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INFORMATION STATEMENT AND CONSENT FORM

HREC Project Number: 520221155939385

Research Project Title: Is brain activity altered in people with patellofemoral pain and pain-related fear of movement?

Chief Investigator: Dr Kathryn Mills, Senior Lecturer

You are invited to take part in this research project, *Is brain activity altered in people with patellofemoral pain and pain-related fear of movement?* because you have identified that you experience pain at or around your kneecap regularly in a way that restricts your activity. This study aims to gain greater understanding of pain-related fear in people with kneecap pain.

This Participant Information Sheet tells you about the research project, and what is involved. Knowing what is involved will help you decide if you want to participate. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Fluent in writing and speaking in English
- Consent to take part in the research project
- Consent to the use of your personal and health information as described.

Please keep save a version of this form to your computer.

1. What is the purpose of this research?

This study aims to gain a better understanding of how the experience of how kneecap pain has impacted you. Specifically, we are interested in investigating if and how brain activity changes when people with kneecap pain watch videos of people performing activities and tasks that typically aggravate pain around the kneecap.

2. What does participation in this research involve?

This study requires you to attend Macquarie University for a single data collection session that will take approximately 2 hours. You will be asked to fill in questionnaires regarding your experience and mood living with kneecap pain. We will then assess the sensitivity of your peripheral nervous system using two tests - one involving a pressure and one using a fine-point that we push against your skin – both involve provoking a degree of pain for a short period of time. Finally, you will undergo a Functional Magnetic Resonance Imaging (fMRI) of

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your brain. fMRI detects changes in brain blood flow. We can measure this in response to certain behavioural tasks to infer neural/brain activity. All procedures employed in fMRI scanning are completely non-invasive and does not involve any radiation.

When undergoing fMRI, you will be asked to change into a hospital gown (provided) and to remove any magnetic materials from your clothing and your person (e.g., wrist watch, earrings). If you have magnetic material permanently fixed to your body (e.g. cardiac pacemaker, metal rods, plates or screws, or dental work not including fillings such as braces) then please do not volunteer for this study. If you are unsure, please check with the researcher. Once you enter the room where the MRI scanner is located, you will lie down on a bed and padding foam will be used to help you maintain your head in a stable position. A blanket will be provided if you desire.

During the fMRI, you will be watching 6 short videos on repeat. These videos depict a variety of daily activities that involve moving through the knee, some of which you may find aggravate your knee pain if you were attempting to do them e.g., climbing up or down stairs. We will not ask you to perform any knee movements that provoke your own knee pain. The fMRI will last for approximately 45 minutes including short breaks, when we will ask you to close your eyes and relax.

6-months after this session, we will email you a link to the two surveys that you completed when you expressed interest in this study. These questionnaires can be completed online and submitted directly to us. These questionnaires will take 5 to 10 minutes of your time to complete.

3. Do I have to take part in this research project?

Participation in this study is voluntary, if you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw. The easiest way to withdraw is to contact Dr Kathryn Mills.

4. What are the possible benefits of taking part?

All participants who complete the study will receive a $50 gift voucher as a thank-you.

5. What are the possible risks and disadvantages of taking part?

There are no known or foreseeable risks or side effects associated with fMRI recording. However, during scanning, the scanner makes loud noises, so you will be given hearing protection. In addition, it is important that you lie very still during the measurement since movements interfere with the data. **If you have claustrophobia or think that lying still in a small space will make you uncomfortable then please do not take part in this study. Although there are no known risks to a foetus from fMRI, if there is a chance you may be pregnant, please do not take part in this study.** You will be able to communicate with the researcher throughout the scanning session. You will be shown a safety buzzer to press should you wish to interrupt scanning. If you feel distressed at any time during the experiment, then you just need to press the buzzer and the experiment will be stopped.

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You are participating in a research study that is not designed for clinical purposes. However, all scans are routinely reviewed by a clinical radiologist and there is a remote chance that this will detect an abnormality in your brain. If an abnormality is detected, and the radiologist / neurology specialists at Macquarie University Hospital have the opinion that it should be followed-up, you will be contacted by a Dr Mills. Please note that although unlikely, if an abnormality is detected, it may have implications for life insurance policies or your employment. **If you do not want to be contacted in the event of an abnormality, then please do not take part in this study.** As this is a research scan and the clinician is reviewing the scan on this basis, we may not collect information that would enable us to detect an abnormality if one is present.

6. What if I withdraw from this research project?

If you choose to withdraw from the study, you will not be impacted in any way. This includes any current or future relationship with Macquarie University, or any other university associated with the research team.

7. What will happen to information about me?

All data that we collect from you will be de-identified as soon as you have completed your data collection session. Your name will be replaced with a randomly generated number so that your data can be stored and analysed in a manner that respects your privacy. To match these data with the surveys you return at 6-months, a separate file matching your name and participant number will be created. This file will be password protected and only accessible by Dr Mills. Both your data and coding file will be stored on secure Macquarie University server that is hosted within Australia. Your data will only be accessible by the researchers involved in this study.

At the conclusion of the study, a file containing all de-identified data will be archived on a Macquarie University approved server. Details about the study (study meta-data) will be moved to Macquarie University approved data repository for indefinite storage. In line with the Australian Policy on Data Management, these data may be made available via request to researchers within and outside this university who have gained institutional ethics approval for accessing and using the data for studies that are extensions of this study or for closely related studies.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected.

8. Who is organising and funding the research?

This study is being conducted by Dr Kathryn Mills (Macquarie University), Associate Professor Niamh Maloney (Auckland University), Professor Paul Sowman (Macquarie University), Dr Natalie Collins (the University of Queensland) and Dr Samantha Bunzli (the University of Melbourne). The study is being funded by a Macquarie University Research Acceleration grant.

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9. Who has reviewed the research project?

The ethical aspects of this research project have been approved by an Ethics Committee at Macquarie University.

10. Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on:

Research contact person

Name	*Kathryn Mills*
Position	*Senior Lecturer, Department of Health Sciences*
Telephone	*(02) 9850 6624*
Email	*Kathryn.mills@mq.edu.au*

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving

Reviewing HREC name	*Macquarie University Ethics Committee*
Telephone	*(02) 9850 4459*
Email	*Ethics.secretariat@mq.edu.au*

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By signing and returning this form, you acknowledge and consent to:

1. Participate a single data collection session involving questionnaires, sensitivity testing and fMRI
2. Undergoing fMRI procedures, including completing the medical checklist, removing all metal and changing into the hospital gown prior to the scan
3. Be contacted by the research team 6-months after this session
4. Complete and submit 2 online surveys 6-months after the data collection session
5. Have your name and participant ID stored on a password protected file and your data stored in a de-identified manner on a password protected secure server hosted by Macquarie University
6. Have your de-identified data archived on a Macquarie University data repository and accessed by future researchers with ethics approval

Participant Name:_____

Signature: _____

Date: _____

Consent Witness:_____

Signature: _____

Date: _____