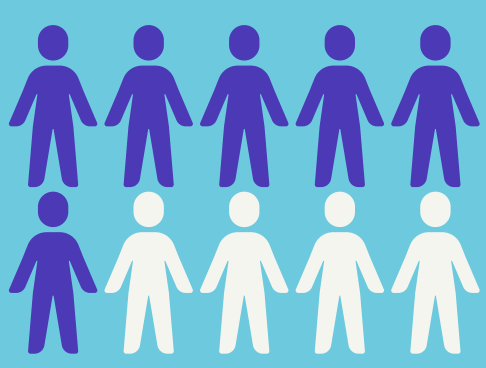
Participant Information Sheet

Study title:
Meniscal Transplant Surgery or Optimised Rehabilitation Study

Chief Investigators: Mr Andrew Metcalfe & Mr Tim Spalding

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.



FUNDED BY NIHR | National Institute for Health and Care Research

Information about the trial

Background Information

The meniscus is a firm rubbery curved structure in the knee. There are two of them in each knee, sitting on the edge of the joint.

One of the roles of the meniscus is to cushion impact and protect the joint from wear.

Tears of the meniscus are a common injury, and removing some meniscus (a meniscectomy) is a common operation.

After this operation, most people's pain and symptoms improve over time. But for some people, the pain and symptoms get worse.

At present, there are various treatment options for people who have pain after a previous meniscectomy

Possible treatment options include:

Personalised knee therapy (physiotherapy, sometimes bracing, advice on work or activities and how to improve pain; may also be known as optimised rehabilitation)

An operation to insert a replacement meniscus taken from someone who has died, this is known as a 'meniscal transplant'

Information about the trial

What is the purpose of this study?

We do not know whether this problem is best treated with personalised knee therapy or surgery to replace the meniscus. Both could improve your pain and restrictions.

Personalised knee therapy and advice can strengthen your knee muscles, reduce pain and improve movement in day-to-day life. There are studies for many similar knee problems to show that patients who have personalised knee therapy have good outcomes.

Meniscal transplant is thought to improve pain and activity by replacing the lost meniscus and providing cushioning to the joint surfaces. There is information from studies showing that people who have a meniscal transplant have good improvements in pain and function and it appears to be safe. However, it has a long recovery period and the operation carries risks associated with surgery.

Right now, doctors do not know whether a meniscal transplant is better or worse than personalised knee therapy (in other words specific physiotherapy and optimised rehabilitation). There is not enough evidence for either treatment in people with this problem at present. In this study, we will answer this by comparing the two treatments so we know which is best for people like you.

Study design

Study lead and supporting team

This research will be led by:

Mr Tim Spalding
Co-Chief Investigator

A consultant knee surgeon at University Hospital of Coventry and Warwickshire. He has extensive clinical experience managing patients with post-meniscectomy pain both surgically and non-surgically.

Mr Andrew Metcalfe
Co-Chief Investigator

A consultant knee surgeon at University Hospital of Coventry and Warwickshire and Associate Professor at the University of Warwick Clinical Trials Unit. He has expertise and experience of leading studies like this, that compare different treatments to work out which is best.

and managed by a team at Warwick Clinical Trials Unit.

The team include some of the most internationally-recognised experts in physiotherapy, surgery, trials, statistics and health economics as well as our patient partners.

The study will take place in 12 NHS Trusts across the United Kingdom and internationally, in Belgium, Canada and Australia. Hospitals taking place will have a lead consultant knee surgeon who will be a supporting member of the trial team.

Who is organising and funding the research?

This research has been organised by the University of Warwick. It has been funded by the UK NHS research body, the National Institute for Health Research.

FUNDED BY NIHR | National Institute for Health and Care Research

WARWICK CLINICAL TRIALS UNIT

Study information

Why have I been invited?

You have been invited to take part as you have been identified by your medical team as you have knee pain after previously having some meniscus removed from your knee.

The person treating you thinks that your symptoms might be improved by personalised knee therapy, or by an operation to insert a donor meniscus.

In total, 144 patients, from across the UK and overseas, will be involved in the study.

Do I have to take part?

No. Participation in this study is completely voluntary and choosing not to take part will not affect you in any way. You can also choose to withdraw your participation without giving a reason by contacting one of the research team.

A decision to withdraw at any time will not affect the care you receive.

If you have a strong preference for one treatment or another, you do not have to take part and can speak to the team at your hospital about the best treatment option for you.

Further details about withdrawing from the study are provided later on in this document.

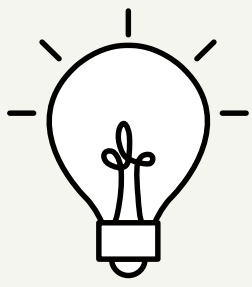
What will happen if I take part?

If you decide to take part you will be asked to sign a consent form. In order to make our study work, it is crucial that we have equal numbers of participants in each treatment group.

To ensure this is fair, a computer will decide at random which treatment you will have.

Whichever treatment you have, your care will be based on meeting your individual needs and you will continue with the same team of healthcare professionals.

Study information



Before your treatment

You will be asked to complete a questionnaire about your knee and your general health.

Follow-up

You will be contacted by the study team at 3,6,12,18, and 24 months, after joining the study. If you do not receive your treatment within six months of entering the study, we will ask you to re-do several questionnaires a few weeks prior to your treatment starting.

At each of these time points, you will be asked to fill in a questionnaire. You can do this electronically via an App, over the phone, or by completing a paper version of the questionnaire and posting it back to us in a freepost envelope.

If you prefer to do questionnaires via the App we will provide your phone number and email address to the app developers so they can enable the app to send you reminders to complete questionnaires. Your contact details will not be used for any other reasons.

If you agree, we will send you a text message or email to remind you that a questionnaire is due.

If you need help completing a questionnaire a researcher can contact you by phone to help you. Patient travel at baseline, 12 and 24 months will be reimbursed.

Which treatments?

If you are allocated to the Personalised Knee Therapy group: you will receive a knee therapy course that has been specifically designed to treat people with this problem. This is a essentially optimising your rehabilitation.

Expert physiotherapists have developed a personalised rehabilitation programme so that you will have the best chance of improving your knee. Instead of a standard set of exercises, each therapy course will be unique to you, as it will be tailored to your needs by a senior physiotherapist. You will be assessed in a one-to-one visit by a senior physiotherapist at <<site name>>, to design a treatment plan.

Study information

If you would benefit from braces or any other device, we will recommend and help organise this for you.

On-going treatment will remain at the specialist hospital, or if this is a long way from your home, we will send instructions for your treatment to a hospital closer to you.

OR

If you are allocated to the meniscal transplant group:
then you will be placed on a waiting list for an operation at <<site name>>.

The operation itself is either done using keyhole surgery, with small cuts over the knee, two that are 2-3cm, and two that are 1cm, or through a small open incision of around 8-10cm. Once inserted, the transplant will be held in a position by strong stitches. The new meniscus is from someone who has died recently, they are carefully checked to ensure they have not had any diseases, and no one is known to have ever caught a virus from a meniscus transplant.

After surgery, you will be given crutches to help you walk and then will have some physiotherapy to help you recover from the operation. After six-eight weeks you will be able to put weight on your leg.

Both treatments will be subject to NHS waiting lists. The wait for a meniscus transplant can be variable, even in places with normally short waiting lists, as the surgeons have to wait for a transplant of the right size to be available. This can be quick or it can take many months.

Are these new treatments?

Both of these treatments are already used within the NHS. However, it is important to perform research that compare one type of treatment to another so that we can offer the best possible treatment in the future.

Further information

What are the possible disadvantages and risks of taking part?

There are no other special risks over and above what your doctor would normally inform you about.

There are risks with meniscal transplant surgery, including surgical risks of tearing the new meniscus, persistent knee pain, infection and blood clots, but these are the same risks for patients that do not take part in the study. The risks of the operation will be discussed in more detail with you by the clinical team who are looking after you in hospital, as part of your consent to treatment.

The risks associated with personalised knee therapy are also the same for patients that do not take part in the study. These may include temporary muscle soreness from exercise.

A knee brace may be offered as part of both personalised therapy and they are routinely used in recovery from surgery. They may provide good pain relief and are important after surgery to protect the recovering tissues. They may be uncomfortable or inconvenient.

The personalised knee therapy programme is likely to be a shorter wait compared with surgery. We do not know which treatment would give a better improvement in the long term, that is what this study is trying to find out.

What are the possible benefits of taking part?

There are no specific benefits to taking part. Both treatments are designed to help reduce the symptoms you currently feel in your knee. By taking part in the trial, you are helping to decide about the best treatment for people in the future.

What happens when the study ends?

You will be in the study for 24 months . If you are still having problems after this, we will arrange for you to have an appointment with a specialist to assess your ongoing care. When we have enough people in the study to answer the question, we will stop entering new people into the study. If you have consented but the study ends before you have had your operation, your surgeon will decide what treatment option may be best and offer that to you.

Further information

What if new information becomes available

Sometimes during the course of the research project, new information becomes available about the treatment that is being studied. If this happens, your consultant will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your surgeon will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

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

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick Official, entirely independent of this study:

Deputy Director/ Head of Research Governance

Research and Impact Services
University House
University of Warwick
Coventry
CV4 8UW

Tel: 02476 575733
Email: *researchgovernance@warwick.ac.uk*

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our responses or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)

Further information

Who has reviewed this study?

This study has been reviewed and given favourable opinion by (Add ethics details). It has been reviewed by numerous experts throughout the United Kingdom and by the National Institute of Health Research (NIHR). It has also been reviewed by an independent steering committee who oversee this study.

Will my taking part in this study be kept confidential?

The University of Warwick is the sponsor for this study, based in the United Kingdom, and will act as the data controller. This means that the University of Warwick are responsible for looking after your information and using it properly.

The University of Warwick will keep identifiable information about you for a minimum of 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Please follow the link below to find out how the University of Warwick handle your personal data processed in connection with the study:
https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice

You can also find out more about how we use your information and privacy statement can be found at:
<< insert trial website>>

Hospital sites will collect information from you and your medical records for this research study in accordance with our instructions. Hospital sites and the University of Warwick will use your name, contact details and next of kin contact details to contact your about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Warwick and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Hospital sites will pass these details to the University of Warwick along with information collected from you and your medical records.

Data management

The only people in University of Warwick who will have access to information that identifies you will be people who need to contact you to follow up on the progress of your recovery, contact you regarding questionnaires or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details however IT administrators will have access to this information. NHS sites will keep identifiable information about you from this study for a minimum of 10 years after the study has finished.

The data controller for this project will be the University of Warwick. The Information and Data Compliance Team at Warwick will provide oversight of activities involving the processing of personal data, and can be contacted via gdpr@warwick.ac.uk. The Data Protection Officer for the University of Warwick is . Your personal data will be processed for the purposes outlined in this notice. The legal basis that would be used to process your personal data is Article 6(1b) a task in the public interest.

In addition to the legal basis for processing personal data, the University of Warwick must meet a further basis when processing special category data, including: racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, data concerning health, data concerning a natural person's sex life or sexual orientation. The basis for processing your special category personal data is Article 9(2j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

If you agree to take part, your GP and other doctors who may treat you, but are not part of this study, may be notified that you are taking part in this study.

University of Warwick will collect information about you for this research study from your medical records. This information will include ethnicity, race and health information, which is regarded as a special category of information. We may use this information for future research.

What will happen to the results of the research study?

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. Once all participants have been followed up and the results analysed, we will make a copy of the study results available which will outline what was found during the study and make them available for you by post via an end of study letter and by listing it on the trial website.

Data management and next steps

What if something goes wrong?

In the event that something goes wrong and you are harmed during the research due to someone's negligence, then you may have grounds for legal action for compensation against the University of Warwick. Claims may also be made against the responsible NHS Trust in cases of negligence.

Contact: Head of Research Governance
Address: University of Warwick, Research & Impact Services, University House, University of Warwick, Coventry, CV4 8UW.
Email: researchgovernance@warwick.ac.uk
Telephone: 02476 575733

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital and GP. If you do not want this to happen, tell us and we will stop.

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

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

- at www.hra.nhs.uk/information-about-patients/ and www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to <<add address>>
- By ringing us on: <<insert number>>
- Contacting the University of Warwick's Data Protection Officer on: DPO@warwick.ac.uk.

Contacts for further information

If, at any time, you would like further information about this research project you may contact your local Research Team on <<local research contact details>> or email METEOR2@warwick.ac.uk

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