Chronic anterior knee pain: a prospective longitudinal study

Department of Mechanical Engineering

Plain Language Statement

We invite you to participate in our research project “Chronic anterior knee pain: a prospective longitudinal study”. We would like to give you some background information on why we think this project is important and on what we would like you to do if you decide to join us in this research.

What is the purpose of the study?
Chronic anterior knee pain, or kneecap pain, is one of the most common knee injuries and affects as many as 30% of people who have a physically active lifestyle. It causes pain at the front of the knee during activities such as squatting, stairs and running, and can therefore affect participation in daily and work activities, as well as exercise. Importantly, there has been suggestion that anterior knee pain in young adults is related to kneecap arthritis later in life, for which there is no cure. Therefore, it is important that we better understand the relationship between these two conditions, so that we can identify people with anterior knee pain who may be at risk of developing arthritis. This will help us develop treatments that may help to keep those affected as pain-free as possible for as long as possible, and possibly prevent arthritis or slow the progression of arthritis.

In this project we will investigate:
1. The relationship between pain and symptoms, x-ray findings, clinical tests and leg joint motion in people with chronic kneecap pain;
2. How many people with chronic kneecap pain develop kneecap arthritis over five years; and
3. Which factors can predict whether someone with chronic kneecap pain will develop kneecap arthritis, or experience worsening of kneecap arthritis, over five years.

This study has been funded by Arthritis Australia.

Who can participate?
You can participate in the study if you are aged 27 to 50 and currently have pain behind or around your kneecap that is aggravated by activities such as walking up or down stairs, squatting and running.

You are not eligible if you have moderate or severe arthritis in the main joint of your knee; current pain from other knee, hip or back conditions that impairs your function; if you have had or are planning knee surgery; are unable to walk without help; or if you cannot understand written and spoken English. Furthermore, in order to have the x-rays, you may not participate if you are pregnant, if there is a chance that you may be pregnant, or if you are breastfeeding.

A component of this study (PART C) involves taking a magnetic resonance imaging (MRI) scan of your knee. Because this uses a strong magnet, if you have a pacemaker, a history of metallic foreign body in the eye, previous surgery for cerebral aneurysm, or any other implanted metal material (e.g. a cochlear implant), there is potential for harm and you will not be eligible to undergo MRI. Also, because the MRI scan requires you to lie still in an enclosed chamber, you may not wish to participate in this component of the study if you suffer from claustrophobia. However, you may still be eligible for the main part of the study even if you are not suitable to undergo MRI.
What does the project involve?
This project involves three main components. In total, this will involve attending a radiology clinic on three occasions, as well as the Biomechanics Laboratory at the Department of Mechanical Engineering at The University of Melbourne a total of six times. These will be spread out over a five-year period.

PART A
PART A consists of x-rays and clinical tests, and will be completed by all participants in the study.

Initially, you will be asked to attend a radiology clinic to have x-rays of your knees. This will be on top of any previous x-rays that you may have undergone for your knee or other body part. The x-rays will be at no cost to you and will take approximately 30 minutes. A radiographer will initially review your x-rays, and inform your usual doctor if any unusual findings are present (e.g. fractures, tumours). The investigators will then examine your x-rays for signs of moderate or severe arthritis in your main knee joint, which would make you ineligible to participate in the study, and inform you of these findings. They will also provide information from Arthritis Victoria about what you can do to manage your knee arthritis. Once all participants have been entered into the study, which may be up to two years after you start the study, all x-rays will be examined for signs of kneecap arthritis, and measures of knee alignment taken. Once this has been completed, the investigators will inform you in person whether or not you have signs of kneecap arthritis on x-ray. This will be done during your one- or two-year follow-up visit, or may require a separate visit to the Laboratory if you wish to receive your results sooner. The investigators will also provide information from Arthritis Victoria about what you can do to manage your kneecap arthritis. A copy of your x-rays will be made available for you.

Once your x-rays have been taken, you will be asked to attend your first testing session at the Biomechanics Laboratory. This will take up to three hours of your time. The researcher may perform some simple clinical tests to confirm that you have chronic kneecap pain. You will also complete simple questionnaires asking about your knee symptoms, physical activity levels, and general health. A Physiotherapist will be present to answer any questions you may have about the questionnaires. Please note that some of these include questions about your mental well-being. If your results indicate that there may be a serious mental health problem, we will refer you to your usual doctor for appropriate management. For female participants who provide consent, this will also include a questionnaire about your menstrual cycle.

You will also be asked to complete some functional tests, including standing up from sitting, squatting, and balancing on one leg. Some of these tests may also be performed with and without different treatments (such as shoe inserts). We will video your performance during one test (the single leg squat). These videos will not include your face, so you won’t be identifiable from the footage. If any part of your face or head is inadvertently videoed, this will be masked (by electronically blurring this area) prior to data analysis. We will also take clinical measurements of your height, weight, leg length, leg and foot alignment, muscle strength and joint movements. Once again, you will be asked to inform the researcher if you experience any pain or discomfort during these tests.

After testing has been completed, you will be provided with a physical activity monitor to wear for one week during waking hours (i.e. not when you’re sleeping). This is a small device worn at the hip, which is barely noticeable, that continually records your body motion. You will be asked to return this device to our laboratory at no cost to you.
In addition, female participants who provide consent will be asked to complete a daily diary for the first three months of the study. Each day you will be asked to record how severe your knee pain is, whether you have taken the oral contraceptive pill that day, and whether or not you are menstruating. This will take you less than two minutes to complete each day.

Once you have completed your initial testing, we will monitor your condition regularly over the following five years. This will involve:

- Completion of some of the same questionnaires via a website, at three-month intervals (this can be done from your home or work computer);
- Retesting of the clinical measures in the Biomechanics Laboratory, and wearing of the physical activity monitor for a one-week period, once a year for up to five years; and
- Repeat x-rays at two years and five years.

All testing and scans will be provided at no cost to you.

Are there any potential risks or side effects?
Some of the tests may require you to perform a task until you first experience the start of your knee pain or an increase in your knee pain. Because we stop this test immediately once this has occurred, it is not expected that this will aggravate your knee pain. You may feel some discomfort in your joints or muscles during or following the assessment. Please report to the researcher any undue discomfort or pain experienced during the testing. If the pain or discomfort is deemed to be excessive by yourself or the investigators, then testing will cease. This won’t affect your participation in the rest of the study.

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from all the extra studies will be less than 0.015 mSv at each x-ray occasion, or 0.045 mSv over the five years. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. This risk is believed to be minimal, even if you have recently had x-rays to your knee or other region.

While any treatments that we may test are used safely in clinical practice, some people may notice new pain or an exacerbation of their knee pain. However, as they will only be applied for a short period (maximum 30 minutes), it is not anticipated that this will be a problem for the majority of participants. If this does occur, you will receive the appropriate treatment to reduce your pain. Tape may irritate the skin of some people. We will use a special solution on your skin to reduce the likelihood of any skin irritation. Individuals with a known sensitivity to tape will not undergo this component of testing.

If required, the Department of Mechanical Engineering emergency procedures will be used to deal with any medical event that arises during the testing.

**PART B**

If you provide consent, you may also participate in PART B, which involves more detailed evaluation of how your leg joints move during functional tasks, such as walking.

During your first testing session at the Biomechanics Laboratory, you will then be asked to wear short shorts and a sleeveless top, and some reflective markers will be attached to your skin at various sites such as the arms, pelvis, and legs. You will also have electrodes attached to your skin to record the activity of muscles in your legs. You will be asked to perform functional activities such as walking, running, and single leg squat. You may be asked to repeat these tasks while wearing shoes with inserts.
On subsequent visits to the Biomechanics Laboratory to undergo clinical tests (once a year), this procedure may be repeated to determine whether your movements have changed.

**ARE THERE ANY POTENTIAL SIDE EFFECTS?**

You may get some skin irritation, resulting in a slight stinging sensation, associated with the electrodes used to test your muscle activity. If required, antiseptic gel will be applied to reduce the stinging sensation.

If required, the Department of Mechanical Engineering emergency procedures will be used to deal with any medical event that arises during the testing.

**PART C**

If you are eligible, and provide consent, you will undergo an MRI scan of your affected knee at the same time that you have your knee x-rays taken. For the MRI measurement, you will be asked to lie on a narrow table that will slide your lower body inside a large tunnel-like tube within a scanner. The scanner creates a magnetic field around you, then pulses radio waves at the knee. Several sets of images are required, each taking from 2 to 15 minutes. You will not feel anything during the measurements and there is NO ionizing radiation involved. The MRI scans will also be at no cost to you, and will take approximately 30 minutes extra on top of the x-rays. These will also be read initially by a radiographer, who will inform your usual doctor if any unusual findings are present (e.g. fractures, tumours). Once all participants have been entered into the study, the investigators will use your MRI scans to evaluate your kneecap joint and measure your kneecap position. These findings will be communicated to you in person once the measures have been completed, which may be up to two years after you start the study. A copy of your MRI scans will be available for you.

The MRI scans may then be repeated at two and five years, when you undergo your repeat x-rays.

**ARE THERE ANY POTENTIAL SIDE EFFECTS?**

MRI is potentially harmful to individuals with metal inside the body. Thus it is imperative that you inform the investigator of your medical history and of any metal implants. You will be given a safety screening form to complete to ensure that it is safe for you to be scanned by the MRI machine. If the practitioner who is assessing your MRI scan believes that you have an abnormal finding that is potentially significant (e.g. fracture or tumour), your usual doctor will be notified for further management.

**Other information**

**WHAT IF I WISH TO HAVE TREATMENT FOR MY KNEE PAIN DURING THE STUDY PERIOD?**

During your time in the study, you are free to seek medical or other treatment for your knee condition as you see necessary, at your expense. This includes tests such as x-rays and MRI scans. This will not affect your participation in the study. However, we ask that, if you do undergo further testing or treatment related to your knee, that you inform the investigators regarding the type and amount of treatment that you receive, so this can be considered when we look at your results. This information will be kept confidential, along with all other data collected during the study (as below).

**WHAT IF I HAVE ANY CONCERNS DURING THE STUDY?**

The Responsible Researcher, Dr Natalie Collins (03 8344 3910), will be available throughout the study if you have any questions. The other investigators will be available if required. This project has been approved by the Human Research Ethics Committee of the University of Melbourne. If you have concerns about the way the study is being conducted you should contact the Executive Officer, Human Research Ethics, The University of Melbourne, ph: 03 8344 2073; fax 03 9347 6739.
Can I withdraw from the study if I wish?
Your participation in this study is voluntary. If you do not wish to take part you are under no obligation to do so. Also, if you decide to take part but later change your mind, you are free to withdraw from the project at any stage. You may also withdraw any unprocessed data previously supplied by you. If you are a staff member at the University, your decision whether to take part or not to take part, or to withdraw, will not affect your future employment in any way. If you are a student at the University, your decision whether to take part or not to take part, or to withdraw, will not affect your future grades or assessment in any way. If you are a patient of any of the investigators, your decision whether to take part or not to take part, or to withdraw, will not affect your management in any way. The researchers understand that not all people will want to participate in this research project, and respect the wishes and rights of every volunteer.

Will my details be kept confidential?
The anonymity of your participation is assured by our procedure, in which a code number and not your name will identify you. No findings that could identify you will be published and access to individual results is restricted to the investigators. Coded data will be destroyed five years after publication of study results. All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The chief investigator is responsible for maintaining this confidentiality. This project is subject to the requirements of the Human Research Ethics Committee of the University of Melbourne. However, you must be aware that there are legal limitations to data confidentiality.

How do I get more information?
You should ask for any information you want. If you would like more information about the study, or if there is any matter about it that concerns you, either now or in the future, do not hesitate to ask one of the researchers. Before deciding whether or not to take part you may wish to discuss the matter with a relative or friend or with your local doctor. You should feel free to do this. Please be aware that, due to the nature of the study, your results may not be available to you for one to two years.

About the researchers
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Consent Form

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Chronic anterior knee pain: a prospective longitudinal study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigators</td>
<td>Dr Natalie Collins, Associate Professor Kay Crossley, Prof Bill Vicenzino, Dr Anthony Schache, Prof Marcus Pandy</td>
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1. I, __________________________________________________________ (participant’s name), consent to participate in the above project, the particulars of which - including details of tests or procedures - have been explained to me and are appended hereto.

2. Specifically, I consent to participate in the following components of the project (please sign and date next to all that apply):

| PART A: x-rays, questionnaires, clinical tests | Participant’s signature | Date |
| PART B: detailed assessment of leg movements (biomechanics) | |
| PART C: MRI scans | |
| Provision of data regarding my menstrual cycle (female participants) | |

3. I acknowledge that:
   a. The possible effects of the tests or procedures have been explained to me to my satisfaction;
   b. My participation is voluntary and I have been informed that I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied;
   c. The project is for the purpose of research and not for treatment;
   d. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements.

| Name of Participant | |
| Signature of Participant | |
| Date | |