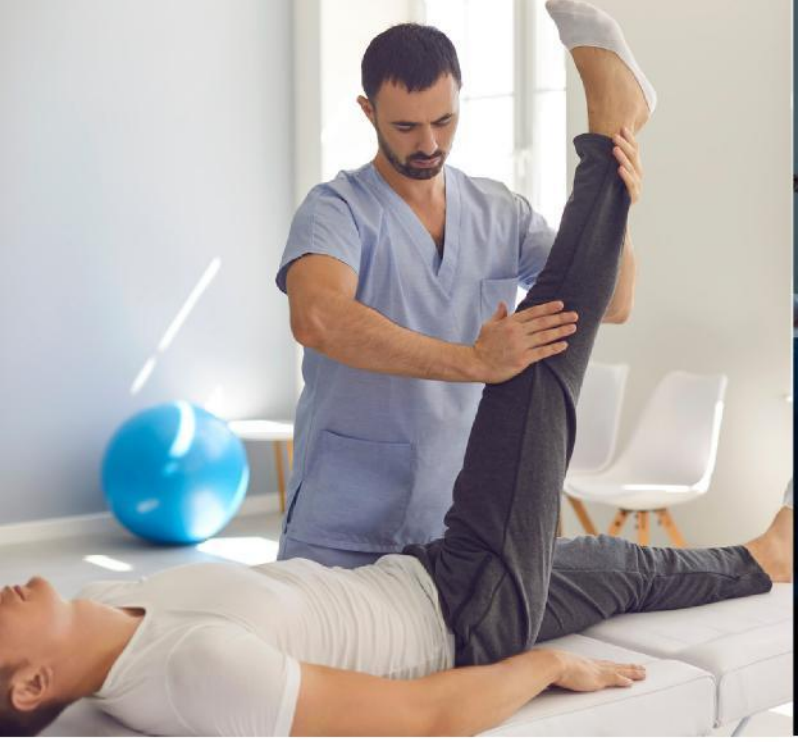

REPPORT

RECURRENT PATELLAR DISLOCATION:
PERSONALISED THERAPY OR OPERATIVE TREATMENT?

Participant Information Sheet

Study title:

REcurrent Patellar dislocation: Personalised therapy or OpeRative Treatment? (REPPORT)

Chief Investigators:

Professor Toby Smith & Professor Andrew Metcalfe

We invite you take part in this study.
Before you decide whether to take part, you need to understand why the research is being done and what it would involve for you.

Please take some time to read this information sheet & talk to other people about the study if you wish.

If anything is not clear, or if you would like further information about this study, please contact your local research team on:

xxxx

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WARWICK CLINICAL TRIALS UNIT

Information about the study

Background Information

- The patella, or kneecap, sits at the front of your knee and is an important part of how your knee works.
- Sometimes, the kneecap can slip out of the knee, and sit to the side – this is a dislocation.
- If your kneecap dislocates, it is painful and makes your knee feel unstable.
- For some people, the kneecap only ever dislocates once and is then fine.
- For others, the kneecap dislocates more than once, or they get a feeling that it is unstable or is going to dislocate.
- This may happen a lot and can be upsetting and uncomfortable. This often needs some form of treatment.
- There are two ways of treating this problem:

Personalised Knee Therapy (Physiotherapy)

- You may have had physiotherapy before but not all physiotherapy is the same.
- We have developed a treatment programme of best available physiotherapy to treat kneecap dislocation.
- It has been designed with the best evidence. It is tailored to the specific needs of the person.
- PKT may include exercise, education, advice, manual therapies and more.

We have called this:
Personalised Knee Therapy (PKT).

Surgery

Two types of surgery have been recommended by specialist surgeons and your surgeon will decide on the best operation for you.

- Medial Patellofemoral Ligament (MPFL) reconstruction: a tendon is taken from near the knee and attached to the kneecap at one end and the thigh bone at the other.
- Tibial Tubercle Osteotomy (TTO): involves cutting and moving a piece of bone that attaches to the kneecap.

These two operations may be done on their own but are sometimes done together.

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Information about the study

Background Information

Aim :	To find which treatment is best for people with repeated kneecap dislocations.
Why :	Although we know that physiotherapy and surgery are both options for treating repeated kneecap dislocations, we do not know if one is better than the other.

Who is organising and funding the study?

- This research has been organised by the University of Warwick.
- It has been funded by the UK Department of Health funding body; the National Institute for Health and Care Research (NIHR).

Study Team

This research is led by:

Professor Toby Smith
Co-Chief Investigator

A senior orthopaedic physiotherapist at Norfolk & Norwich University Hospital NHS Foundation Trust and Professor at the University of Warwick Clinical Trials Unit .

He has extensive experience treating patients with kneecap dislocations and leading studies like this, to compare how different treatments work.

Professor Andrew Metcalfe
Co-Chief Investigator

A consultant knee surgeon at University Hospital Coventry & Warwickshire and Professor at the University of Warwick Clinical Trials Unit.

He has expertise and experience in 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, clinical trials, statistics, and health economics as well as our patient representatives.

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Information about the study

Why have I been invited to take part:

You have been invited to take part in the study because you have reported that your kneecap has dislocated more than once and your medical team have identified that this needs treatment. The person treating you thinks that your symptoms might be improved by personalised knee therapy, or by an operation.

We plan to recruit 276 people from at least 16 UK hospitals involved in the study.

Do I have to take part?

No. It is up to you whether you take part and participation is completely voluntary. You can also choose to withdraw your participation at any time without giving a reason, by contacting a member of the research team. This will not affect any of the care that you receive. Further information about withdrawing from the study is provided later on in this information sheet.

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

What happens if I take part?

Consent

You will be given time to consider all of the information that you have received about the study. Then, if you decide to take part you will be asked to sign a consent form or give verbal or electronic consent. We will also ask you to consent to long-term follow-up (at five and 10 years) if we obtain funding to do this work.

Randomisation

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 system will be used to randomly decide which treatment you will have — either Personalised Knee Therapy or surgery.

Before your treatment

A member of the research team will collect some general information about you. This will include things such as how long you have had problems with your knee, what treatment you have already had for your knee, as well as any other medical problems you may have. You will also be asked to complete a questionnaire about your knee and your general health. We will ask you to complete a short version of this questionnaire in the 4 weeks before your treatment starts. We will also ask you for contact details about your next of kin, which you can only give us if you have their permission to do so.

What happens if I take part? (continued)

Follow-up

- You will be contacted by the research team at 6, 12, 18, and 24-months after joining the study to fill in a questionnaire. You can fill in your questionnaires either electronically via an App, online, over the phone, or by completing a paper version and posting it back to us in a freepost envelope. We will send you a text message or email to remind you that a questionnaire is due.

- As part of the questionnaires we ask you about pain relief you have been *prescribed* for your knee. You can find this information in the NHS App however it may help to keep a brief diary noting the name of medication, the number of prescriptions you have received and the method of delivery (e.g. tablet, liquid).

- You will be sent a £30 shopping voucher at the 18- month follow up timepoint.

- If you need help completing any questionnaire, a researcher can contact you by phone to help you.

Which treatment will I get?

- Half of the people involved in the study will get Personalised Knee Therapy (PKT) and the other half will have surgery.

- If you agree to take part in the study, you have a 50:50 chance of receiving either treatment.

- Both treatments are already available on the NHS and treatment within the trial will be subject to NHS waiting lists. However, it is important to do this research so we know if one treatment is better to offer first to future patients.

- All of the operations used in this study have been available on the NHS for over 10 years and there will be no new or experimental operations used on your knee.

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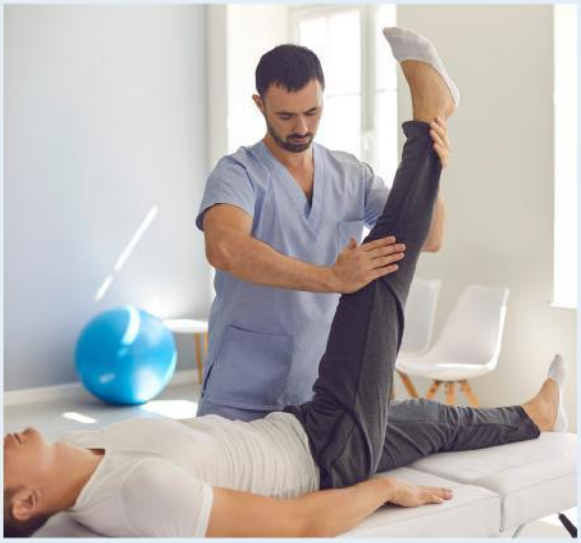
Information about the study

Which treatment?

Personalised Knee Therapy (PKT)

- PKT is a programme developed by world-recognised experts from across the UK using the best-available evidence for people after kneecap dislocation.
- It may include exercise, education, advice, pain relief, manual therapies, increasing physical activity, and more.
- We will provide a booklet and electronic information with advice, exercise pictures and videos and information that can be tailored to you, this has been specially designed for the study.
- You will be referred to a fully-qualified physiotherapist who has experience in managing knee problems and has been trained in PKT.
- They will ask about you and the problems you have with your knee, and perform a detailed physical assessment of you and your knee. Based on this, they will work with you to design a 'personal' treatment plan. This is PKT.
- You will be invited to attend around six sessions of PKT over a three-month period but may be invited for more if you need it. These will be face-to-face or online appointments or a mixture of the two.
- The initial session may be up to an hour, but other sessions will typically be a bit shorter.
- Your treatment will progress over time as your symptoms change and improve.
- When the programme is finished you will be given instructions about how to carry on your rehabilitation, to maintain the improvements you have made.
- If you do need surgery at any time in the future, having PKT will not stop this or add any risks to future surgery.



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Information about the study

Which treatment?

Surgery

Your surgeon will decide on the best operation for you. Typically, this involves a medial patellofemoral ligament reconstruction, and may also include a tibial tuberosity osteotomy.

Medial Patellofemoral Ligament reconstruction:

- 3 small incisions (around 4cm each) over the knee, plus 2 keyhole scars (around 5mm)
- A tendon is used to make a new ligament and is attached to the kneecap and the thigh bone. This ligament is not tight normally but pulls tight when the kneecap tries to dislocate.
- The ligament starts to heal after six weeks but takes approximately three months to heal well.
- You do not always have to wear a brace after this operation, but this will be decided by your surgeon.

Tibial Tuberosity Osteotomy:

- A 10cm incision at the top of the shin, where the tendon under the kneecap attaches to the bone at the top of your shin.
- A piece of bone approximately 3 cm wide, 2 cm thick and 8 cm long is cut under the tendon and is moved by 5-10 mm.
- The bone is then fixed back in place using 2 or 3 screws or a metal plate. This moves the kneecap into a different position. The bone takes approximately 6 weeks to heal.
- You usually need to wear a brace after this operation, but this will be decided by your surgeon.

Your surgeon and their team will be able to provide you with further details of your surgery if required.

If you have an operation you will be seen by a physiotherapist afterwards to help you recover.

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Further Information

What are the possible benefits of taking part?

Both treatments are designed to help you and your knee.
The information that you provide us with by taking part in the study may inform us about the best treatment for people in the future.

What are the possible disadvantages and risks of taking part?

- Both treatments are currently available in the NHS. Therefore, taking part in the study means that there are no extra risks over and above what your physiotherapist or surgeon would normally tell you about.
- There are very few risks with Personalised Knee Therapy, although some people may have some muscle soreness for a few days after exercise. There is a risk that given the problems with your knee, further dislocations will happen, but the treatment is designed to prevent this.
- There are risks with surgery, including blood clots, infection, stiffness, and pain but these are the same risks for people that have surgery but do not take part in the study. There is a risk of further kneecap dislocations, but the treatment is designed to prevent this. The risks of the operation will be discussed with you in more detail by the clinical team who are looking after you in hospital, as part of your clinical consent to treatment.

What happens when the study ends?

- If you take part, you would be in the study for 24 months. But there is a possibility that we would like to contact you again in 5 or 10 years time. 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. These will be made available to you by post or email with an end of study letter and by listing it on the study website **www.warwick.ac.uk/fac/sci/med/research/ctu/trials/repport/.**

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatments that are being studied.

If this happens, your surgeon or team 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 may be asked to sign an updated consent form.

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Further Information

Who has reviewed this research?

This study has been reviewed and given favourable opinion by the East Midlands: Nottingham 2 Research Ethics Committee.

It has been reviewed by numerous experts throughout the United Kingdom and by the National Institute for Health and Care Research (NIHR). It has also been reviewed by an independent steering committee who oversee this study.

What if something goes wrong or I wish to make a complaint?

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.

If you have any complaints about the way you have been dealt with during the study or any possible harm you might have suffered, these will be addressed.

Please contact this Senior University of Warwick Official, who is entirely independent of he 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:

infocompliance@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).

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Data Management

All information collected about you during the study will be kept strictly confidential. The study is sponsored by the University of Warwick who will act as data controller. This means that they are responsible for looking after your information and using it properly to complete the study. The University of Warwick will collect information about you for this research study directly from you, from your medical records and from information held and maintained by NHS England and other Central UK NHS Bodies. We may link this information to the information we collect directly from you (including personally identifiable data). 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.

There will be the option for you to complete data collection via an App called MyRecoveryApp. The company who provide this App are called Future Health Works. The data collected via this App for the purposes of this study will be stored on servers located in the UK or European Economic Area. Your data (including personal data) will be removed from their records once we have completed the final follow up of the final participant. Future Health Works' privacy statement can be found here: **https://appsupport.team/privacy-uk-en/**

Hospital sites, the University of Warwick, and MyRecoveryApp will only use your name, contact details, or next of kin contact details to contact you about the study, to make sure that relevant information is recorded for your care, to oversee the quality of the study, and approach you about long-term follow-up. Only those who need to know who you are will be able to access your contact details. Your data will have a study ID number. All information about you will be kept safe and secure, in accordance with the UK GDPR. Individuals from the University of Warwick and regulatory organisations may look at your medical and research records to check for accuracy.

At the end of the study, the University of Warwick will keep anonymised information about you for a minimum of 10 years. We will only keep your personal identifiable information until all data collection is complete and we have contacted you to inform you of the trial results. However, we also hope to do a long-term follow-up study. If this long term follow up study goes ahead, we will need to keep your contact details for longer so we can contact you for up to 10 years. 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, or are no longer able to take part in the study, we will keep the information that we have already collected. To safeguard your rights, we will use the minimum amount of personally -identifiable information as possible. In the future we might agree to share your anonymous data with other, carefully selected researchers running studies in this organisation and in other organisations. Any such sharing will be closely monitored by the University. These organisations may be Universities or NHS organisations. Your identity will never be made accessible to other researchers or organisations. Please follow the link below to find out how the University of Warwick handles your personal data processed in connection with the study:
https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice

The Information and Data Compliance Team at the University of Warwick will provide oversight of activities involving the processing of personal data. They can be contacted via: **infocompliance@warwick.ac.uk.** If you agree to take part, your GP will be notified and other doctors who may treat you, but are not part of this research, may be notified that you are taking part.

Further Information

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 the information about you that we already have unless you specifically ask us to delete it. 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 about how we use your information at:
www.hra.nhs/uk/information-about-patients/
and
www.hra.nhs.uk/patientdataandresearch
or
contacting the University of Warwick's Data Protection Officer at:
infocompliance@warwick.ac.uk

Contacts for further information

If at any time you would like further information about this research study, you can contact your local research team on:

XXXX

or email REPPORT@warwick.ac.uk

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

REPPORT
RECURRENT PATELLAR DISLOCATION:
PERSONALISED THERAPY OR OPERATIVE TREATMENT?

This study is funded by the NIHR [Health Technology Assessment (HTA) Programme (HTA Project: NIHR134398). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.