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

Submission date
12/04/2023

Recruitment status
Recruiting

Registration date
09/06/2023

Overall study status
Ongoing

Last Edited
08/08/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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

Study website
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/repport/

Contact information

Type(s)
Scientific

Contact name
Mrs Manjit Aujla

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
312908

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Secondary outcome measures
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.

Overall study start date
01/01/2023

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

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 276; UK Sample Size: 276

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
England

Northern Ireland

Scotland

United Kingdom

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

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

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
-
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

Sponsor details
University House
Gibbet Hill Road
Coventry
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United Kingdom
CV4 7AL
+44 2476575733
sponsorship@warwick.ac.uk

Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/08/2028

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) de-identified 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?
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
Protocol file	version 4.0	29/11/2023	18/06/2024	No	No
Protocol article		21/08/2024	23/08/2024	Yes	No
Protocol file	version 6.0	25/10/2024	25/03/2025	No	No