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

Chief Investigator: Associate Professor Stephen McDonnell

14-15 YEARS | PARTICIPANT INFORMATION SHEET

We would like to ask you if you would like to take part in a study called **ACL STARR**. Before you decide if you want to take part, it is important that you understand why we are doing this study and what it would involve for you. Please read this information carefully and talk to your parents or guardians about the study. Ask us if there is anything that is not clear or if you want to know more. Take time to decide if you want to take part. It is up to you if you want to do this. If you do not then that is fine, you will be looked after just the same.

An explainer animation video is available to watch by clicking here. <add link>

What is ACL STARR?

ACL STARR is about finding out which is the best surgery option for people like you, who have torn their Anterior Cruciate Ligament (ACL). This type of injury is common in young people, and it often happens when participating in sports like football.

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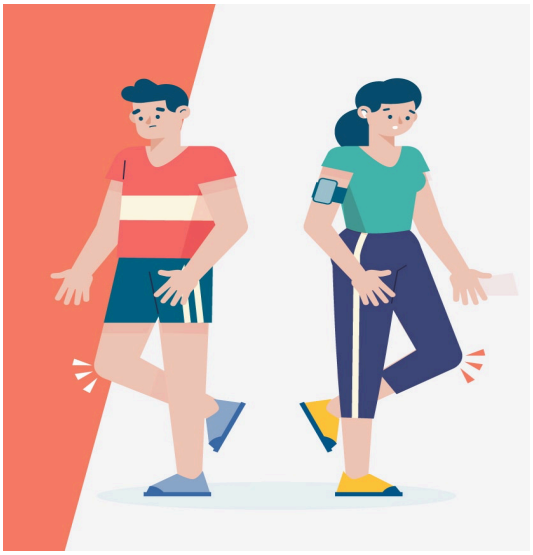
Not everyone with a torn ACL has surgery; you will spend time with your surgeon and family discussing which is the best option for you.

When people decide to have surgery to fix a torn ACL, there are two options:

One is very commonly used and is tried and tested. This is called a 'reconstruction,' which means that the torn ligament is replaced using tissue from elsewhere in your body.

The other is called a 'repair,' which means that your torn ligament is kept and repaired. Not every ACL tear is suitable for repair, so the doctors will need to look closely to make sure yours is.



We are going to compare these two different types of surgery to see if one is better than the other.

The important finding will be how well you function (walk/run/participate in sport) two years after surgery.

Why are you asking me to take part?

You are being asked to take part because your doctor believes that either of these surgeries (reconstruction or repair) might be suitable for you. We are asking lots of people from all around the country, aged 14 and older.

Do I have to say yes?

No, you do not. If you decide to say no, nobody will mind. You will be looked after by your doctors and physiotherapists, and together with your parents/guardians, you will decide which is the best treatment to have.

What will happen to me if I say yes?

You will be asked to sign a form online or on paper. This says that you understand the study and what will happen. You will be given a copy of the form to keep, as well as this information leaflet. As you are under 16, your parents/ guardians will also need to sign a separate form. When you reach 16 years of age, we will contact your parent/guardian to check with them that you are happy to continue taking part in the study, and we will ask you to sign a consent form to continue your participation.

We will then ask you to complete questionnaires about your knee and arrange for you to come into hospital for surgery.

We will divide participants into two equal groups, with one group having reconstruction, and the other having repair.

We will learn which surgery you are having by a process called randomisation. A computer picks a surgery for you, completely at random. This will be done at the start of your operation, so that your surgeon can look at your ligament and be sure that it is suitable for either surgery.

Your surgery will be undertaken as soon as possible, but **no longer than 50 days from the date of your injury**.

We will not be telling people which surgery they have had.

Once you have had surgery, you will have physiotherapy to help you in your recovery. Both groups will have the same care before and after surgery.

We will ask you to complete some simple pain scores at three and six weeks after your operation, and more questionnaires at 6, 12 and 24 months after your operation.

At the start of your operation, your surgeon may find that your ACL tear is not suitable for both types of surgery. If this is the case, you will not be randomised, and you will have reconstruction surgery. This means you will no longer be a participant in the study and will not be asked to complete the follow-up activities (pain scores and questionnaires). You will be looked after as normal after your surgery.

Figure 1a. Your journey in the study (Part 1)

What happens if I change my mind?

You can change your mind at any time, and we will stop contacting you about this study. If you do change your mind, please let your doctor or one of the research team know. You do not have to tell us why.

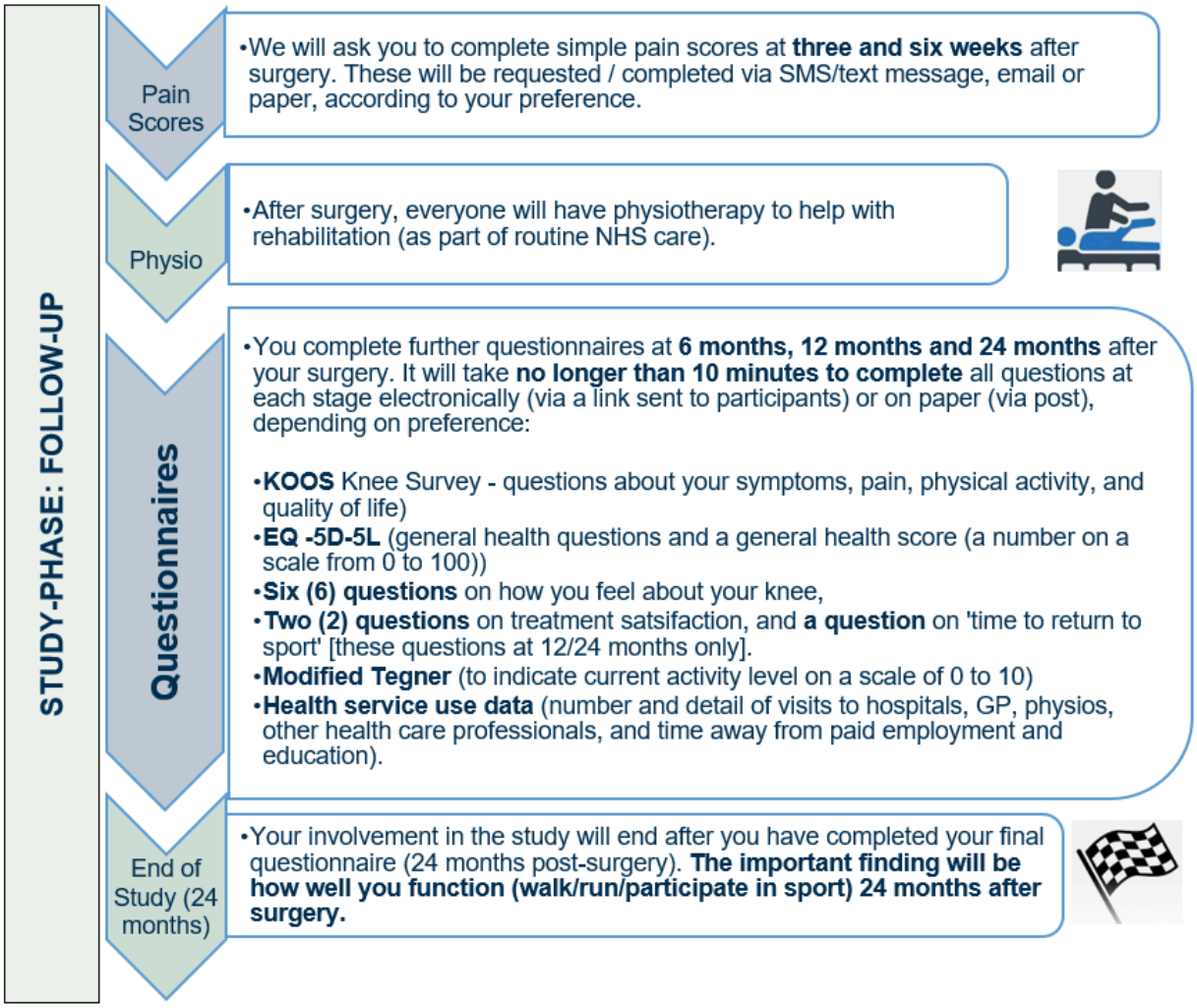


Figure 1b. Your journey in the study (Part 2)

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 and your parent/guardian by the clinical team looking after you in hospital.

Image to be added

Are there any possible benefits from taking part?

Both operations are designed to help reduce the symptoms you are currently experiencing in your knee. Both reconstruction and repair are successful treatments, we are doing the study find out if one is better than the other.

The clinical team looking after you in hospital will discuss the surgery with you and your parent/guardian in detail, so you can decide if it is right for you.

Who will know I am in this study?

You will be given a special identification number and any information that you give us will be linked only to this number. This means that only the people who are treating you, or who need to contact you, will know who you really are. Your name, phone number and your NHS number will be kept safe and secure so no one else can see information about you.

We will tell your GP surgery that you are taking part (if you are randomised into the study). You can tell people too if you would like.

Who is running the study?

Surgeons and researchers are helping to run this study. It is sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge, and being managed by SITU & Oxford Clinical Trials Research Unit (Oxford University). An organisation called the National Institute for Health and Care Research (NIHR) has given us the money to run the study. The NIHR give money to lots of people to help them improve treatments for children and adults in the UK.

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 you have agreed to take part in the study, the data we collect will include your:

- name,
- NHS number (only if your parents/guardians agree to long term follow-up) and
- your/your parent or guardian's contact details.

We 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 (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.

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.

If your parents/guardians agree to us keeping your NHS number to enable long term follow up, using routinely collected NHS data, and to us keeping your name for contacting them about future research, we will keep this information until you are 16 years of age, when we will ask you to sign your own consent form to continue your participation.

How will hospital sites use information about you?

Your hospital will collect information for this research study from you and your medical records, and your doctor will pass these details to the University of Oxford (including a copy of your parent/guardian's signed consent form, if your parent/guardian agreed to contact about future research studies up until you are 16).

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.

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/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: cuh.gdpr@nhs.net
- For University of Cambridge, please visit: https://www.medschl.cam.ac.uk/research/information-governance/, 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 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
- By visiting http://www.hra.nhs.uk/patientdataandresearch

What will happen at the end of the study?

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

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

The results will be shared with other doctors in medical journals and at conferences. Any data that could identify you will not be included in the results.

What if I have questions or there is a problem?

If you have any questions or worries about the information in this leaflet or anything else related to the study, please speak to one of your doctors or nurses. Further details of the study can be found in the parent version of the information leaflet given to your parent/guardian, and is available online at the following address: www.aclstarr.com

Thank you for taking the time to read this information sheet and for considering taking part in the ACL STARR study.