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PARTICIPANT INFORMATION LEAFLET

STRAP ACL: A study testing if adding a strong tape during knee ligament surgery helps people more than surgery without the tape.

You can read this information online at the study website www.warwick.ac.uk/strapacl/public or by scanning the QR code:

Invitation to join the STRAP ACL Study

We are asking if you would like to help us with a research study. Before you say yes or no, it is important you understand what the study is about and what you would need to do.

This document tells you why we are doing the study, what will happen if you join, and what it means for you. You can talk to your family or someone you trust before deciding.

This document is quite long, and that is because we want to give you all the information so that you can make an informed decision on whether you want to take part. If you would prefer a shorter, simpler version, please scan the QR code above.

Why are we doing this study?

The anterior cruciate ligament (ACL) is a piece of strong tissue inside your knee that helps keep it stable. Sometimes, the ACL can tear - this is a common injury, especially in people who play sports or are highly active. If it is not treated, the knee can become weak and wobbly, making it hard to do sports or even normal daily activities.

Doctors can repair the ACL with an operation called ACL reconstruction (ACLR). In this operation, the torn ligament (tissue) is replaced to help your knee work well again. Some people, however, still feel that their knee is weak or wobbly after the operation, or they find it hard to get back to their usual activities.

Surgeons are trying to make ACLR operations work better. One way which may help is adding a strong, man-made tape inside the knee to help the new ligament heal (the blue, dashed line on the image). This is known as synthetic tape augmentation. The idea is that this tape stops the new tissue

from stretching too much and helps protect it - like a seat belt. This is being used more often by surgeons to treat ACL tears.

However, we are not yet sure whether the tape helps, and that is why we are doing this study. We want to look at whether the tape helps patients' knees heal better, and if there are any limitations to this, for example the age of the patient and their activity levels. We also want to look at whether the tape is worth the extra cost to the NHS.

In the STRAP ACL study, patients who have an ACL tear and are going to have ACLR surgery, will receive their usual NHS care, either **with or without the tape.**

Why am I being asked to take part in this research study?

We are asking if you would like to take part in this study because you have had an ACL tear and are going to have surgery to repair this.

You can join the study if:

- You are 16 years old or older
- You have a torn ACL and need an operation to fix it
- You can sign a form to say you want to take part
- You are okay with filling out online questionnaires. These will be in English.
- You are not, or haven't been in the past, a professional or semi-professional sports person
- You have not already joined this study for your other knee.

We are hoping that 318 patients join the study.

Do I have to take part?

No. You can choose if you want to be in this study or not. It is up to you. If you say no, it will not affect the quality of care you receive. This may be the same as the treatment you would have received by taking part in the study.

Even if you change your mind after completing the consent form, you can withdraw at any time without giving a reason - just tell your doctor, call the STRAP ACL team on 02476 528046, or email strapacl@warwick.ac.uk.

What will happen if I decide to take part?

Consent:

If you want to join the study after reading this document, you will be asked to say yes by signing a consent form at the hospital or say yes on a video call with the research staff at the hospital. You will get a copy of this document and the consent form to keep. If you are aged 16-17, we will ask if a guardian would like to sign this too. This is optional.

When you come in for your operation, we will check that you still want to take part. If you do, you will be randomised into the study and receive your surgery with or without the tape.

Being randomised:

This means that a researcher will put your details into a computer and it will select at random which group you go into (tape or no tape). You and your doctor cannot pick the group. Being randomised helps us make sure the study is fair.

You will not be told which group you are in or which treatment you had after your operation. This also helps keep the study fair. If people know what treatment they had, it might change how they feel or act, even if the treatment didn't really change anything.

After your operation, you will follow your hospital's usual recovery plan to help your knee get better.

Study questionnaires:

We will ask you to fill out some online questionnaires before your operation, and again at 3, 6, 12, and 18 months after your operation. Each one takes about 20 minutes to complete. These questions help us understand how your knee is doing, how you feel, and if there are any problems.

18-month appointment:

At around 18 months after your surgery, we'll ask you to see your hospital's research team for a simple knee check called a pivot shift test. This is a routine test often done for people who have had ACL injuries and it helps the team assess how stable your knee is.

Whether this means an extra hospital visit depends on your hospital's usual follow-up schedule:

- Some hospitals already bring patients back at 18 months, so the test can be done during that routine appointment.
- Other hospitals normally see patients at 12 months instead, so in those cases you would need another visit at 18 months for this test.

Contact from the STRAP ACL study team:

We will contact you during the study to ask you to fill in your study questionnaires. If you do not complete the questionnaires, we will send you reminders to finish these. If we don't hear from you, we may also ask your next of kin to remind you to fill them in, so you will need to check that they are happy with this and provide some contact details for them and let them know you have done so. You can link them to the Data Information Leaflet via the QR code above where they can read about how we will use their data.

We will usually contact you by text or email, but may also get in touch via phone or post.

We will also send you participant newsletters to keep you up to date with the study, and a link to the results at the end of the study.

After the study has ended, we will make a copy of the study results and a lay summary available on the study website and send you a link to this.

How long does the study last?

The study is due to run until 2029, but you will be part of the study for just over 18 months. During your time in the study, you will have your surgery, fill out your questionnaires and visit the hospital either as a routine appointment or as an additional visit for your pivot shift test.

There is a possibility that we will contact you again in the next 20 years to see how your knee is doing.

What are the benefits of taking part in the study?

This is a research study; it might help you, or it might not. **What we learn from the study could help other people with knee injuries in the future.**

You will not receive payment to take part, but we will pay you for your time in the form of vouchers. You will receive a £15 voucher at baseline (before your operation) and at the 3, 6 and 12-month follow-up timepoints after your operation.

We will try to plan your study visits at the same time as your regular hospital check-ups, so you don't have to make another visit. However, you may need to make an additional visit to the hospital at 18 months. You will receive a £25 voucher at the 18-month timepoint, and this larger amount factors in the possible additional visit and any costs incurred with this (e.g. hospital parking).

What are the disadvantages or risks of taking part in the study?

Both types of operations (with tape and without tape) are normally done in NHS hospitals. Joining the study doesn't make your treatment riskier, because you are getting the standard care for your ACL.

If you get put in the group of participants to receive the tape, you will receive a tape that is already used in the NHS. The tape will have a CE mark, which shows that the manufacturer has checked the product meets health and safety requirements and shows that it follows the law and is allowed to be used in the UK.

What if something goes wrong?

There are no special compensation arrangements. The University of Warwick will arrange appropriate insurance for this study. If you are harmed due to someone's negligence, depending upon the problem, you may have grounds for legal action, but you may have to pay for it.

Depending upon the problem, NHS bodies are legally liable for the negligent acts and omissions of their employees. The University of Warwick has insurance cover in the unlikely event of you being harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team.

Non-negligent harm by NHS staff is not covered by the NHS indemnity scheme.

Who should I contact if I wish to make a complaint?

If you have any concerns about any part of this study, you can contact the researchers at your hospital:

Insert hospital research team contact details.

You can also seek independent advice from <insert local Patient Advice and Liaison Service and contact number or relevant local contact> or follow the NHS complaints procedure in your country.

If you remain unhappy and wish to complain formally, you can do this by contacting the person below, who is a senior University of Warwick official and is independent of this study:

Associate Director of Research Culture, Research & Impact Services

University House, University of Warwick

Coventry, CV4 8UW

Email: researchgovernance@warwick.ac.uk

Telephone: 02476 575733

Can I change my mind and stop being in the study?

Yes, being in the study is your choice. You can stop at any time, and you don't have to say why. We will still keep the information we already have about you.

If you decide that you don't want to receive questionnaires anymore, we may still ask your hospital for updates about your health. If you don't want that either, just tell us and we will stop.

If you leave the study, it won't change the care you get at the hospital.

In the unfortunate event that you lose capacity during your time on the study, you will be withdrawn from the study, and any data collected up until that point will be retained and used.

Will my taking part in this study be kept confidential?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study.

We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

In most cases, the information we share will be anonymised or pseudonymised, which means it will not include your name or details that directly identify you.

At the end of the trial, we may make data available for commercial and non-commercial use. This will not include your name or details that directly identify you.

There is a separate Data Information Leaflet that you should read before deciding if you would like to take part. You can find this by scanning the QR code at the top of this leaflet.

Who is running and paying for the study?

The University of Warwick is in charge of the study. The Warwick Clinical Trials Unit is helping to run it, and this is part of The University of Warwick.

The study is funded by the National Institute for Health and Care Research, Health Technology Assessment (NIHR172043).

Who has checked the study?

People who have had ACL surgery helped plan this study and have reviewed documents, such as this one.

Any research that involves the NHS and patients is reviewed by an independent group of people called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and been approved by the South Central – Oxford A Research Ethics Committee.

Who can I talk to if I have more questions?

If you have any questions now or later, you can talk to your local research team:

[local research contact details].

Alternatively, please contact the STRAP ACL study team at the University of Warwick by emailing us at strapacl@warwick.ac.uk.

Thank you for thinking about joining this study.

We really appreciate your time and interest.

UNIVERSITY OF WARWICK

NHS University Hospitals Coventry and Warwickshire NHS Trust

NHS Cambridge University Hospitals NHS Foundation Trust

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