# Physiotherapy or surgery for repeat kneecap dislocation: a randomised controlled trial

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
12/04/2023		[X] Protocol		
Registration date	Overall study status Ongoing  Condition category Musculoskeletal Diseases	Statistical analysis plan		
09/06/2023		Results		
Last Edited		Individual participant data		
08/08/2025		[X] Record updated in last year		

#### Plain English summary of protocol

Background and study aims

A kneecap (patellar) dislocation, where the kneecap comes out to the side of the knee, is very painful. It is a common problem for people in their teens and early twenties. After the first dislocation, the weakened muscles and structures around the knee can allow this to happen again. People often feel that the kneecap is going to dislocate and change their activities to prevent it coming out. This combination of repeated dislocations, and the feeling that it is going to happen, is unpleasant, painful, and stops people getting on with their normal lives (education, work and social activity). We do not know the best way to treat this problem. Some specialists believe that without surgery, dislocations and restriction will continue. Others believe that physiotherapy works well and avoids the risks and cost of surgery. We will offer and compare two different treatments to people who have repeated kneecap dislocation; personalised knee therapy, which includes physiotherapy and individual care and advice to prevent dislocation, or surgery which tightens structures around the knee to prevent dislocation.

Who can participate?

Individuals will be eligible for the trial if they are aged 16 years and over and have experienced at least two (self-reported) lateral patellar dislocations affecting the same knee.

#### What does the study involve?

Participants will be provided information about the trial and given the opportunity to ask questions before providing informed consent. Participants will then be randomly assigned to receive either personalised knee therapy, which includes physiotherapy and individual care and advice to prevent dislocation, or surgery, which tightens structures around the knee to prevent dislocation. We will collect health and medical information from these participants before they are randomly assigned to each treatment options, as well as 6, 12, 18 and 24 months after

What are the possible benefits and risks of participating?

There are no additional risks over and above what the surgeon/treating clinicians would normally inform people about. The requirement to undergo surgical consent or consent for treatment remains in place following normal site specific NHS policies and procedures. The risks with surgery include persistent knee pain, infection and blood clots, but these are the same risks

for patients that do not take part in the study who undergo surgery. The risks of PKT are minimal but include post-intervention pain, muscle soreness, or tiredness. The risk associated with PKT are also the same for patients that do not take part in the study but have routine physiotherapy.

Where is the study run from?

The study is led by the University of Warwick and participants will be recruited at various NHS hospitals across the UK.

When is the study starting and how long is it expected to run for? January 2023 to August 2027

Who is funding the study?

The study is funded by the NIHR Health Technology Assessment (HTA) programme (UK)

Who is the main contact?

Mrs Manjit Aujla: REPPORT Trial Manager; REPPORT@warwick.ac.uk

### **Contact information**

#### Type(s)

Scientific

#### Contact name

Mrs Manjit Aujla

#### Contact details

Warwick Clinical Trials Unit University of Warwick Coventry United Kingdom CV4 7AL +44 24 765 74996 REPPORT@warwick.ac.uk

#### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

312908

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

CPMS 55618, IRAS 321908

### Study information

#### Scientific Title

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

#### **Acronym**

**REPPORT** 

#### **Study objectives**

Clinical outcomes will be different between people with recurrent patellar dislocation who are offered physiotherapy or surgery as their first line treatment.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 30/03/2023, East Midlands: Nottingham 2 REC (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 2071048016; nottingham2.rec@hra.nhs.uk), ref: 23/EM/0075

#### Study design

Randomized; Interventional; Design type: Treatment, Physical, Surgery, Rehabilitation

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Recurrent patellar dislocation

#### **Interventions**

#### Randomisation:

After consent has been obtained and baseline data have been collected, participants will be randomly allocated to one of the two treatment groups via a central computer-based randomisation system provided by Warwick Clinical Trials Unit's programming team. Randomisation will be in a 1:1 ratio using a minimisation procedure with a random factor of at least 70%, stratified by age group (<22/≥22), site of recruitment, and presence of patella alta in the study knee.

#### Trial interventions:

A full summary of the PKT and surgical interventions will be available in the REPPORT manuals which will be prepared following surgical and non-surgical consensus meetings. These manuals will be made available on the REPPORT trial webpage for ease of access for participants randomised to respective allocation groups.

#### Personalised Knee Therapy (PKT)

The PKT programme is an optimised package of tailored non-operative care for patellar instability and will be based on the PKT programme developed for the PIPS feasibility trial. It will be developed further using data from the PIPS participant interviews, an evaluation of current relevant literature, our 2020 physiotherapy survey findings, and a consensus meeting of expert patients, PPI representatives, physiotherapists, health psychologists, and other stakeholders and practitioners with a specialist interest in knee rehabilitation.

#### Surgery

A REPPORT surgical manual will be produced based on published British Orthopaedic Association Standards for Trauma and Orthopaedics (BOAST) guidelines and the outcomes of a surgical consensus meeting comprising surgeons, patients, physiotherapists and other key stakeholders. The most widely recommended surgical procedure for patellar dislocation is medial patello-femoral ligament (MPFL) reconstruction. Participants with patella alta may also undergo a simultaneous tibial tubercle osteotomy. All care, including the choice of anaesthetic, the surgical procedure, and post-operative analgesia, will be in accordance with usual procedures and care at participating sites.

Fidelity and process measures will be assessed and recorded on a case report form (CRF). These will include details of surgery (surgical procedure, surgical findings, theatre time, tourniquet time, any other procedures) and the anaesthetic used.

Rehabilitation following surgery will based on the minimum standard of care consistent with normal NHS practice, as used in the PIPS feasibility trial

#### Intervention Type

Mixed

#### Primary outcome(s)

Knee Osteoarthritis Outcome Score (KOOS4) score at 18 months after randomisation

#### Key secondary outcome(s))

- 1. KOOS4 at baseline, pre-intervention, six, 12, and 24-months.
- 2. The five individual KOOS domains (symptoms, pain, activities of daily living, sports, quality of life) at baseline, preintervention, six, 12, 18, and 24-months post randomisation.
- 3. Norwich Patellar Instability (NPI) score at baseline, pre-intervention, six, 12, 18, and 24-months post-randomisation.
- 4. Health utility (EQ-5D-5L) at baseline, pre-intervention, six, 12, 18, and 24-months post-randomisation.
- 5. Work or education status (time off, change to status) at baseline, six, 12, 18, and 24-months post randomisation.
- 6. Satisfaction with social roles (PROMIS Satisfaction with Social Roles and Activities 4a Short Form) at baseline, six, 12, 18, and 24-months post randomisation.
- 7. Satisfaction with treatment at six, 12, 18, and 24-months post-randomisation using a 5-point Likert scale.
- 8. Patient global impression of change (PGIC) scale (single item) at six, 12, 18, and 24-months post-randomisation.
- 9. Patellar dislocations at baseline, six, 12, 18, and 24-months post-randomisation.
- 10. Adverse events including surgical complications at six, 12, 18, and 24-months post-randomisation.
- 11. Further knee surgery (either arm) at six, 12, 18, and 24-months post-randomisation.
- 12. Resources used by interventions and assessed at six, 12, 18, and 24-months post-randomisation.

#### Completion date

31/08/2027

### Eligibility

Key inclusion criteria

- 1. Experienced at least two (self-reported) lateral patellar dislocations affecting the same knee
- 2. Age 16 years or over

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

16 years

#### Sex

All

#### Key exclusion criteria

Current participant exclusion criteria as of 18/06/2024:

- 1. Open growth plates on standard care imaging (typically but not restricted to MRI). Surgery in the skeletally immature requires different surgical techniques and is beyond the scope of this trial.
- 2. Presence of another knee condition which may cause instability (e.g., cruciate ligament instability, unstable meniscal tear)
- 3. Previous patellofemoral surgery, except simple arthroscopy with/without lateral release
- 4. Severe trochlea dysplasia which in the opinion of the treating clinician requires trochleoplasty.
- 5. Malalignment of femur or tibia requiring corrective osteotomy (not including tibial tubercle osteotomy).\*
- 6. Osteochondral/chondral injury requiring surgery, except removal of loose body.
- 7. Medial patellar dislocation or dislocations when the knee flexes (i.e., the patella is located in extension and dislocates every time the knee flexes).
- 8. Previous randomisation into the trial (i.e., the other knee).
- 9. Unable to have either physiotherapy or surgery.
- 10. Unable to adhere to trial protocols or completion of questionnaires (the need to offer translations will be kept under review by the trial team).
- \* These are uncommon, <10% of the population, and challenging to treat.

#### Previous participant exclusion criteria:

- 1. Open growth plates on standard care imaging (typically but not restricted to MRI). Surgery in the skeletally immature requires different surgical techniques and is beyond the scope of this trial
- 2. Presence of another knee condition which may cause instability (e.g., cruciate ligament instability, unstable meniscal tear)
- 3. Previous patellofemoral surgery, except simple arthroscopy with/without lateral release
- 4. Severe trochlea dysplasia requiring trochleoplasty\*
- 5. Malalignment of femur or tibia requiring corrective osteotomy (not including tibial tubercle osteotomy)\*
- 6. Osteochondral/chondral injury requiring surgery
- 7. Medial patellar dislocation

- 8. Previous randomisation into the trial (i.e., the other knee)
- 9. Unable to adhere to trial protocols or completion of questionnaires (the need to offer translations will be kept under review by the trial team)
- \*These are uncommon, <10% of the population, and are challenging to treat

## **Date of first enrolment** 01/07/2023

Date of final enrolment 31/10/2025

#### Locations

#### Countries of recruitment

**United Kingdom** 

England

Northern Ireland

Scotland

Wales

Study participating centre
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
North Tyneside Health Care NHS Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

## Study participating centre Royal Preston Hospital

Sharoe Green Lane North Fulwood Preston United Kingdom PR2 9HT

#### Study participating centre Manchester University NHS Foundation Trust

Cobbett House Oxford Road Manchester United Kingdom M13 9WL

#### Study participating centre Stepping Hill Hospital

Poplar Grove Stockport United Kingdom SK2 7JE

#### Study participating centre Queen Elizabeth Hospital Birmingham

University Hospitals Birmingham NHS Foundation Trust Mindelsohn Way Birmingham United Kingdom B15 2TH

#### Study participating centre

Royal Devon University Healthcare NHS Foundation Trust

Royal Devon University NHS Ft Barrack Road Exeter United Kingdom EX2 5DW

#### Study participating centre University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters Marlborough Street Bristol United Kingdom BS1 3NU

#### Study participating centre Norfolk and Norwich University Hospitals NHS Foundation Trust

Colney Lane Colney Norwich United Kingdom NR4 7UY

## Study participating centre NHS Lothian

Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

## Study participating centre Cardiff & Vale University Lhb

Woodland House Maes-y-coed Road Cardiff United Kingdom CF14 4HH

#### Study participating centre Dewi Sant Hospital

Albert Road Pontypridd United Kingdom CF37 1LB

#### Study participating centre

#### **St Cadocs Hospital**

Lodge Road Caerleon Newport United Kingdom NP18 3XQ

### Study participating centre Belfast Health and Social Care Trust

Trust Headquarters A Floor - Belfast City Hospital Lisburn Road Belfast United Kingdom BT9 7AB

## Study participating centre St Georges Hospital (wandle Annexe)

St. Georges Hospital Blackshaw Road Tooting London United Kingdom SW17 0QT

#### Study participating centre Cumberland Infirmary

Newtown Road Carlisle United Kingdom CA2 7HY

#### Study participating centre University Hospital Monklands

NHS Lanarkshire, Monkscourt Ave Airdrie United Kingdom ML6 0JS

#### Study participating centre

#### Musgrove Park Hospital

Somerset Foundation Trust, Parkfield Dr Taunton United Kingdom TA1 5DA

#### Study participating centre Broomfield University Hospital

Broomfield Hospital
Court Road
Chelmsford
United Kingdom
CM1 7ET

#### Study participating centre Bolton Royal Hospital

Minerva Road Farnworth Bolton United Kingdom BL4 0JR

## Study participating centre Southmead Hospital

Southmead Road Westbury-on-trym Bristol United Kingdom BS10 5NB

## Study participating centre William Harvey Hospital

Kennington Road Willesborough Ashford United Kingdom TN24 0LZ

#### Study participating centre Queen Elizabeth the Queen Mothers Hospital

East Kent Hospitals University NHS Foundation Trust, Ramsgate Rd

Margate United Kingdom CT9 4AN

**DD1 9SY** 

#### Study participating centre Ninewells Hospital Ninewells Avenue Dundee United Kingdom

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

## Study participating centre Calderdale and Huddersfield NHS Foundation Trust

Trust Headquarters Acre Street Lindley Huddersfield United Kingdom HD3 3EA

## Study participating centre Western Health and Social Care Trust

Mdec Building Altnagelvin Area Hospital Site Glenshane Road Londonderry United Kingdom BT47 6SB

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square

Leicester United Kingdom LE1 5WW

#### Study participating centre Swansea Bay University Health Board

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Port Talbot United Kingdom SA12 7BR

### Study participating centre Ipswich Hospital

Heath Road Ipswich United Kingdom IP4 5PD

#### Study participating centre Colchester General Hospital

Colchester District General Hosp.
Charter Way
Turner Road
Colchester
United Kingdom
CO4 5JL

## Study participating centre Royal Gwent Hospital

Cardiff Road Newport United Kingdom NP20 2UB

#### Study participating centre Queen Margaret Hospital

Whitefield Road Dunfermline United Kingdom KY12 0SU

## Study participating centre Southampton

Southampton General Hospital Tremona Road Southampton United Kingdom SO16 6YD

#### Study participating centre New Cross Hospital Royal Wolverhampton

Wolverhampton Road Heath Town Wolverhampton United Kingdom WV10 0QP

#### Study participating centre Queen Alexandra Hospital

Southwick Hill Road Cosham Portsmouth United Kingdom PO6 3LY

#### Study participating centre St James's University Hospital

Beckett Street Leeds United Kingdom LS9 7TF

### Study participating centre

Milton Keynes University Hospital NHS Foundation Trust Standing Way Eaglestone Milton Keynes United Kingdom MK6 5LD Study participating centre Torbay Hospital Newton Road Torquay United Kingdom TQ2 7AA

### Sponsor information

#### Organisation

University of Warwick

#### **ROR**

https://ror.org/01a77tt86

### Funder(s)

#### Funder type

Government

#### Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR134398

### **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Warwick Clinical Trials Unit (WCTU) Data Sharing Committee (WCTUDataAccess@warwick.ac.uk) once the study is complete and published. De-identified data that underlie the results reported in the study will be available for non-commercial use, up to one year after publication of the final trial data, or from metadata stored in a university repository up to ten years without investigator support. To access trial data, third parties must complete a data-sharing agreement with the sponsors, have an ethically approved protocol in place for use of the data, and agree the approved protocol with the WCTU data sharing committee. Data may be used for commercial purposes, according to the conditions above, but will need specific agreements in place prior to access being agreed, this may include a license fee. Analyses may include individual patient data meta-analyses or other purposes as agreed with the WCTU data sharing committee. Available data will include (but is not exclusive to) deidentified individual participant data that underlies the results reported in trial publications, the study protocol, statistical analysis plan, master copy of the informed consent sheets and analytic codes used.

### IPD sharing plan summary

Available on request, Data sharing statement to be made available at a later date

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/08/2024	23/08/2024	Yes	No
Participant information sheet	version 3.0	04/04/2023	09/06/2023	No	Yes
Participant information sheet	version 5.0	29/11/2023	18/06/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.0	29/11/2023	18/06/2024	No	No
Protocol file	version 6.0	25/10/2024	25/03/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes