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NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

The **POP-ACLR** Study: The **P**re**O**perative Management of **P**atients Awaiting **A**nterior **C**ruciate **L**igament **R**econstruction

Participant Information Sheet

Version 1.2 – 21/12/2023

We would like to invite you to take part in our research study called POP-ACLR. The POP-ACLR study is looking to support patients to make decisions about the treatment of their Anterior Cruciate Ligament (ACL) injury. This will involve you using a shared decision making tool during your consultation with a clinician.

Before you decide whether to take part or not, we would like you understand why the research is being done, and what it would involve for you.

Please take time to read the following information, it should take you approximately 5-10 minutes. If you would like any further information, please ask us, our contact details are at the end of the sheet.

What is the purpose of the POP-ACLR study?

The purpose of the POP-ACLR study is to understand acceptability of the shared decision making tool amongst patient and clinicians. The shared decision making tool is designed to help you decide on the treatment for your ACL tear.

The ACL is the most commonly injured ligament in the knee. ACL tears can be treated surgically or non-surgically. Patients in previous research have reported difficulty with making decision about treatment. Shared decision making tools have been used in other patient groups, such as those with knee osteoarthritis, and have shown to help patients make decisions about treatment. Shared decision making tools provide evidence-based information about treatment options such as what treatment entails and the associated benefits and harms. They help patients to consider what matters most to them to help with making a decision.

Research about shared decision making with ACL patients has not been done before. This remains an important gap in the evidence.

Why am I being invited to take part?

You are being invited to take part because you have been diagnosed with an ACL rupture.

We are hoping to recruit 20 patients.

Do I have to take part?

No, you do not have to take part if you do not wish, taking part in this or any research study is optional. You do not have to decide straight away. Please feel free to discuss this study with your friends, family or healthcare professional.

What will happen if I take part?

We will check you are eligible to take part in the study over the telephone/in-person and answer any remaining questions you may have.

If you agree to take part, we will ask you to sign a paper or online consent form. After this, we will arrange a time, convenient for you, to complete an initial questionnaire which will ask some questions about you and your injury (for example, your age and when you injured your knee). You will then be provided with the shared decision making tool. The shared decision making tool is made up of 2 parts:

1. An information leaflet for you to read. This will explain key information about your ACL injury and the treatment options available.
2. An 'option grid' for you to read and work through with your clinician(s). The option grid compares the 2 main treatments for an ACL injury and will help you to think about what is important to you during treatment and what treatment your clinician(s) recommend.

The shared decision making tool will be available on paper and/or online. Which format you use (paper, online or both) is up to you.

You will be referred to physiotherapy where you will have an appointment with a physiotherapist and discuss the shared decision making tool. This appointment will last approximately 30 minutes. After the appointment you will be asked to fill in a questionnaire (via paper or online).The questionnaire will ask you how you found using the shared decision making tool (for example if they gave you the information you wanted) and about your satisfaction with the decision you made. If you decide not to fill in the questionnaire straight away, we will send you reminders to do so over a 4 week period.

You may also be asked to take part in an interview to discuss your experience of using the shared decision making tool. You can participate in the study but not the interview if you wish. You will be asked to provide consent to take part in the study alone or the study and the interview.

The interview can be completed virtually or in-person depending upon your preference. IT will last approximately 30-60 minutes and will be recorded. The recording will be converted into text by a third-party transcription service that complies with data security regulations. Some quotes may be used in a written report. These quotes will be anonymised, so no one will know it was you who made the comment. There will be no other use of the recording.

Your overall participation in the study will involve:

1. An initial questionnaire
2. A physiotherapy appointment using the shared decision making tool
3. A follow up questionnaire

In total, your involvement in the study will last approximately 6 weeks (if you fill in the follow-up questionnaire shortly after your physiotherapy appointment, it will likely be shorter than this).

Expenses and Payments

You will be offered a £20 voucher on completion of the final questionnaire. If you also take part in the interview, you will be offered a second £20 voucher. If participation in the study has caused you to travel out of your way and/or disrupted usual childcare arrangements, you will be reimbursed for reasonable travel and childcare costs.

What are the possible benefits of taking part?

The main benefit from your participation in this study will be the information we collect. This may help inform future research and treatment for patients with anterior cruciate ligament injuries.

What are the disadvantages or possible risks of taking part?

There are no anticipated risks of taking part in this study. The main disadvantages are that you will need to take time out of your day to complete the questionnaires and look at the shared decision making tool. Participation in the interview could make you feel uncomfortable when discussing your experiences. If this is the case, you can end the discussion at any point and you will not be forced to discuss anything you do not wish to.

What happens at the end of the study?

At the end of the study, the results will be reported to the study funder. A summary of the study results with details of where to find further information, will be sent to all participants.

We also plan to publish the results in a medical journal and present them at conferences, so others can read about and learn from the results of the study.

This research will also contribute to the fulfilment of a doctoral thesis.

What happens if I don't want to carry on with the study?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. Your information will have been anonymised. This information may therefore still be used in the project analysis.

If you chose to stop being part of the study, your medical care or legal rights will not be affected.

If you would like to stop being part of the study, you can contact the study sponsor or researcher via the contact details on page 5 and 6.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details held by the University Hospitals of Derby and Burton NHS Foundations Trust. The electronic data system used in the study (REDCap) is hosted by The University of Nottingham (as the Chief Investigator is a PhD student at the university). Access to identifiable data will be restricted to ensure only relevant and necessary research personal will have access. Identifiable data will also be removed prior to data archiving. La Trobe University have no access to identifiable data and data will only be shared (de-identified) with the collaborator Professor Kate Webster for support during analysis and write up.

You will be allocated a study number and research staff not directly involved with your care will know you only by this number. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. We will write our reports in a way that no-one can work out that you took part in the study.

In the unlikely scenario that you lose mental capacity, you will be withdrawn from the study. The non-identifiable data collected up to the point of withdrawal will be retained and used.

Your personal data (name and email address) will be kept for 6 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data, including interview recordings) will be kept securely for 5 years in line with the hospital policy. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- By asking one of the research team (contact details are at the end)

- The Health Research Authority provides some useful resources for you to look at:
  - www.hra.nhs.uk/information-about-patients/
  - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

- By contacting the Data Protection Officer at the University Hospitals of Derby and Burton NHS Foundation Trust:

  Emily Griffiths
  Information Governance, Level 3 M&G
  Royal Derby Hospital
  Uttoxeter Road
  Derby
  DE22 3NE

  Email: uhdb.dataprotectionofficer@nhs.net
  Tel: 01332 788 645

Who is organising and funding the study?

The study is being organised by the University Hospitals of Derby and Burton NHS Foundation Trust.

Hayley Carter, Clinical Doctoral Research Fellow, NIHR302104, is funded by Health Education England (HEE) / NIHR for this research project.

Have patients and the public been involved in the study?

Yes. A patient and public involvement and engagement (PPIE) group have contributed to the design of the study and will continue to be involved throughout the study, overseeing its progress.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nottingham 1 Research Ethics Committee (reference number: 23/EM30263).

What is there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.

You can also contact the University Hospitals of Derby and Burton NHS Foundation Trust, the sponsor of the study.

Research and Development Department
Medical School, Royal Derby Hospital

Uttoxeter Road
Derby
DE22 3DT

Email: uhdb.sponsor@nhs.net
Tel: 01332 724 639

You can also contact the University Hospitals of Derby and Burton NHS Foundation Trust Patient Advice and Liaison Service (PALS):

Royal Derby Hospital
Uttoxeter Road
Derby
DE22 8NE

Tel: 01332 785 156
Text: 07799 337 500
Email: uhdb.contactpalsderby@nhs.net

Further information and contact details

Hayley Carter, NIHR/HEE Clinical Doctoral Research Fellow / Specialist Physiotherapist

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Tel: 0115 823 0235

Thank you for reading this information and considering taking part in our study.