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Physiotherapy rehabilitation post patellar dislocation – is a full-scale trial feasible?

Submission date
05/07/2022

Recruitment status
No longer recruiting

Registration date
09/08/2022

Overall study status
Completed

Last Edited
28/01/2025

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
The kneecap (patella) is a round shaped bone at the front of the knee. Normally, the kneecap sits in a groove in the thigh bone. Kneecap dislocations occur when the kneecap moves out of this groove. This is a sudden painful injury and most people need to go the Emergency Department. To help them recover, patients are normally referred to a physiotherapist. After assessing the injury, physiotherapists give patients advice and exercises to do to help them return to their normal activities. Unfortunately, not everyone recovers fully. Sometimes the knee remains painful or the kneecap dislocates again. Occasionally, people need to have surgery.

At the moment, we do not know if giving patients more physiotherapy sessions makes a difference to how well they recover after a kneecap dislocation. To find this out we would need to compare different physiotherapy treatments in a large study. To decide if a large study would work, we first need to compare these treatments in this smaller study.

Who can participate?
Patients at least 14 years old who have had a recent kneecap dislocation

What does the study involve?
Patients who take part will be allocated at random to one of two physiotherapy treatments:
1. “Self-managed rehabilitation”. This involves one session with a physiotherapist who will give participants advice and exercises to help them recover. Participants will then manage their own recovery by following advice and exercises available on a study website. If participants are struggling, they can contact the physiotherapist for advice or to arrange an additional session.
2. “Supervised rehabilitation”. This involves 4-6 physiotherapy sessions over a maximum of six months. These participants will also have access to the advice and exercises on the study website. The additional sessions in this treatment will enable the physiotherapist to tailor and progress participants’ exercises to try and prepare them for the activities they want to return to.

We will ask participants to complete questionnaires when they join the study, then 3, 6 and 9 months later. We will send questionnaires to participants by email and/or text message, or by post if they cannot complete questionnaires online.

We will also interview up to 20 patients, including patients who decline to take part in the study, to understand what they thought of the study, and their experience of injury, treatment, and recovery.

What are the possible benefits and risks of participating?
The main benefit from this study is it will help us decide if a future larger study in this area will work, and if so, what we need to change to make this future study better. This later larger study will find out which physiotherapy treatment is better for patients with a recent kneecap dislocation who are treated in the NHS.

People who participate are unlikely to be harmed by the treatments in this study. The study treatments are within the range of normal physiotherapy treatment provided for patients with a recent kneecap dislocation in the NHS. The study treatments will be provided by registered and fully-qualified physiotherapists. Participants may experience some soreness after completing exercises, but they will be given advice on how to manage this. For some people, talking about their experience can bring back memories and feelings. If this happens the researcher will provide support, offer a break, or offer to continue the interview at another time. Participants can choose not to answer any questions and can stop the interview whenever they want to.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
October 2021 to September 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Colin Forde, prepped@ndorms.ox.ac.uk

Study website
https://prepped.octru.ox.ac.uk/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
312280

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 312280, CPMS 53637

Study information

Scientific Title
PRePPeD - Physiotherapy Rehabilitation Post Patellar Dislocation: supervised versus self-managed rehabilitation for people after acute patellar dislocation: a multicentre external pilot randomised controlled trial and qualitative study

Acronym
PRePPeD

Study objectives
Is it possible to conduct a full-scale trial comparing the clinical and cost-effectiveness of supervised versus self-managed rehabilitation for people after acute patellar dislocation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/08/2022, East of Scotland Research Ethics Service (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY, UK; +44 (0)1382 383871; tay.eosres@nhs.scot), ref: 22/ES/0035

Study design
Multicentre parallel two-arm external pilot randomized controlled trial and qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Patients aged 14 years or older with an acute first-time or recurrent patellar dislocation

Interventions
Participants will be randomly allocated 1:1 using a web-based service to “supervised rehabilitation” or “self-managed rehabilitation”. Randomisation will be stratified by study site and first-time/recurrent dislocation.
1. Self-managed rehabilitation involves a single physiotherapy session of advice and exercise lasting up to 60 minutes. Participants will then self-manage their recovery following advice and exercise videos on a study website. If participants are struggling with exercise technique or progression, they can initiate one follow-up physiotherapy session.
2. Supervised rehabilitation involves 4-6 physiotherapy sessions of advice and exercise over a maximum of 6 months. Initial sessions will last up to 60 minutes and follow-up sessions will last up to 30 minutes. The additional sessions will enable physiotherapists to re-assess participants, prescribe an individually tailored exercise programme, and help participants solve any problems. Participants will also have access to advice and exercise videos on the study website.

Intervention Type
Behavioural

Primary outcome measure
This study aims to determine if a full-scale randomised controlled trial comparing supervised versus self-managed rehabilitation for people after acute patellar dislocation is feasible by assessing the:

1. Willingness to be randomised: proportion of eligible patients approached who are randomised over the recruitment period;
2. Recruitment rate: number of participants recruited per month per site over the recruitment period;
3. Intervention adherence: proportion of participants allocated to “supervised rehabilitation” and “self-managed rehabilitation” attending at least four physiotherapy sessions and one physiotherapy session, respectively;
4. Retention: proportion of participants that return KOOS4 outcome data at 9 months; and
5. Understanding participants’ experience of recovery, and the acceptability of the study interventions and follow-up methods to participants through semi-structured interviews conducted over the 9-month follow-up period

Secondary outcome measures
To assess if the planned outcomes for the full-scale trial can be collected, we will collect them in this study. Secondary outcome measures are:
1. Knee symptoms and function measured by the average of four of five domains of the Knee Osteoarthritis Outcome Score (KOOS4) and all KOOS subdomains at baseline and 3, 6, and 9 months after randomisation
2. Health-related quality of life measured using the EuroQol 5 Dimensions (EQ-5D-5L) at baseline, and 3, 6 and 9 months after randomisation
3. Return to pre-injury sport/physical activity level using a using a trial specific questionnaire at baseline, and 3, 6 and 9 months after randomisation
4. Global rating of change measured using participant-reported rating of change in their injured knee compared to when they agreed to enter the study on a 7-point Likert Scale at 3, 6, and 9 months after randomisation
5. Adherence to prescribed exercise using a trial specific questionnaire at 3, 6 and 9 months after randomisation
6. Health resource use using a trial specific questionnaire at 3, 6 and 9 months after randomisation
7. Complications using a trial specific questionnaire and site reporting at 3, 6 and 9 months after randomisation

Overall study start date
04/10/2021

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Aged ≥14 years
2. First-time or recurrent patellar dislocation confirmed if:
2.1. The patellar dislocation was reduced by a healthcare professional or
2.2. The patient reports a visible lateral patellar dislocation or sensation of the patella ‘popping out’ of joint followed by reduction and the assessing clinician diagnoses a lateral patellar dislocation
3. Willing and able to provide informed consent (patients aged ≥16 years), or for patients aged <16 years the parent is willing and able to provide informed consent for their child’s participation and the patient is able to provide assent should they wish to do so

Participant type(s)
Patient

Age group
Mixed

Lower age limit
14 Years

Sex
Both

Target number of participants
At least 50

Total final enrolment
50

Key exclusion criteria
1. >14 days from injury
2. Previous patellar stabilisation surgery on the affected knee
3. Requires acute surgical intervention (e.g., due to concurrent osteochondral fracture)
4. Contraindication(s) to participation in the study interventions
5. Patient is unable to adhere to study procedures
6. Previously randomised into the study

Date of first enrolment
12/12/2022

Date of final enrolment
29/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Headley Way
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OX3 9DU

Study participating centre
Horton General Hospital
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Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
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BA1 3NG

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
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Sponsor type
University/education

Website

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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol and results will be published in open-access peer-reviewed journals. The embedded qualitative study will be published in an open-access peer-reviewed journal if data are sufficient.
Reporting will follow relevant guidelines, including the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines for study protocols, the Consolidated Standards of Reporting Trials (CONSORT) extension to randomised pilot and feasibility trials, and the template for intervention description and replication (TIDieR) guidelines.
We will disseminate our findings through presentations at academic conferences and by sharing a lay summary of the study results on the study website. Updates about the study's progress and results will be shared on social media.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Colin Forde (colin.forde@ndorms.ox.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	05/07/2022	15/07/2022	No	No
Protocol file	version 3.0	03/11/2022	18/11/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol article		10/07/2023	11/07/2023	Yes	No
Protocol file	version 4.0	17/05/2023	19/07/2023	No	No