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***ACL STARR-UK Study: Anterior Cruciate Ligament Repair or Reconstruction?***

*Chief Investigator: Associate Professor Stephen McDonnell*

# PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in our research study, to help us find the best surgical option for treating tears of the Anterior Cruciate Ligament (ACL). Before you decide, it is important that you understand why the research is being done and what it would involve. Please read this information sheet and discuss it with others if you wish.

An explainer animation video is available to watch at http://www.aclstarr.com/.

If there is anything that is not clear or if you would like more information, please ask your surgeon or the research team.

## Study Background


The knee is the most commonly injured joint. The ACL is an important band of tissue that supports the knee. It is a strong structure in the centre of the knee which attaches the femur (thigh bone) to the tibia (shin bone).

The ACL is often injured during manual work or sports. Injury to the ACL can lead to the knee becoming unstable, giving way, and people may experience a loss of confidence in their knee. An unstable knee can cause damage to other parts of the knee such as the cartilage or meniscus (shock absorbers), which can lead to osteoarthritis (OA) developing in later life.

ACL injuries can be treated with either surgery or rehabilitation. You will decide, together with your surgeon and family/carers, whether to have non-surgical treatment (rehab physiotherapy), or surgery followed by physiotherapy.

The ACL can be injured in several ways. One type of injury is a tear to the ligament close to the point where it attaches to the bone, this is called a proximal tear. We are inviting you to take part because you have a proximal tear to your ACL and have, following discussion with your surgeon and family/carers, decided to undergo surgical treatment.

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**There are two surgical options for treating people with a proximal ACL tear (see Figure 1):**

| Reconstruction | Repair |
|---|---|
| The most common operation for a torn ACL is **reconstruction**, which uses tissue from other parts of the body, to act as a replacement (graft). This is usually done by keyhole surgery. The surgeon will create a tunnel through your upper shin bone and lower thigh bone and thread the graft through the tunnel and fix it in place. This operation is well tried and tested. | There is another less commonly used option, which involves direct **repair** of the torn ligament. Repair involves re-attaching the damaged ligament back from where it has been avulsed (pulled off). This is less invasive than a reconstruction as there is no graft harvest, and smaller tunnels drilled in the bone, and because you keep your ligament, there is the potential for less pain, and a more normal feeling knee. |

There have been research studies already undertaken which show that both surgeries are safe. However, there are no large-scale studies which directly compare the two types of surgery to help us know whether the injury is best treated with reconstruction or repair surgery. A randomised controlled trial is needed to answer this question. This involves assigning participants, at random, to the different treatments so the effects of each treatment can be compared fairly. The treatment that you are allocated to will be decided by a computer. You will have an equal chance (50:50) of receiving either Reconstruction surgery or Repair surgery.

We hope our study will provide evidence to better inform treatment options available for patients in the NHS. We are recruiting 286 patients ('participants') from several NHS Hospital Trusts across the UK and will compare all the information collected to find out the best treatment to use.

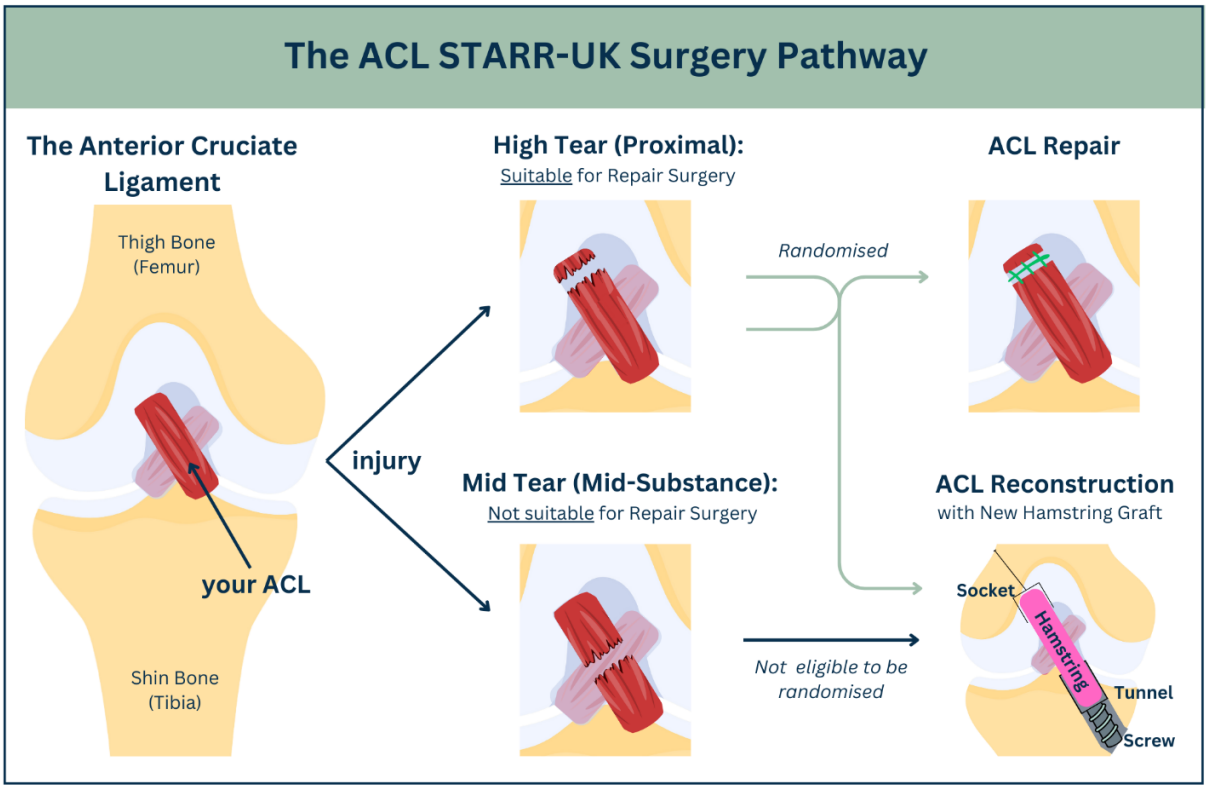


**Figure 1**. The Surgery Pathway

## What will happen to me if I decide to take part? See Figures 2 & 3

- After you have read this Participant Information Sheet, and if you are interested in taking part in this study, we will ask you to sign a consent form (to record your decision).
- Before your surgery, you will be asked to complete a first set of questionnaires about your knee and knee injury.
- Your surgery will be undertaken as soon as possible, but **no longer than 50 days from the date of your injury.**
- You may be enrolled (i.e. signed the consent form), but not randomised if, once in theatre, the surgeon decides that the ligament is not suitable for both types of surgery. In this case, reconstruction surgery will be performed, and you will not continue in the study. Subsequent clinical care will not be affected, and you will not be asked to complete the follow-up activities (pain scores and questionnaires).
- After surgery, everyone will have physiotherapy to help with rehabilitation (as part of routine NHS care).

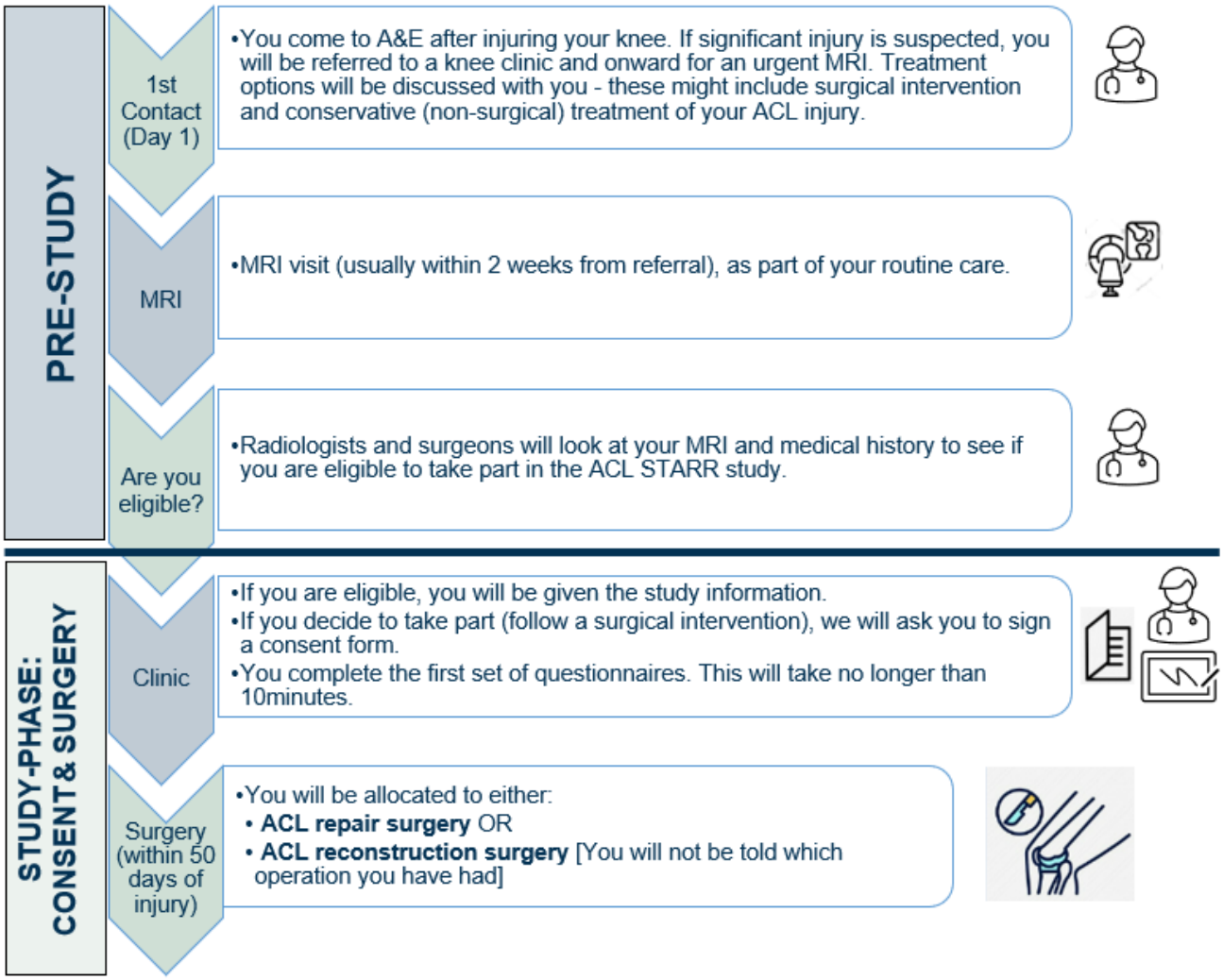


**Figure 2**. The Participant Pathway: Day 1 to Surgery

## Do I have to take part?

No. Taking part in this study is entirely voluntary. If you decline to take part, or withdraw from the study, your clinical care from the NHS will not be affected. You can withdraw from the study at any time without giving a reason. This can be done by contacting any member of the clinical or research teams. Any surgical details and questionnaires collected to that point will be used for research as described in this participant information sheet. These will be de-identified, so there will be no way of identifying you from the information collected.

## What should I consider?

- As both operations are already performed in the NHS, they, along with clinic appointments and MRI scans will form part of your routine NHS care. The randomisation to which surgery you receive and the collection of questionnaires are extra activities that we are undertaking as part of this research study.
- Your GP surgery will be notified of your participation in this study (if you are randomised in the study).
- You will not be able to take part if you have had previous surgery on your knee, including any open surgery or arthroscopies (keyhole surgery).
- You need to be willing and able to complete the study questionnaires at all the time points set out in Figure 3.


**Figure 3**. The Participant Pathway: Post-surgery and Follow-up

## Are there possible disadvantages or risks from taking part?

There are risks associated with both ACL repair and reconstruction surgery, such as re-rupture or graft failure.

Other risks associated with these surgeries include pain, infections, tendon, ligament or nerve damage, scars, blood clots and swelling. These are the same risks for patients who do not take part in the study and decide to have ACL surgery. The risks will be discussed in detail with you by the clinical team looking after you in hospital.

## What are the possible benefits of taking part?

- We do not know whether one of these operations will be better for patients than the other. We hope that by comparing them, we will gather evidence to show which surgical option is better for people like you.
- Both surgical procedures are designed to help reduce the symptoms you are currently experiencing in your knee.

## Will I be reimbursed for taking part?

There should be no costs to you for taking part in this research. Your appointments at MRI, knee clinic and surgery would be all a part of your normal routine care. We ask you to complete questionnaires from home, via email or prepaid post, and there are no planned additional visits to hospital for this research. If, however, there is a reason you need to attend a hospital appointment for research purposes (e.g. a visit to speak further with a clinician about the study before signing a consent form), reasonable travel expenses will be reimbursed. Please visit https://finance.admin.ox.ac.uk/how-to-claim-expenses-claimants-external-to-the-university for details of how to claim travel expenses.

We are giving everyone who takes part in this study a £20 voucher as a thank you gift.

## Who is organising the study?

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are the sponsors of this study. The Chief Investigator is Associate Professor Stephen McDonnell.

The study is managed by the Surgical Intervention Trials Unit (SITU), a part of the Oxford Clinical Trials Research Unit (OCTRU) at the University of Oxford.

The study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme.

## Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Cambridge South Research Ethics Committee (REC Reference 25/EE/0016). The Health Research Authority, UK

Independent researchers, patient representatives, each hospital's Research and Development department and your healthcare professional have also reviewed and agreed to support this study.

The study followed a 2-stage application process, with assessments at each stage by the HTA Funding Committee.

## DATA MANAGEMENT

### What will happen to the results of this study?

At the end of this study, we will present our findings in medical journals and at medical conferences. Participants will not be identified from any report or publication placed in the public domain. A description and results of this clinical study will be available at https://www.isrctn.com/.

A summary of the results will be made available via the study website: www.aclstarr.com once the results have been published.

### How have patients and the public been involved in this study?

We held several patient and public involvement (PPI) focus groups to assist us in developing different elements of this study. Together with the groups, we refined the research question, and decided on which questionnaires to collect, based on outcomes that are important to patients (e.g. pain after surgery and a quick return to sports and work). Our focus groups were made up of a diverse range of patients from across the UK (most had recovered from ACL injuries). In total, 15 patients provided their input. We also held separate meetings with young people (aged 14-16 years), as this age group are commonly affected by ACL injuries and may also benefit from repair surgery. After this, 10 members of a Cambridge-based PPI panel reviewed this participant information sheet. Thanks to their feedback, we have changed some words, removed a section, and improved the layout, to make it easier to understand. We will continue to work with our PPI groups throughout the study.

*Please visit the following links to general information about taking part in research:*

- https://www.nihr.ac.uk/get-involved/take-part-in-a-study
- https://www.nhs.uk/conditions/clinical-trials/

### How will we (the Sponsors) and the University of Oxford use information about you?

We will need to use information from you and your medical records for this research project. After consent, the data we collect will include your:

- name
- contact address
- contact phone numbers (landline and mobile)
- email address
- NHS/CHI number (for long term follow-up only, if you agree), and
- date of birth.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will use the information to request the completion of post-surgery pain scores (via text message, email, or post), send you the follow-up questionnaires and gift voucher (via email or post), and send any reminder messages.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research (i.e. sending automated SMS text messages to collect pain scores at 3 weeks and 6-weeks post-surgery). Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

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.

To be reimbursed for travel expenses, your name, postal address, email address and bank details will be shared with the University of Oxford's Finance team. These details will be securely retained by the Finance team for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose.

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are the sponsors of this research and, together with the University of Oxford, are responsible for looking after your information. We will keep all information about you safe and secure by:

- Ensuring all information collected about you because of your participation in the study is kept strictly confidential.
- Your personal and medical information will be kept securely and be treated in the strictest confidence.
- The people who analyse the study information will not be able to identify you and will not be able to find out your name, NHS number or contact details.
- Only anonymous study data, without any personal information will be published at the end of the study.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

At the end of the study we will archive your study data for **5** years. De-identified data may be shared with other researchers at the end of the study.

## How will hospital sites use information about you?

Your hospital will collect information for this research study from you, your medical records, and your treating clinicians and will pass these details to the University of Oxford (including a copy of your signed consent form, if you have agreed to either of the optional aspects of consent, i.e. contact about future research, or long-term follow-up). Queries may be returned to the site to ensure accuracy of the collected information.

Your hospital and the University of Oxford will use your name and contact details to contact you about the research study, to make sure that relevant information is recorded for your care, and to oversee quality of the study.

Your data from the questionnaires will be made available to your local study team at your hospital, in this way your treating health professionals will have full oversight of the data relating to your study participation.

If you agree to take part, and are randomised in the study, your GP surgery will be notified. Your hospital will keep identifiable information about you from this study for 5 years after the study has finished.

## International transfers

We will not share data about you outside the UK for research related purposes during the study. However, we are running a mirror study with our colleagues in Australia. Their study will mirror the one described in this information sheet. This will enable us to collect more data across relevant populations. This means that de-identified results will be shared between the UK and Australia at the end of the study for data analysis. No information will be shared which could identify you and will not be combined with other information in a way that could identify you.

We will only share the data that is needed.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law.

## 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.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to us keeping your NHS/CHI number to enable long term follow up, using routinely collected NHS data, we will keep this information for **5** years from the date of your consent into the study.
- If you agree to us keeping your personal details for contacting you about future research, we will keep this information for **5** years after the study has finished.

Please follow the links below to find out how the data controllers manage your personal data processed in connection with the study:

- For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/patient-privacy/patient-privacy-notice/ or email the Data Protection Officer at: cuh.gdpr@nhs.net
- For University of Cambridge, please visit: https://www.information-compliance.admin.cam.ac.uk/data-protection/medical-research-participant-data or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk
- For University of Oxford, please visit: https://compliance.web.ox.ac.uk/individual-rights or you can find out more about how they will use your information by contacting acl_starr@ndorms.ox.ac.uk

## Where can I find out more about how my information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- By asking one of the research team
- By sending an email to acl_starr@ndorms.ox.ac.uk
- http://www.hra.nhs.uk/patientdataandresearch

## What if there is a problem regarding the study?

If you have a concern about any aspect of this study or wish to complain about any aspect of the way in which you have been approached or treated, or how your information is managed, please speak with the Principal Investigator or a member of the clinical research team.

| | |
|---|---|
| *Principal Investigator* | Name: <add><br>Telephone: <add> |
| *Research/Specialist Nurse* | Name: <add><br>Telephone: <add> |

Cambridge University Hospitals NHS Foundation Trust, and the University of Cambridge as Sponsors, have appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment provided.

## What if I am concerned about my clinical care?

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. Your local PALS team contact details are:

- <insert relevant NHS site phone number>
- <insert relevant NHS site email>

For support in Scotland, please contact the Patient Advice & Support Service (PASS)
PASS national helpline phone number: 0800 917 2127
PASS website (webchat): https://pass-scotland.org.uk/

For support in Northern Ireland please contact the Patient and Client Council (PCC)
PCC national helpline number: 0800 9170 222
PCC website: https://pcc-ni.net/

## Contacts for further information:

If, at any time, you would like further information about this research study, please contact:

ACLSTARR Study Team,
RCS Surgical Intervention Trials Unit (SITU)
Botnar Research Centre | Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences | University of Oxford
Nuffield Orthopaedic Centre
Windmill Road, Headington | Oxford OX3 7HE
07798 571116 | Email: acl_starr@ndorms.ox.ac.uk | Website: www.aclstarr.com

***Thank you for considering participation in this study and for taking the time to read this information sheet.***