Participant Information Sheet

Understanding Knee Osteoarthritis Pain Experiences (U-KOPE)

Coordinating investigator: Mr Mark Overton

Lead Investigator: Dr Ramakrishnan Mani

Ethics committee ref.: 21CEN89

Contact phone number: 03 479 3485

Location: School of Physiotherapy, University of Otago, Dunedin, New Zealand

You are invited to take part in a study that explores pain experiences in people with knee osteoarthritis. 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 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 nine pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Participating in this study is completely voluntary. You are free to decline participating at any time. Declining to participate will not affect your participation in treatment or result in any other negative consequence. If you do decide to participate, this study will include an initial assessment made up of questionnaires and physical tests followed by two weeks of smartphone symptom monitoring which involves the completion of a brief questionnaire three times daily. A follow-up assessment will involve the completion of additional questionnaires.

What is the purpose of the study?

The nervous system (i.e. nerves, the spinal cord and brain) becomes sensitized to your sore knee joint(s). The purpose of the study is to assess whether nervous system sensitivity is linked to pain experiences in people with knee osteoarthritis. This study's findings could contribute to the development of specific treatments to address knee osteoarthritis pain and improve quality of life.

If you have any questions about the study, you may contact Mark Overton at the Centre for Health, Activity and Rehabilitation Research by email (mark.overton@postgrad.otago.ac.nz) or telephone (03 479 7460).

The study has received ethical approval from the Health and Disability Ethics Committee (HDEC). Ref.: 21CEN89.

WHO CAN TAKE PART IN THE STUDY?

Inclusion criteria: Adults aged 45-85 years, with a diagnosis of knee osteoarthritis experiencing knee pain on most days for a minimum duration of three months will be eligible to participate in the study.

Exclusion criteria: You are not eligible to participate in the study if you have:

- Undergone knee joint replacement surgery.
- Scheduled for knee joint replacement surgery within the next three months.
- Sustained a lower limb injury within the last six months or are still receiving rehabilitation for a lower limb injury.
- Inflammatory arthritis (i.e., Rheumatoid Arthritis, Lupus, Gout).
- Infective arthritis.
- Neurological conditions (i.e., stroke, sensory loss, spinal cord injury, multiple sclerosis, traumatic brain injury, peripheral neuropathy, dementia, Alzheimer's disease).
- Uncontrolled hypertension.
- Skin conditions (i.e. fragile skin, psoriasis).
- Psychiatric illness.
- Cognitive impairment.
- Difficulty or inability to read or understand English or provide informed consent.
- Are unable to use a smartphone.
- Pregnancy or within six-months post-labour.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

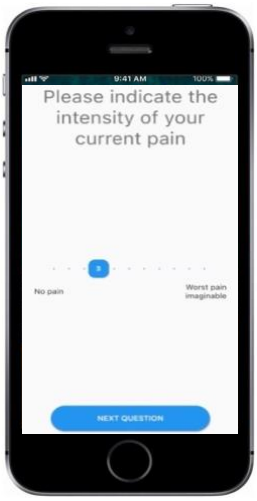
This study aims to recruit 100 people with knee osteoarthritis in New Zealand.

Baseline assessment: Following eligibility screening via telephone, you will be invited to attend a 90-minute session at the University of Otago School of Physiotherapy to undergo an assessment conducted by a research team member. **Questionnaires:** You will be asked to complete an online survey containing questions: about yourself (age, gender, education, ethnicity, current medications, address), and your knee pain (duration, location, nature, intensity and function) and thoughts associated with pain. You will also complete questionnaires asking about your physical activity, sleep, psychological states, the extent of social support, and the presence of other health issues (e.g. mood, diabetes, and other diseases). Height, weight, waist circumference, hip circumference and handedness will be collected.

Testing your pain sensitivity: To assess your pain sensitivity, the following simple test procedures will be administered at the painful knee and a distant location (non-dominant wrist). You are asked to bring shorts or pants that can be easily rolled up to expose the knee joint for testing purposes. Sensation testing is likely to result in short-lived increases in discomfort. **Light touch:** with a nylon filament and a brush - you will be simply asked to tell us whether you are feeling a sensation of touch or pain. If you feel pain, you will be asked to rate your intensity of pain on an 11-point scale (where 0 represents no pain and 10 represents the worst imaginable pain). **Pressure to pain testing**: pressure will be gradually applied by using a blunt toothpick and a rubber-tipped pressure device. You will be asked to indicate immediately when the pressure sensation changes to discomfort/pain. These procedures will be carried out over the painful knee and non-dominant wrist when you are resting, as well as immediately following two minutes of hand immersion in a cold-water bath maintained at ~12 degrees Celsius. **Cold**: an ice-cube will be placed on your affected knee and your non-dominant wrist for 10 seconds where you will be asked to rate the intensity of pain on an 11-point scale (where 0 represents no pain and 10 represents the worst imaginable pain). **Vibration**: a tuning fork will be placed on the skin at your affected knee and non-dominant wrist. You will be asked to report when the sensation of vibration disappears. **Repeated stimulus testing:** Repeated pressure using a nylon filament will be applied at the painful knee and then non-dominant wrist. You will be asked to report the intensity of pain before and afterwards on an 11-point scale (where 0 represents no pain and 10 represents the worst imaginable pain).

Physical performance: You will be asked to perform simple physical tasks (e.g. repeated sit-to-stand, 6-minute walk) that will be timed and observed to rate your performance. You will also be asked to provide ratings of knee pain before, during and then immediately following each task on an 11-point scale (where 0 represents no pain and 10 represents the worst imaginable pain).

Smartphone symptom reporting: You will receive a smartphone to complete a brief questionnaire (maximum duration: two minutes), three times daily for two weeks. The brief questionnaire will ask you to record the following items: pain severity, pain bothersomeness, activity interference, symptom flare-up's, fatigue, mood levels, social contact, sleep quality and previous day sitting duration. You are asked to carry the smartphone with you for the duration of the study and complete questionnaires when prompted. After the two-week period, you will return your allocated smartphone and complete a follow-up assessment.



Follow-up assessment: All participants will be contacted after the completion of the smartphone monitoring to attend a 30-minute final assessment. This will involve the completion of follow-up questionnaires that assess your pain, function, fatigue, participation and quality of life. Nine weeks following the baseline assessment, you will be asked to complete two further questionnaires that assess your pain and function.

Group interviews: If you consent, a selected group of participants will be contacted and invited to participate in a group interview with the coordinating researcher and 3-4 other people with knee osteoarthritis. Semi-structured interview topics will include: describing your experience with smartphone symptom reporting, smartphone and app useability, perceived usefulness of reporting knee osteoarthritis information in your natural environment, any challenges you faced, how other people could benefit as well as the overall acceptability of smartphone symptom reporting. Each group interview will last for approximately one hour.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Benefits: There is no direct benefit to participants by taking part in this study. This study will highlight the role of nervous system sensitivity in your lived experiences, which could help develop new treatments targeting sensitivity that improve pain and disability. Additionally, this study could support the use of smartphone-based assessment for capturing the experiences of people with knee osteoarthritis in routine clinical practice and research.

Risks: Sensory testing may result in some short-lived discomfort. You may feel mild pain, tingling, or 'pins and needles' sensation in your hand during or immediately following immersion in a cold-water bath. However, these sensations normally reside immediately following the testing. A slight reddening of the skin may stay following the pressure to pain testing; however, this should disappear within hours of testing. Sufficient rest periods will be provided between each testing procedure to ensure this. You will be closely monitored by a member of the research team during the assessment to prevent any harm.

WILL ANY COSTS BE REIMBURSED?

To recognize the actual or reasonable costs involved with participating in this study, all participants will receive a $100 supermarket voucher on the successful completion of your

part in the study. If you attend the initial assessment but don't meet the inclusion criteria, you will receive a $20 supermarket voucher as recognition of any costs incurred.

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 will record information about you and your study participation. This includes the results of assessments performed. 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 coordinating and lead researcher will have access to your identifiable information. Physical copies of questionnaires will be securely destroyed following organisation and de-identification of data (meaning your data will be identified by a code). Only the research team will have access to your de-identified information. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you. Group interviews will be audio-recorded and the information you supply will be held securely. The raw data will be analysed after the group interview for presentation and/or publication in the de-identified written form. The audio recordings will be destroyed at the end of this project.

Future Research Using Your Information: If you agree, you may be contacted to contribute further information to the research teams projects. Your de-identified information may be used indefinitely for future research by the research team following an appropriate ethical approval process unless you withdraw your consent. It may be extremely difficult or impossible to access your information or withdraw consent for its use, once your information has been de-identified, analysed and shared.

Security and Storage of Your Information: Prior to their secure destruction, physical copies of participant information will be stored in a locked filing cabinet in a secure office at the University of Otago School of Physiotherapy. Your de-identified electronic information (including transcribed interviews) will be held at the University of Otago School of Physiotherapy on a secure, password-protected, cloud-based computer server (only accessed by the research team) in a locked and secure premise. After the study it will be transferred to a secure archiving site and stored for at least 10 years, then destroyed. All storage will comply with local 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 de-identified information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your

information 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 and safety tests during the study. If you have any questions about the collection and use of information about you, you should ask the researcher.

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. 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, however, this won't be possible if study analyses have already been undertaken.

Use of Technologies: Use of a smartphone application to collect your experiences is a mandatory component of study participation. Participants will be provided with a smartphone for the duration of the study or be able to use their own phone. The mobile phone application used will be *m-Path*, a free app available from the Google Play and iOS stores. *m-Path* is a newly developed platform that can be used clinically and for research. This smartphone app does not collect identity-related personal information apart from a participant 'nickname.' This allows for data capture while preserving participant anonymity. There is no cost associated with the use of the smartphone application. *m-Path*'s full privacy policy can be viewed at https://m-path.io/LegalPage/legal.html#privacyApp.

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

We will write up the findings from the study, and these may be published in a scientific journal, or presented at a conference. We will not reveal any personal information about participants when we report results. Data will be presented in the statistical form, and every effort will be made to ensure anonymity.

CAN I FIND OUT THE RESULTS OF THE STUDY?

If requested, participants will be provided with a plain English summary of study results at the completion of study reporting (March 2023).

WHO IS FUNDING THE STUDY?

The student researcher is supported by a University of Otago Doctoral Scholarship. The lead/co-investigator is a Senior Lecturer at the University of Otago and received a Jack Thomson Grant from the Otago Medical Research Foundation to assist in carrying out this project.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Central Health and Disability Ethics Committee 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:

Name: Mark Overton **Position**: Doctoral Research Student **Department:** School of Physiotherapy, University of Otago, Dunedin	**Phone number:** 03 479 7460 **Email:** mark.overton@postgrad.otago.ac.nz
Name: Dr Ramakrishnan Mani **Position**: Senior Lecturer **Department:** School of Physiotherapy, University of Otago, Dunedin	**Phone number:** 03 479 3485 **Email:** ramakrishnan.mani@otago.ac.nz
Name: Professor David Gwynne-Jones **Position**: Professor **Department:** Department of Surgical Sciences, University of Otago, Dunedin	**Phone number:** 03 470 9853 **Email:** david.gwynne-jones@otago.ac.nz
Name: Associate Professor Nicola Swain **Position**: Associate Professor **Department:** Department of Psychological Medicine, University of Otago, Dunedin	**Phone number:** 03 470 9451 **Email:** nicola.swain@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 health support please contact :

Arai Te Uru Whare Hauora
Phone: (03) 471 9960
Email: reception@araiteuru.co.nz
Website: http://www.araiteuru.co.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

Understanding Knee Osteoarthritis Pain Experiences (U-KOPE)

Please tick 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 consent to research staff contacting me to participate in group-based interviews following the smartphone data collection.	Yes ☐	No ☐
I consent to be contacted about other knee osteoarthritis research projects being completed by the Centre of Health, Activity and Rehabilitation Research.	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 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 that if I was injured as a part of this study, that I am eligible **to apply** for compensation from ACC.		
Data collected from me in this study may be used for future research.	Yes ☐	No ☐
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:

Declaration by member of the 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: