning this project of if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the lead investigator:

Dr Rebecca Meiring, Department of Exercise Sciences, University of Auckland,
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Phone 64 9 923 4815
rebecca.meiring@auckland.ac.nz

Approved by the Health and Disability Ethics Committee on 11 September 2020 for three years. Reference number 20/CEN/200

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You are eligible to participate in this study as you have been diagnosed with knee or hip osteoarthritis by a medical professional.

If you decide to participate, we would like to measure your activity for one week. We will send you an accelerometer to wear continuously for seven days and nights. We will send you detailed instructions on how to position and attach the accelerometer. You will also be asked to keep a sleep diary to record your going to bed and waking up times for every day of that week. We will provide you with a pre-paid envelope to post back the accelerometer to us after the seven days.

We would like you to attend the Health and Rehabilitation Clinic at the University of Auckland on two occasions. The first is a session of exercise assessments before taking part in the intervention. The intervention will take place over 8 weeks, after which we would like you to come into the Clinic a final time for measurements after the intervention. The research assistants will assist you in all these sessions.

Assessment session: When you first come to the clinic, we will first ask you to complete some questionnaires related to your osteoarthritis and how you feel about physical activity

and exercise. During this session the researchers will provide you with a short educational video and you will engage in interactive tasks in the video. This means that you will be asked to think about and write some answers down about your usual habitual activity. The aim of this workshop is to provide support, education and motivation for behaviour change. We will also measure your height and weight and take you through some exercise assessments that will allow us to design a personalized exercise program for you over the 8 weeks. These assessments include measures of muscle strength and a sub-maximal cycling test. The assessment session will take approximately 90 minutes. You are encouraged to bring a member of your whānau along to this workshop for support. Refreshments/kai will be available at the session. We will send you an accelerometer to wear continuously for seven days and nights. We will send you detailed instructions on how to position and attach the accelerometer. You will also be asked to keep a sleep diary to record your going to bed and waking up times for every day of that week. We will provide you with a pre-paid envelope to post back the accelerometer to us after the seven days.

Intervention: After completing the assessment session, you will be placed into either an intervention group or a control group. You will not be able to choose which group you are placed into as this will be a random process. Both groups will receive an individualized exercise program to do once a week over an 8-week intervention period. You may choose to either do this exercise session at our Health and Rehabilitation Clinic or you can do the exercise session at home. In addition, people who are placed into the intervention group will also take part in an additional intervention. If you are in the intervention group, we would like you to take part in five more sessions like the educational video in the assessment session. These five sessions will take place over 8 weeks and will be delivered via an online conferencing platform such as Zoom or Skype. In these sessions, the trained researcher assistant will deliver a behavioural intervention through having conversations with you regarding your physical activity. The researcher will ask you questions and will sometimes ask you to engage in tasks and activities such as setting goals and discussing ways to make sure the goals are attained. These five sessions will last approximately 30 minutes each. We will arrange the most appropriate time for you to take part in these 30-minute sessions.

If you are placed in the control group, you will carry on receiving your usual care together with your exercise program. At the end of the 8 weeks we would like you to return to the clinic one last time to have the same assessments done as before the start of the intervention. If you are part of the usual care group, you will be able to have access to the behaviour strategies that were used in the intervention group to go home with for your own use.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Benefits

You may experience benefits to your physical activity as a result from participating in this study. These benefits include an increase in the amount of activity you engage in and also an improvement in the symptoms associated with osteoarthritis. These benefits include a reduction in joint pain and stiffness and an improvement in overall quality of life. After you have completed the study, your results from the physical activity monitoring will made available to you should you wish to see whether you meet the current recommended guidelines for physical activity. If you are part of the usual care group, you will be able to

have access to the behaviour strategies that were used in the intervention group to go home with for your own use.

Risks and adverse effects
The risks for taking part in the project very low and are similar to the risks associated with any exercise training program. There is an increased risk of muscular or skeletal injury associated with physical activity and exercise. You may experience muscle soreness when completing the muscle strength tests and training, although this should subside within a few days. You may experience increased joint discomfort during or after the exercise program. Every effort will be made to minimize joint discomfort, and this will be monitored during your assessment session. We will not hesitate to terminate the session if we have concerns about your safety or discomfort. In addition, if you are unable to continue to perform the assessment session or the exercise program due to pain, you may stop at any time. Your data will not be used in the analysis of the results.
A researcher who is trained in first aid will be with you at all times during the exercise assessment session and this person will monitor you and your signs to determine a safe level for you to exercise at. Appropriate medical equipment and first aid equipment will be available in the event of an emergency. However, all exercise assessments will be supervised by trained staff who are experienced exercise physiologists and have first aid training. If you are feeling unwell during an exercise assessment or session, please tell us and we will stop your participation in the project, if necessary provide first aid, and/or call an ambulance. You are encouraged to bring a member of your whānau or friend with you to the workshop for support or if you think you may be upset by or may need some assistance with any of the assessments or tasks. If you feel uncomfortable at any time during the study, please tell us.

WHO PAYS FOR THE STUDY?

The study will not cost you anything except your time. You will be reasonably compensated for your travel into the Clinic for each session by way of a $20 gift voucher. Refreshments will also be provided at all clinic visits.

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 ARE MY RIGHTS?

- Your participation in this study is entirely voluntary and you have the right to withdraw from the study at any time without giving a reason.
- You may withdraw your data from the study up to two weeks following your participation.
- Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment with your healthcare provider or your relationship

with the University of Auckland.

- You have the right to access the information that is collected about you as part of this study. The researchers will happily share your results with you.

- All information and data collected about you is kept confidential, unless you agree to it being released. If you consent to take part in this study, you are assigned a code so you cannot be identified and the data collected for the study will only be seen by the research team (listed above) and research assistants. Your questionnaires and the written information obtained in any of the sessions will be stored separately from your personal information in a locked filing cabinet in a secure office in the Department of Exercise Sciences. Electronic data will be stored on a password protected computer that is the property of the University of Auckland and that is regularly backed up.

- After 10 years, your data will be deleted from the disk and your consent form and all related paperwork put through a shredder.

- If at any time during the workshop or the intervention you feel uncomfortable, you have the right to stop and withdraw from the study.

- You are encouraged to consult with your whānau/family, hāpu or iwi regarding participation in this project.

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

If you are part of the usual care group, you will be able to have access to the behaviour strategies that were used in the intervention group to go home with for your own use at no cost to you.

If you change your mind, you have the right to withdraw your participation at any time during the study without giving a reason. You may withdraw your data from the study up to two weeks following your participation.

Data collected for this study may be used in future research for example to inform other studies of a similar nature, however all data will be de-identified if used for that purpose. You are asked to consent for your data to be used for future research. All the information that is shared in the education session will be kept confidential and will not be recorded. It is the intention of the researchers that the study findings will be reported at academic conferences and in written reports in journals or books. If you would like to be informed of the outcomes you may leave your contact details on the consent form in the space provided. The researchers will send you a letter in due course.

Records and data will be stored for at least 10 years and then will be destroyed by shredding or permanent deletion from the hard drive of the computer that it is stored on.

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 and the face-to-face conversations during the intervention. If needed, information from your hospital records and your GP may also be collected. This is so that we can ensure that you meet our eligibility criteria. You cannot take part in this study if you do not consent to the collection of this information.

IDENTIFIABLE INFORMATION

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the researchers will have access to your identifiable information.

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

The following groups may have access to your coded information:

- The sponsor, for the purposes of this study.

FUTURE RESEARCH USING YOUR INFORMATION

Only if you agree, your coded information may be used for future research related to the behavioural intervention or osteoarthritis. Only if you agree, your coded information may also be used for other medical and/or scientific research that is unrelated to the current study.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about any / some 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 Auckland during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based 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.

Your coded physical activity data is being sent overseas to be analysed by our research collaborators at La Trobe University, Australia. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

RIGHTS TO ACCESS YOUR INFORMATION AND RESULTS

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

You can request a letter telling you about the study results. The letter will be sent to you once the final study report is available (this can take 1 – 2 years). A description of this trial will also be available on the Australia and New Zealand clinical trials registry website. This website will not include information that can identify you. At most, it will include a summary of study results.

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 and safety tests during the study.

If you have any questions about the collection and use of information about you, you should ask the Principal Investigator.

RIGHTS TO WITHDRAW INFORMATION

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

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.

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:

Dr Rebecca Meiring
Department of Exercise Sciences
University of Auckland
Building 907-288 / End of Suiter Street
Newmarket
Auckland 1023
Phone 64 9 923 4815
rebecca.meiring@auckland.ac.nz

OR you may contact the Head of Department of Exercise Sciences:

Professor Michael Kingsley
Head, Department of Exercise Sciences, University of Auckland
Building 907-233 / End of Suiter Street
Newmarket, Auckland 1023
Ph 64 9 373 7599 Ext 82975
michael.kingsley@auckland.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/

If you require Māori cultural support, talk to your whanau, iwi, hapu or kaumatua in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext. 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext. 3204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Email: hdecs@health.govt.nz

Consent Form

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Please check to indicate you consent to the following

I have read or have had read to me in my first language, and I understand, the Participant Information Sheet.		
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, whānau/ 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 understand that my usual health care provider has provided assurance that my participation or non-participation will not affect my relationship with them, their staff or their care of me going forward.		
I consent that my coded information may be used for future research related to the behaviour intervention or osteoarthritis. (*please check Yes or No*)	Yes ☐	No ☐
I consent that my coded information may be used for other medical and/or scientific research that is <u>unrelated</u> to the current study.	Yes ☐	No ☐
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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
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.	
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:

Signature: Date:

Email address (if you wish to receive a summary of results):

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:

Signature: Date: