Participant Information Sheet

Study title:	**Exploring brain-pain adaptations in people with chronic non-specific knee pain**	
Principal investigator	**Name: Dr Jerin Mathew** **Department: Department of Anatomy, School of Biomedical Sciences, University of Otago** **Position: Lecturer in Clinical Anatomy**	Contact phone number: 035565036

Introduction

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate.

If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

What is the aim of this research project?

Patellofemoral pain (PFP) refers to non-specific knee pain, either because of problems with the joint between the kneecap (patella) and thighbone (femur) or the muscles around the knee joint. Persistent pain is the primary complaint in individuals with PFP, and the ongoing pain can lead to anxiety, sadness, and fear of movement. Although many people live with chronic PFP (pain > 3 months), we do

not fully understand the factors contributing to the persistence of PFP. Recent research in other persistent musculoskeletal pain conditions (e.g., low back pain, osteoarthritis) has shown altered brain function, increased nervous system sensitivity, and irregularities within pain-mediating brain regions. However, to date, no research has been conducted to understand brain adaptations and their relationship with pain, physical function, cognitive/psychological measures, and pain-quantifying outcomes in people with PFP compared to age- and sex-matched healthy controls. Therefore, this project will investigate brain changes (neural markers) associated with chronic PFP using electroencephalography (similar to measuring the electrical activity of the heart) and explore their relationship with pain and function. Understanding the neural mechanisms and brain regions in PFP may inform innovative and targeted treatments, including non-invasive approaches such as brain-wave training, mindfulness meditation, and pain-self management techniques.

Who is funding this project?

This research is supported by the School of Biomedical Sciences Strategic Research Support Funding.

Who are we seeking to participate in the project?

This research aims to investigate how brain activity differs between people with chronic patellofemoral pain (PFP) and groups of healthy individuals who are similar in age and sex.

Inclusion criteria – PFP participants: Adults aged 18–75 years with symptoms of PFP that are unrelated to a traumatic event, and pain lasting for > 3 months. Score at least ≥ four on an 11-point numerical rating scale, and PFP present during at least two of the following activities: going up or down stairs, running, kneeling, squatting, prolonged sitting, jumping or palpation of the medial and/or lateral facet of the patella. A score of ≤ 85 on the Anterior Knee Pain Scale.

Inclusion criteria – Control participants: No signs or symptoms of PFP or other chronic pain conditions.

The presence of the following conditions will be screened for both groups: lower limb inflammatory conditions, patellar subluxation or dislocation, patellar tendinopathy or meniscal tears, bursitis, and knee ligament injuries.

Exclusion criteria: Previous knee surgery, currently taking oral steroids, current back, hip or ankle joint injury or pain, and any neurological condition that affects movement.

If you participate, what will you be asked to do?

The study phases are summarised in Figure 1.

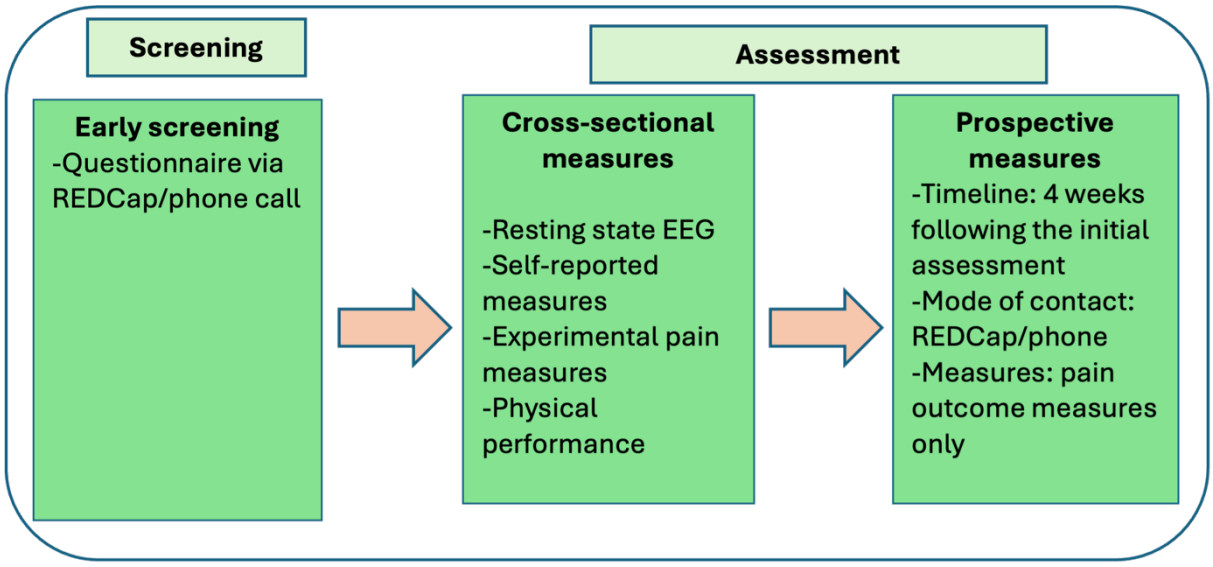

Figure 1: Study stages and measures

Preliminary/eligibility screening

The preliminary screening process will be conducted either via an online survey or over the phone, based on your preference. Following eligibility screening, you will be invited to attend a 90-minute session at the Department of Anatomy, University of Otago, to undergo the assessments, as described below.

On the assessment day

You are asked to bring shorts or pants that can be easily rolled up to expose your painful knee joint for sensory testing purposes.

The brain activity can be affected by various factors as listed below. Therefore, we request that you avoid:

- Eating large meals for 2 hours before the session
- Drinking alcohol for 24 hours before the session
- Smoking for 4 hours before the session
- Consuming caffeinated drinks for 1 hour before the session
- Applying any hair products (oil, gel) before the session.

You will be provided with some refreshments (e.g., crackers, tea, or juice) after the assessment session.

Written informed consent will be obtained from you before the assessments.

Questionnaires: You will be asked to complete questionnaires about yourself (age, gender, education, ethnicity, well-being), and your pain (location, nature, intensity, function, thoughts about pain and coping strategies) and how much this affects your daily life, current medication history (including pain relief), sleep, psychological states, the extent of social support, and the presence of other health issues if any. Your physical activity levels and sitting time in the past 7 days; and, height, weight, waist and hip circumference, leg/hand dominance will be recorded.

Brain activity recording: After completing the questionnaires, you will be asked to wear a cap with electrodes attached to it (see Figure 2). The assessment is called electroencephalography (EEG). Electrode gel will be applied for recording better signal quality. According to Māori culture, the head is considered sacred "he tapu te upoko" and the brain is regarded as the wairua (soul). The researcher will obtain permission from you before touching your head. You will rest in a comfortable chair with your eyes closed for 10 minutes, and your brain activity will be recorded.

Figure 2. Brain wave testing setup

Testing your sensation: After recording the brain activity, the following simple test procedures will be administered over the painful knee and at a distant location (non-painful body part) for comparison purposes. Please note that the research team does not expect participants to feel more than mild pain with these tests.

- Repeated light touches with a thin and blunted nylon filament – you will simply be asked to tell us whether you feel a sensation of touch or pain. If you feel pain on repeated touch, you will be asked to rate your intensity of pain on a 0–10-point scale, of 0 (no pain) to 10 (worst imaginable pain).
- The pressure to pain sensation testing: Pressure will be gradually applied by using a rubber-tipped pressure device. You will be asked to indicate immediately when the pressure sensation changes to discomfort or when you first feel pain. This procedure will be carried out over the painful knee and on the wrist when you are resting.

- Vibration threshold: Your ability to detect vibration will be tested using a tuning fork placed on the top of your knee.
- Physical performance: You will be asked to perform simple physical tasks (e.g., repeated sit-to-stand) that either will be timed or observed to rate your performance. You will also be asked to rate your knee discomfort on a 0 (no discomfort) to 10 (extreme discomfort) numeric scale before and after the task.

Post-assessment: You will be contacted by the researcher after four weeks of the assessment session, with a request to complete the questionnaires about your pain and function, which will take a maximum of 5 minute. This will be recorded via a brief online survey or via a phone call based on your convenience.

To recognise the actual or reasonable costs involved in participating in this project, all participants will be reimbursed $50 Gift Voucher for completing the survey and attending the testing session.

Is there any risk of discomfort or harm from participation?

Previous studies show that brain activity recording is safe. There are no known risk or adverse events associated with brain activity recording procedure used in this study. Your brain activity is recorded using the electrode cap, which is a safe and harmless procedure. Application of electrode gel may cause inconvenience, and you are welcome to use the shower facilities in the Department.

We do not anticipate any form of discomfort for pain sensation testing that would last following the test procedures. You may feel mild pain, tingling, or pins and needles sensation in your hand/knee during or immediately following pain testing. These ranges of sensations should normally disappear immediately following the testing. You will be closely monitored for your responses during sensory testing procedures, and sufficient rest periods will be provided between each testing procedure. A slight reddening of the skin may stay following the pressure to first pain testing, and it should disappear within hours of testing.

What specimens, data or information will be collected, and how will they be used?

Following consent, we will collect various health measures (e.g., pain, physical function, mood, thoughts, responses to pain sensation testing, brain activity) by way of questionnaires, physical and physiological outcomes. The study data will be coded and securely stored in a locked filing cabinet or electronically with password protection by the principal investigator, such that only those involved in

the research program will have access to it. Personal information such as contact details and names will be destroyed at the end of the study. However, as required by the University's research policy, any raw data on which the results of the project depend will be kept in secure storage for ten years, after which it will be destroyed.

All the health information and questionnaires will be collected using the REDCap survey software. REDCap (Research Electronic Data Capture) is:

- A secure web-based survey application available for University of Otago staff and students to use.
- Recommended for surveys where the design is complex and/or surveys that will include personal information which is either covered by Health Information Privacy Principles, the Privacy Act, or specific Ethics Committee requirements for a secure survey tool.

What about anonymity and confidentiality?

The study researchers and auditors from regulatory bodies as required by law will have access to your data. Every attempt will be made to preserve your confidentiality and anonymity. All personal data will be coded and stored either in a locked filing cabinet or electronically with password protection. It will be held by the principal investigator at the Department of Anatomy, School of Biomedical Sciences for a period of ten years after the completion of the study. It will then be destroyed as per the University of Otago policies. Any personal information [such as names, contact details, email address] held on the participants for practical purposes during the study period will be destroyed once the study is completed.

The data collected from this study may be used in future research to answer a different question.

The data management protocol for this study will be followed at all times when managing any collected data.

If you agree to participate, can you withdraw later?

You are free to withdraw from the study at any time

Any questions?

If you have any questions now or in the future, please feel free to contact either:

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Name: Dr Stephanie Woodley **Position: Professor** **Department: Department of Anatomy, School of Biomedical Sciences, University of Otago, Dunedin**	Contact phone number: 03 479 7353 stephanie.woodley@otago.ac.nz

This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email humanethics@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.