RACER

Robotic Arthroplasty:
A Clinical and cost Effectiveness
Randomised controlled trial

PARTICIPANT INFORMATION SHEET

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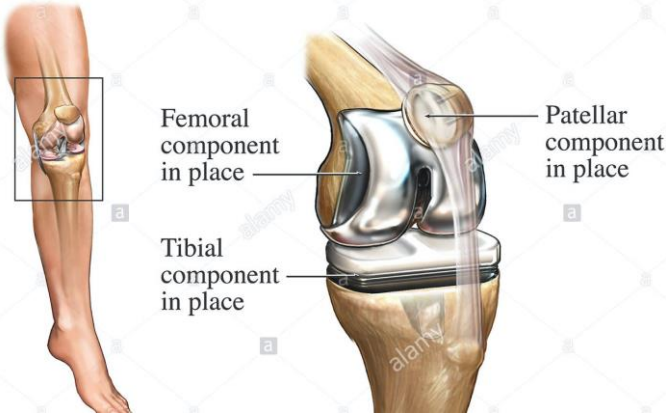
Introduction

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.

What is the study about?

Knee arthritis is a painful condition which can limit people's activities. When knee arthritis is very bad, it can be treated with a knee replacement. These operations are often very successful at reducing pain and improving the amount of activity someone can do. They can be painful in the few weeks after the operation, and many people still have some knee symptoms, even some time after surgery.

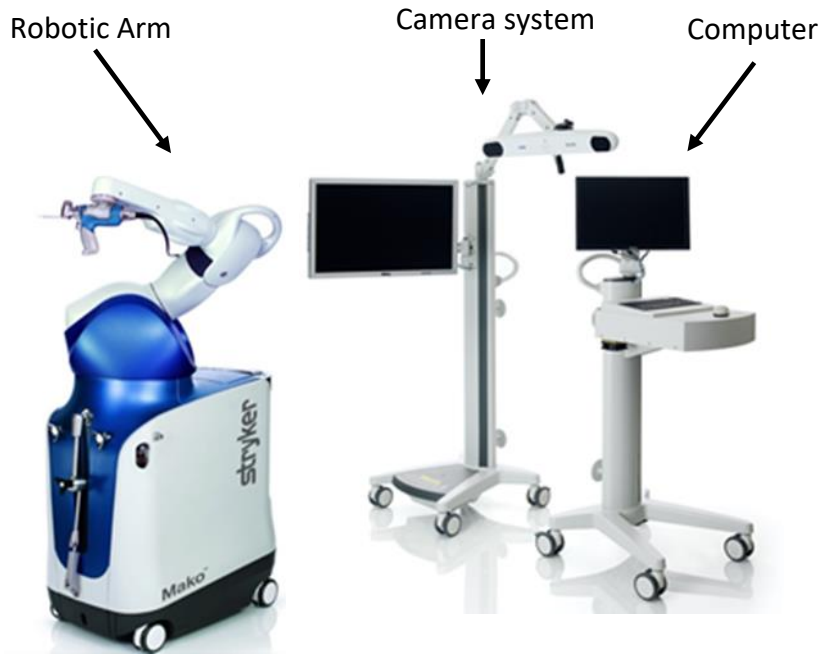


Picture 1. A knee replacement

Knee replacements have for many years been put in by surgeons using their experience and skill, with a standard set of instruments. These are instruments that knee surgeons are very familiar with, and they have learned how to use them to get the best results. This is the way that the majority of surgeons perform knee replacements.

Some surgeons have started using a robotic arm to help them

perform a knee replacement. The robotic arm is held by the surgeon during the operation and the surgeon always remains in control. The robot helps move the instruments into the correct position by sensing the position of the leg.



Picture 2. The parts of a robotic system for knee surgery

People who believe that standard instruments are better think that the operation is quicker and simpler without the robot. They argue that they can make decisions and cut the bone with the same amount of precision and without the added expense of a robot. People who think the robot is better believe it makes them more precise, and that

they can get a better result using the guidance provided by the robot.

No one yet knows if using the robot to help perform a knee replacement is any better or worse than performing a knee replacement with standard instruments.

What is the purpose of this study?

We will look at which operation is best at reducing pain in the days after surgery. Then we will find out which operation results in better movement, strength, and quality of life in the long-term. We will also find out whether the use of the robot is worth the additional cost.

Why have I been invited?

You have decided to undergo a knee replacement. Your surgeon believes that your best treatment option is a total knee replacement. Your surgeon and their team are helping us to find out whether using a robotic system is better than standard instruments.

What would taking part involve?

The way for us to find out which of the two treatments options is better than the other is to carry out a randomised controlled trial. This study is a randomised controlled trial.

In order to make our study work we need to have equal numbers of participants in each treatment group. To ensure this is balanced and fair, a computer will decide at random which operation you will have. This will be done on the day of surgery. Your surgeon will not be able to influence this decision.

To make the comparisons fair between the two operations, we will not tell you which operation you have had until the end of the study. Approximately three years after your operation (once the results are published), we will send you a summary of our findings and tell you which group you were in.

People having a robotic-assisted operation will have two 1cm incisions towards the top of the shin. People having the standard operation will also have these two additional 1cm incisions (even though they will not be used). This is to ensure that people in the study do not know which group they are in. These are very low risk and will not affect your recovery. Some surgeons use a slightly longer incision for the knee replacement instead of these extra incisions. If so, they will do the same whether you have the robotic-assisted operation or not. Therefore, the incisions you have on your leg will be the same whichever type of surgery you have.

The same implants will be used whichever treatment arm you are in, these will be the 'Stryker Triathlon' implants cemented into the bone, which have been widely used in the UK for over a decade with good results and are popular with surgeons. More information on the procedure and the operations is included below.

Before your surgery

If you decide to take part, you will be asked to sign a consent form. If you are unable to sign the consent form in person, the research nurse or clinician will book a telephone or video call with you to explain the study processes and confirm that you agree to participate. This phone

call will be witnessed by someone from the NHS staff, and we will document your decision in your medical notes.
You should only give consent if and when you are happy to take part.

After you have signed the form, you will be asked to fill in a questionnaire about you and your knee, and how it affects your life. It takes 10-15 minutes to complete. A trained member of staff will assess how much movement you have in your knee.

CT scan and X-rays

In a separate visit, before the operation, your surgical team will organise a scan called a CT scan. This will be performed on every person who takes part in the study, whether you have the robotic surgery or not. Due to pressure on capacity in the NHS, it is possible that your CT scan will be booked at another centre. Your surgeon or research nurse will be able to provide you with the details of the location where you will have your CT scan.

Everyone's bone positioning is a little different, so the scan is used to make a plan to best fit the knee replacement to your bones.

The scan is performed with your knee in a CT scanner which is shaped like a narrow 'doughnut' (see picture 3). A short scan of your hips and ankles is also performed. The rest of your body will be outside of the scanner, so it does not feel like being in a small space, but it can be a little noisy.

In order to plan the surgery using specialist planning software, the images will be sent outside of the European Union (EU) to the

company that supplies the robot (Stryker, USA). These images will contain at least two identifiers (for example, your name, hospital number or date of birth), but these will only be seen by employees of Stryker to plan your operation and will not be shared with any other party.

This scan would not normally be needed for people who have a standard knee replacement, but it is needed for people who have the robotic surgery. As part of the study, you will also have a short CT scan of the knee and x-ray of the whole leg three months after the operation. Also, for this appointment it may be that due to pressure on capacity in the NHS, it is possible that your CT scan will be booked at another centre. Your surgeon or research nurse will be able to provide you with the details of the location where you will have your CT scan. The trial office will post you a £5 shopping voucher to compensate for any expenses related to the attendance to this appointment. All other x-rays you have will be part of your normal care.

Because of this, you will have a slightly higher dose of radiation to your body than if you did not take part in the study. The risk from this radiation is very low. The normal risk of getting life-threatening cancer at some point in life is 50%. With this study it increases to 50.03%.

Picture 3. A CT scanner.

On the day of the operation

When you come into hospital, but before your surgery, a member of staff will check with you whether you are still happy to take part.

Whichever treatment you have, your care will be based on meeting your individual needs, and you will continue with the same team of surgeons and healthcare professionals. All surgeons involved in the study are very experienced and have been trained on the robotic system.

All of the care you receive, except for the decision about whether to use the standard instruments or the robot, will be the same throughout. You will receive the same high-quality care as any other patient.

During the operation

You may or may not see robot equipment in theatre. Equipment may be wheeled in or out so this will not indicate which type of surgery you are getting. If the robot is used for the operation, it may take 10 or 15 minutes longer than it would with standard instruments.

A representative of the company that makes the knee replacement and robotic system and possibly another surgeon may be in theatre during the procedure to provide technical advice. This is a normal and often necessary part of delivering the surgery safely.

Images of the computer screens used during surgery are routinely saved as a hospital record, this does not include pictures of you, but it does include pictures of your scans. For this study, a copy of the images of the computer screens will be sent to researchers at University Hospitals Coventry and Warwickshire, and The University of Warwick.

After the operation (in hospital)

On the day after the operation, and for the following two days, a member of staff will come and ask you about the pain you feel in your knee. If you leave hospital before the third day after your operation, we will give you a form to fill in at home, or we will telephone you at home to ask how your pain is.

We will review your medical notes after you have left to find out how many painkillers or other treatments you received. We will use your blood test results to work out how much blood you have lost, and we

will take details about the operation and any other relevant treatments you received before or after the knee replacement.

After the operation (follow-up)

You will be given a discharge booklet (including advice and exercises) which explains what you will have to do after the operation. If the surgical or physiotherapy team treating you think you need to see a physiotherapist after the surgery, they will organise this for you. If not, they will give you exercises to do yourself. We have prepared a special booklet to help you with that and guide you through the recovery.

You will receive a very short questionnaire whilst you are in hospital, six weeks after the operation and further questionnaires to fill in 3, 6 and 12 months after the operation. We will also send you follow-up questionnaires two years, five years, and 10 years after the operation. We will ask you to post them back in the freepost envelope provided if for any reason you are not using the mobile app. The questionnaires are very important to know how you are doing.

The RACER researchers are looking into using a mobile phone app as an option for those participants who prefer to use it to complete the questionnaires. We will need to provide your phone number to the app developers so they can enable the app to send you reminders to complete your questionnaires. Your phone number will not be shared for any other purpose.

If you need help filling any of the questionnaires in or using the mobile application, please let us know. If you agree, we can send you a reminder that the questionnaire is due, based on the contact information that you give us. A researcher might also contact you by phone to help you complete the questionnaires or may talk to you in clinic.

You will be invited to attend for an x-ray of the leg and a CT scan of the knee, three months after the operation. More details are given in the 'CT and X-ray' section above.

You will be seen by your surgeon or their team at various times during the recovery period and will have a planned visit one year after the surgery to assess your progress and measure your knee movement. If you have not filled in the postal questionnaires, we may also ask you to do so when you come to clinic. The trial office will post you a £5 shopping voucher to compensate for any excess expenses related to this visit.

Information about the two types of surgery being tested

Knee replacement with standard instruments

Your surgeon will use their normal approach to perform a knee replacement and will be allowed to make whatever adjustments they think they need to get the best result for you. They will perform this using their usual instruments, as they would for any standard knee replacement, using the experience and skill they have built up in their clinical practice. All of your care will be to the same high standard that anyone else would get in the hospital in which you are treated.

Knee replacement using the MAKO robotic system

The robotic system we are testing is the Stryker MAKO system. This is the most widely used robotic knee replacement system at present. It has been used many thousands of times, in the UK and abroad, and we can be confident it is safe. It has a CE mark and is licenced for use in the UK.

The surgeon starts the operation, and inserts some pins into the bone, at the top of the shin, often through two small (1cm) incisions. The pins are used to show the computer where the bones are. The surgeon then performs the operation as usual, but instead of using their normal instruments, they use a robot to guide where they cut the bone, making whatever adjustments they think they need to get the best result for you. They will then insert the knee implants with cement in the normal way.

For NHS patients in your hospital, the surgeons are only allowed to use the robot to perform total knee replacements for people who are taking part in the study. You will not be able to request the robotic surgery outside of the study.

Cleaning the robotic system

The robotic system includes cutting tools which are single use only, so they get replaced after each operation. The parts of the robot that are in the surgical area are sterilised. The large base of the robot is covered in a special sterile plastic drape which means that it does not actually touch anything during surgery.

Do I have to take part?

No, it is up to you whether or not to take part. You can choose to withdraw your participation at any time, without giving a reason and it will not affect you or your medical care in any way.

What are the possible disadvantages and risks of taking part?

There are general risks with any operation. When having a knee replacement, it is normal to get some early pain, swelling, bruising and some drowsiness or sickness from painkillers. Numbness over the knee and some stiffness is also normal. Risks of having a knee replacement include continued or worse pain, infection, wound problems, stiffness, need for further surgery including redoing the knee replacement, blood clots in the leg or lung, death, or injury to structures around the knee such as nerves or vessels.

The additional risk from taking part in the study is very small. The pins in the bone used by the robot could rarely cause a fracture of the bone, but this is thought to be rare (less than one in every 1,000 cases). The radiation dose from the scans in the study are described in the CT section above, it is very low risk.

What are the possible benefits of taking part?

Both the standard and robot-assisted knee replacement surgeries are carried out within the UK. However, it is not known which provides the best outcome for patients both physically and in terms of well-being. Nor do we know whether the robot is worth the additional cost. By taking part in the trial, you are helping to decide about the best treatment for people in the future.

What if new information becomes available?

Sometimes during the course of a study, new information becomes available about the treatments that are being studied. If this happens, someone will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, you can discuss your continued care with your doctor. If you decide to continue in the study, you might be asked to sign an updated consent form.

What happens when the research study ends?

You will be in the study for two years, although we will contact you at five and 10 years after the operation as well. If you are having any problems with the knee either after this time, or before, your general practitioner can refer you back to hospital to continue your care.

The study will continue until we have enough people taking part. We expect this will take around 18 months. If you have consented but the study ends before you have had your operation, your surgeon will decide what operation is best and offer that to you.

Will my taking part in this study be kept confidential?

University Hospitals Coventry and Warwickshire, and The University of Warwick are the sponsors for this study. The University of Warwick will act as the data controller and will be using information from you and your medical records in order to undertake this study. 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 make sure we minimise the amount of personally identifiable information we use. The University of Warwick has in place policies and procedures to keep your data safe.

This data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project. For further information, please refer to the University of Warwick Research Privacy Notice which is available here:
https://warwick.ac.uk/services/sim/privacynotices/research/

or by contacting the Information and Data Compliance Team at DPO@warwick.ac.uk

Relevant information from you and your medical records (e.g. medical history and images) will be collected by your NHS site for this research study in accordance with our instructions. Your NHS site will use your name, NHS number, hospital number and contact details to contact you 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.

The information collected from you and your medical records, by your NHS site, will be securely passed to the University of Warwick. The only people in the University of Warwick who will have access to information that identifies you (name, NHS number, hospital number, contact details and additional contacts information) will be people who need to contact you to remind you to complete study questionnaires, to follow-up with you about any missing information or to audit the data collection process. The University of Warwick will keep the contact information you provide for the full duration of the follow-up period. Your additional contacts personal data will not be shared or disclosed to any third parties external to the University of Warwick.

Some of your personal information, which may include your postcode, date of birth and NHS number may be used for linking with other NHS datasets including NHS Digital and other Central UK NHS bodies to find out what has happened to you and your knee in the future. These data will all be handled in the strictest confidence in line with GDPR and the Data Protection Act 2018 and to the high standard expected of all NHS bodies.

Individuals from University Hospitals Coventry and Warwickshire, and The University of Warwick regulatory organisations may look at your medical and research records to check the accuracy of the research study.

When you agree to take part in a research study, confidential information (which does not identify you in any way) about your health and care will be stored and may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Your NHS site will keep identifiable information about you for this study for a minimum of 10 years after the study has finished.

Access to identifiable data will be restricted to authorised personnel only.
All of your data will be handled with full data security measures and will not be shared outside of the study team.

Data sharing between organisations, including universities, NHS organisations, or medical companies, is important and helps improve the care we give to patients. It allows us to improve technology and care for the future along with stopping unnecessary repetition of studies. We are, however, very careful with the data we hold about

you and will only share fully anonymised data, that does not identify you in any way, unless we have your full permission otherwise.

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. If we are not able to keep in touch with you, we may contact your GP in the future to collect your health records, so we know if you have had any problems related to the operation.

What happens 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 (contact the Head of Research Governance, Impact Services, University House, University of Warwick, Coventry, CV4 8UW or by email: researchgovernance@warwick.ac.uk or telephone: 02476 522746).

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:

Head of Research Governance
Research & Impact Services
University House

University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

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 response 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).

For independent advice contact the Independent Advice Service/PALS service (Patient Advice Liaison Service) on <<local PALS or patient liaison contact number>> or follow the NHS complaints procedure in your country.

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. If you would like to obtain a copy of the published results, please contact the study manager by emailing: RACER@warwick.ac.uk

Who has reviewed this study?

This study has been reviewed and approved by the XXX Research Ethics Committee and the Health Research Authority. 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.

Who is organising and funding the research?

This research has been organised by University Hospitals Coventry and Warwickshire, and The University of Warwick. It has been funded by the UK NHS research body, the National Institute for Health Research, through its Health Technology Assessment Programme.

Stryker, the manufacturers of the robotic system have agreed to meet the additional costs of robotic surgery within this study. They will not be involved in the analysis or interpretation of the study findings.

Contacts for further information

If, at any time, you would like further information about this research project (HTA Project: NIHR128768) you may contact your local Research Team on <<local research contact details>> or email the study coordination team via: RACER@warwick.ac.uk

RACER - OPTIONAL DATA SHARING INFORMATION

The data we collect in the RACER study include your CT scans, as well as data collected by the robot during surgery and questionnaires about your health. If you agree, the University Hospitals Coventry and Warwickshire and the University of Warwick may share these data with the company that makes the robots (Stryker Orthopaedics), who may pay the hospital and university for providing this data. Stryker will only use your data for future research and development purposes (e.g. developing new and existing instruments, knee replacement products and software), outcome studies and related publications aimed at improving patient care, this will provide commercial benefits for them. They will not use your information to contact you or sell you their products or services.

There are clear legal agreements between Stryker, the University Hospital of Coventry and Warwickshire and the University of Warwick to protect your identity and your personal information will always be held confidentially in accordance with GDPR, these protections will remain even if data is transferred outside the EU, such as to the USA. Whilst they will already have received your CT scans for the purposes of planning the surgery (and could theoretically link the scans to your information) we will have strict contracts in place to ensure this does not happen,

On the Consent Form, there is a specific question about whether you are happy for additional details to be shared with Stryker Orthopaedics. This is optional, and you may still participate in the RACER study if you do not agree to the sharing of your data.

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