Study Title: Supervised versus self-managed rehabilitation for people after acute patellar dislocation: a multicentre external pilot randomised controlled trial and qualitative study

Internal Reference Number / Short title: PRePPeD – Physiotherapy Rehabilitation Post Patellar Dislocation

Ethics Ref: 22/ES/0035

IRAS Project ID: 312280

Date and Version No: V3.0_03Nov2022

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No conflict of interests to declare

Confidentiality Statement: This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. KEY CONTACTS

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2. LAY SUMMARY

Kneecap dislocations account for around 3% of all sporting knee injuries. This injury happens suddenly, often during sport. Teenagers and young adults are most affected. After a kneecap dislocation, most people need to attend the Emergency Department. The kneecap is pushed back into place if it is still dislocated, a knee splint is applied to support the knee, and crutches are provided to help people walk.

To help recovery, patients are normally referred to physiotherapy. Physiotherapy treatment usually involves giving patients advice and exercises to do at home. Exercises usually aim to restore patients' leg strength, balance, and knee flexibility. Despite receiving physiotherapy treatment, not all patients recover fully. The knee can remain painful, some people do not return to all their pre-injury activities, and sometimes the kneecap dislocates again. Occasionally, people need to have surgery. Currently, it is unclear what the best physiotherapy treatment is for this injury.

We want to compare two different physiotherapy treatments to find out which is better for people with a kneecap dislocation. This requires carrying out a large study. To decide if a larger study would work, we will first compare these treatments in this smaller study.

We aim to recruit at least 50 patients, aged 14 years or older, who have had a recent kneecap dislocation. Participants will be randomly allocated 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, assisted by a website with high-quality videos and guidance.
2. Supervised rehabilitation: this involves 4-6 physiotherapy sessions over a maximum of 6 months. The additional treatment sessions will enable physiotherapists to tailor and progress the difficulty of exercises so that they prepare each participant for the activities they want to return to. Physiotherapists will also use strategies to help participants do their exercise, such as planning where and when to do exercises.

This is a pilot study to test:

- The willingness of patients to be randomly allocated to the different physiotherapy treatments, by measuring the proportion of patients that can take part who agree to take part
- The recruitment rate, by measuring the number of patients who agree to take part each month
- How many physiotherapy appointments participants attend
- The retention of participants in the trial, by measuring the proportion of participants who return completed study questionnaires at 9 months

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

The results of this study will show if a large study would work. This later large study will find out what is the best physiotherapy treatment to provide for people with a recent kneecap dislocation who are treated in the NHS.

3. SYNOPSIS

Study Title	Supervised versus self-managed rehabilitation for people after acute patellar dislocation: a multicentre external pilot randomised controlled trial and qualitative study		
Internal ref. no. / short title	PRePPeD – Physiotherapy Rehabilitation Post Patellar Dislocation		
Study registration	The study has been registered with the current controlled trials database under reference number ISRCTN4235231		
Sponsor	University of Oxford		
Funder	National Institute for Health and Care Research - Doctoral Fellowship (NIHR301759)		
Study Design	Multicentre, parallel, two-arm, external pilot randomised controlled trial		
Study Participants	Patients aged 14 years and older with an acute first-time or recurrent patellar dislocation		
Sample Size	At least 50 participants		
Planned Study Period	19 September 2022 to 30 September 2024 Individual participant's involvement: 9 months		
Planned Recruitment period	19 September 2022 to 18 September 2023		
	Objectives	Outcome Measures	Time point(s)
Pilot	Willingness to be randomised	Proportion of eligible patients approached who are randomised	Randomisation
	Recruitment rate	Number of participants recruited per month per site	Randomisation
	Intervention adherence	Proportion of participants allocated to "supervised rehabilitation" and "self-managed rehabilitation" attending at least four physiotherapy sessions and one physiotherapy session, respectively	6 months post randomisation
	Retention	Proportion of participants that return 9-month Knee Osteoarthritis Outcome Score ($KOOS_4$) outcome data	9 months post randomisation
	To understand participants' experience of recovery, and the acceptability of the study interventions and follow-up	Semi-structured interviews (maximum of 20 participants)	≤9 months post randomisation

	methods to participants		
Exploratory (to assess if the planned outcomes for the full-scale trial can be collected)	Knee symptoms and function	$KOOS_4$ and all KOOS subdomains	Baseline (post injury) and 3, 6, and 9 months post randomisation
	Health related quality of life	EuroQol 5 Dimensions (EQ-5D-5L)	Baseline (post injury) and 3, 6, and 9 months post randomisation
	Return to pre-injury sport/physical activity level	Participant-reported percentage return to their main pre-injury sport/physical activity	Baseline (post injury) and 3, 6, and 9 months post randomisation
	Global Rating of Change	Participant-reported global rating of change on a 7-point Likert scale	3, 6, and 9 months post randomisation
	Adherence to prescribed exercise	Participant-reported frequency of performing prescribed exercise	3, 6, and 9 months post randomisation
	Health resource use	Participant-completed follow-up questionnaires, physiotherapy treatment logs, and site reporting	3, 6, and 9 months post randomisation
	Complications	Participant-completed follow-up questionnaires and site reporting	3, 6, and 9 months post randomisation
Intervention	Supervised rehabilitation (four to six physiotherapy sessions)		
Comparator	Self-managed rehabilitation (one physiotherapy session)		

4. ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
DMP	Data Management Plan
EQ-5D-5L	EuroQol 5 dimensions 5 levels questionnaire
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
KOOS	Knee Osteoarthritis Outcome Score
NDORMS	Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OCTRU	Oxford Clinical Trial Research Unit
PI	Principal Investigator
PIS	Participant/Patient Information Sheet
PPI	Patient and Public Involvement
PROM	Patient-Reported Outcome Measure
R&D	NHS Trust R&D Department
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SFQ	Site Feasibility Questionnaire
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group

5. BACKGROUND AND RATIONALE

Characteristics of the disease

The patella dislocates when it is forced out of the femoral trochlear groove, typically in a lateral direction. Most are non-contact injuries and 52% occur during sport [1]. The reported incidence of first-time patellar dislocations is 42 per 100,000 person years, highest in teenagers, and equal between sexes [2]. After a first-time patellar dislocation, 22.7% of people redislocate their patella within 10 years, with the highest redislocation rate being 36.8% which occurs in 10-17 year olds [2].

When the patella dislocates, the soft tissues on the medial aspect of the knee are usually torn, making the knee painful and swollen. Most patients need to attend the emergency department where the patella is relocated if needed, a knee splint is applied, and crutches are provided to help patients walk. Recovery often requires time off education/work.

The most effective treatment for people after acute patellar dislocation is unknown [3]. Current consensus is that these patients should be treated non-surgically with exercise-based rehabilitation [4,5]. Surgery is reserved for those with significant concomitant injuries (e.g., large osteochondral fractures) or where non-surgical treatment is subsequently deemed unsuccessful [4,5]. In the UK, after initial injury management, non-surgical exercise-based treatment provided by a physiotherapist is recommended [5].

Although non-surgical treatment after acute patellar dislocation is the norm, outcomes after this treatment approach are highly variable: 56% of patients reported pain during vigorous activity at 6 months [6], 68% reported patellar-related activity limitations at 3 years [7], and 31% redislocated their patella within 4 years [8]. Despite non-surgical treatment, 9-39% of patients proceed to surgery [8]. The most common surgical procedure has a 26% complication rate [9] and estimated cost of £4,058.07 (HRG tariff code: HN23). Given this injury mainly affects young people, improving physiotherapy treatment could have significant benefits for patients and wider society associated with reduced sickness absence from education/work, reduced healthcare use, and increased participation in valued physical activities.

Possible opportunities for better treatment

Currently, there are no clinical guidelines to guide physiotherapy treatment for people after acute patellar dislocation. A 2018 systematic review could not recommend any one non-surgical treatment for people with a patellar dislocation because of a lack of high-quality trials [8]. We updated this systematic review's search strategy in EMBASE and MEDLINE and searched ClinicalTrials.gov and the ISRCTN registry (searches completed 04 January 2022) but found no published randomised controlled trials (RCTs) that compared exercise-based rehabilitation after acute patellar dislocation. We found one planned RCT (planned sample size = 78) [10] which will compare blood flow restriction training and standard physiotherapy (27 sessions over 9 weeks) versus sham blood flow restriction training and standard physiotherapy. The number of physiotherapy sessions in these interventions far exceeds those normally commissioned in the NHS, so this study's results are unlikely to inform UK NHS physiotherapy practice.

The lack of evidence to guide treatment, has resulted highly variable NHS physiotherapy practice. A 2012 survey showed that NHS physiotherapists' reported treatment for people after first-time patellar dislocation mainly involves advice and prescription of simple home-based exercises, but some also reported using ultrasound and acupuncture [11]. Reported treatment durations ranged from 3-6 weeks to more than 6 months, however these were not based on reference to patients' medical records, so may be overestimated [11]. The number of treatment sessions provided was not reported. Data from the

John Radcliffe Hospital Physiotherapy Department (September – December 2021) showed that patients with an acute patellar dislocation (n=16) received a median of 2 physiotherapy sessions (IQR 1 to 2). Though high-quality data is lacking, these findings indicate the variability in NHS physiotherapy practice for patients with an acute patellar dislocation.

Only one RCT has compared exercise-based rehabilitation programmes after acute patellar dislocation, finding no clinically important difference in knee pain or function between two thigh muscle strengthening programmes in adults (aged ≥16 years) after a first-time patellar dislocation [12]. However, the results were at high risk of bias because 12-month loss to follow-up was 52%. The reasons for the high loss to follow-up are unclear but cast uncertainty over the feasibility of a full-scale trial. The exercise interventions in this RCT were not tailored to individual participant's physical characteristics and activity-related goals, did not follow evidence-based exercise prescription guidelines [13], and did not involve retraining of limb alignment during dynamic activities. Although rehabilitation programmes that focus on restoring lower limb muscle strength and optimising lower limb and trunk alignment during dynamic activities have been recommended [5,14], to our knowledge, no such programme has been evaluated in a RCT.

Our single site feasibility study showed that a programme of up to six, one-to-one, physiotherapy sessions of individually tailored lower limb resistance and dynamic exercise prescribed following evidence-based guidelines appeared acceptable to adults after acute patellar dislocation and was deliverable in the NHS [15]. However, there is no evidence to support this supervised rehabilitation approach. Furthermore, previous studies [16,17] and clinician consultations have shown that patients' attendance at physiotherapy after acute patellar dislocation can be variable. There is also evidence from other trials of musculoskeletal conditions, such as ankle fracture and chronic whiplash, that supervised individually tailored rehabilitation was not more clinically effective that one session of self-managed rehabilitation advice and home exercise [18,19].

Why a new study is needed

Current non-surgical treatment outcomes for this young patient population are highly variable. A full-scale trial comparing "supervised rehabilitation" versus "self-managed rehabilitation" would provide high-quality evidence about the most clinically and cost-effective rehabilitation approach for people after acute patellar dislocation who are treated in the NHS. This would help create clinical guidelines and reduce variation in physiotherapy treatment.

This trial has added relevance given that the third ranked research priority of the James Lind Alliance Physiotherapy Priority Setting partnership is to determine the 'best ways to deliver physiotherapy services to meet patients' needs and improve outcomes for patients and services' [20]. The NHS long-term plan also aims to reduce hospital outpatient appointments [21].

Before a full-scale trial, a pilot trial comparing these interventions is needed to address uncertainties over patients' willingness to be randomised, recruitment, intervention adherence, retention, and acceptability of the interventions and study procedures to participants. This approach follows the current Medical Research Council and NIHR framework for developing and evaluating complex interventions [22].

6. OBJECTIVES AND OUTCOME MEASURES

The aim of this multicentre external pilot RCT and qualitative study is to determine if a full-scale RCT comparing supervised versus self-managed rehabilitation is feasible.

6.1 Pilot Objectives:

To assess the:

- Willingness to be randomised: proportion of eligible patients approached who are randomised
- Recruitment rate: number of participants recruited per month per site
- Intervention adherence: proportion of participants allocated to "supervised rehabilitation" and "self-managed rehabilitation" attending at least four physiotherapy sessions and one physiotherapy session, respectively.
- Retention: proportion of participants that return 9-month $KOOS_4$ outcome data
- To understand participants' experience of recovery, and the acceptability of the study interventions and follow-up methods to participants through semi-structured interviews

6.1.1. Progression Criteria

The progression criteria for pilot objectives measured quantitatively are presented in the table below. A traffic light system for each objective will be used to inform decision making about the feasibility of a full-scale RCT: red = not feasible with current design; amber = modifications required before progressing to a full-scale RCT; green = full-scale RCT is feasible.

The final decision on whether a full-scale RCT is feasible will consider quantitative progression criteria, whether any identified problems are judged resolvable, and qualitative study findings.

Progression criteria for quantitatively measured pilot objectives

Pilot objectives	Stop, not feasible	Continue with modifications	Continue, feasible
Willingness to be randomised	<20%	20 to <50%	≥50%
Recruitment rate	<1 per month per site	1 per month per site	>1 per month per site
Intervention adherence	<60%	60 to <75%	≥75%
Retention	<60%	60 to <80%	≥80%

6.1.2. Rationale for Pilot Objectives:

Willingness to be randomised: It is uncertain what proportion of a mixed sample of adults and young people (<16 years) and their parents, will be willing to be randomised to the study interventions. If the proportion of approached eligible patients that are randomised is low, the recruited sample will need to be assessed to determine if it is representative, and strategies to increase the proportion of approached eligible patients who are randomised will need to be considered.

Recruitment rate: Measuring recruitment will help to estimate the number of sites and duration of recruitment necessary for a full-scale RCT. We will measure recruitment per site because recruitment is often highest at the lead study site which can make overall recruitment figures misleading. We will use screening logs to record the number of patients screened, eligible, and randomised. This could identify problems that could be addressed to improve recruitment for a full-scale trial.

Intervention adherence: Measuring the proportion of participants allocated to "self-managed rehabilitation" that attend at least one physiotherapy session and the proportion of participants allocated to "supervised rehabilitation" that attend at least four physiotherapy sessions as intended, is important to assess if there is sufficient participant engagement with the interventions and a sufficiently different treatment dose between treatment arms to justify comparison in a full-scale trial.

Retention: Retention is the main uncertainty of a full-scale trial based on 52% loss to follow-up in the only published RCT that compared exercise-based rehabilitation interventions after acute patellar dislocation [12]. We will measure retention by reporting the proportion of participants that return 9-month $KOOS_4$ outcome data because this is the planned primary outcome measure and time point for the full-scale trial.

To understand participants' experience of recovery, and the acceptability of the study interventions and follow-up methods to participants: Qualitative research that explores participants' experience of injury and recovery can enhance the design and conduct of the full-scale trial. We will assess acceptability of the interventions through understanding participants' experience of the interventions, how they fit into participants' lives, and their views of how the intervention might be refined. Assessing the acceptability of the follow-up methods is important because the only previous RCT to compare exercise-based rehabilitation had high unexplained loss to follow-up [12].

6.2 Outcome Measures

6.2.1. Primary (Pilot) Outcomes

The primary outcomes for this study are measures of willingness to be randomised, recruitment, intervention adherence, retention that will determine the feasibility of a full-scale trial. These outcomes are described in section 6.1.

6.2.2. Secondary (Exploratory) Outcomes

Because there is no core outcome set for people with a patellar dislocation, we consulted the Generation R Liverpool Young Persons' Advisory Group and two patients with a previous patellar dislocation who all indicated that pain or activity levels are the most important outcomes to assess. To assess if the planned outcomes for the full-scale trial can be collected, we will collect them in this study.

The secondary outcomes are:

Knee symptoms and function: assessed by the average of four of five domains of the Knee Osteoarthritis Outcome Score ($KOOS_4$), a 42-item knee-specific patient-reported outcome measure (PROM). The four domains are pain, other symptoms, function in sports and recreational activities, and knee-related quality of life. Domain scores range from 0 to 100 (higher scores indicate better outcomes). The five domains of the KOOS will also be reported separately (the additional domain is function in activities of daily living). The $KOOS_4$ has been widely used as the primary outcome in RCTs evaluating treatments for patients with knee injuries [23,24]. The KOOS can be used in patients aged ≥13 years [25].

At baseline, we will only collect participants' current KOOS scores. We will not collect pre-injury KOOS scores at baseline because this was deemed potentially too burdensome for this patient population where retention has been an issue [12]. Because the KOOS questionnaire asks participants about their knee during/in the "last week", we have specified in the baseline KOOS questionnaire that if participants

injury occurred “less than 1 week ago”, they should answer questions based on how their injured knee has been “since your injury”. This was completed because participants who complete baseline questionnaires within a few days of injury could misinterpret that “last week” refers to the period before their injury, rather than the current status of their knee as intended.

Quality of life: assessed using the EuroQol 5 Dimensions (EQ-5D-5L) [26], a generic quality of life patient-reported questionnaire. It measures quality of life under five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each domain contains a five-level response: no problems, slight problems, moderate problems, severe problems and unable. Domain responses are combined to provide one overall utility score, ranging from -0.594 to 1 for UK populations (higher scores indicate better quality of life). Participants also rate their health on a visual analogue scale from 0 (worst health you can imagine) to 100 (best health you can imagine). The EQ-5D-5L is intended for people aged ≥16 years but can be used for people aged 12-15 years in studies including participants in both these age categories [27]. At baseline, only current health state will be assessed.

Return to pre-injury sport/physical activity level: participant-reported percentage return to the main sport/physical activity that they did before their patellar dislocation, rated from 0 to 100% (higher scores indicate closer return to main pre-injury sport/physical activity level).

Global rating of change: participant-reported rating of change in their knee compared to when they agreed to enter the study, measured on a 7-point Likert Scale (a lot worse, moderately worse, a little worse, no change, a little better, moderately better, a lot better).

Adherence to prescribed exercise: assessed by asking participants how frequently they perform intervention exercises.

Health resource use: number of physiotherapy sessions (including out-of-study private and/or NHS physiotherapy), and other primary and secondary care appointments collected from physiotherapy completed treatment logs, participant questionnaires, and site reporting.

Complications: all complications will be recorded including deep vein thrombosis, pulmonary embolism, surgery related to patellar dislocation management, recurrent ipsilateral (same leg) patellar dislocation, contralateral (opposite leg) patellar dislocation, increased knee pain or swelling during or after completing the intervention exercises that requires a consultation with a healthcare professional, and any new or exacerbated medical condition that started during or after completing the intervention exercises that requires a consultation with a healthcare professional.

6.2.3 Objectives and Outcome Measures Table

Objectives	Outcome	Outcome measure	Time point of assessment
	Pilot		
Pilot objectives (to determine if a full-scale RCT comparing supervised versus self-managed rehabilitation is feasible)	Willingness to be randomised	Proportion of eligible patients approached who are randomised	Randomisation
	Recruitment rate	Number of participants recruited per month per site	Randomisation
	Intervention adherence	Proportion of participants allocated to “supervised rehabilitation” and “self-	6 months post randomisation

		managed rehabilitation" attending at least four physiotherapy sessions and one physiotherapy session, respectively	
	Retention	Proportion of participants that return 9-month $KOOS_4$ outcome data	9 months post randomisation
	To understand participants' experience of recovery, and the acceptability of the study interventions and follow-up methods to participants	Semi-structured interviews (maximum of 20 participants)	≤9 months post randomisation
	Exploratory		
Exploratory (to assess if the planned outcomes for the full-scale RCT can be collected)	Knee symptoms and function	$KOOS_4$ and all KOOS subdomains	Baseline (post injury) and 3, 6, and 9 months post randomisation
	Health related quality of life	EQ-5D-5L	Baseline (post injury) and 3, 6, and 9 months post randomisation
	Return to pre-injury sport/physical activity level	Participant-reported percentage return to their main pre-injury sport/physical activity	Baseline (post injury) and 3, 6, and 9 months post randomisation
	Global Rating of Change	Participant-reported global rating of change on a 7-point Likert scale	3, 6, and 9 months post randomisation
	Adherence to prescribed exercises	Participant-reported frequency of performing prescribed exercise	3, 6, and 9 months post randomisation
	Health resource use	Participant-completed follow-up questionnaires, physiotherapy treatment logs, and site reporting	3, 6, and 9 months post randomisation
	Complications	Participant-completed follow-up questionnaires and site reporting	3, 6, and 9 months post randomisation

7. STUDY DESIGN

PRePPeD is a multicentre, parallel, two-arm, external pilot RCT and qualitative study, comparing "supervised rehabilitation" versus "self-managed rehabilitation" for people aged 14 years or older with an acute first-time or recurrent patellar dislocation. See section 9.4 for randomisation details.

Screening and recruitment will occur in at least three NHS hospitals over a maximum of 12 months. Participants will receive either 4-6 physiotherapy sessions over a maximum of 6 months ("supervised rehabilitation" intervention) or one physiotherapy session ("self-managed rehabilitation" intervention) at recruiting sites. Additional clinical follow-up will follow standard local hospital policies. Participants will be followed up by the central study team using electronic questionnaires at 3, 6, and 9 months after randomisation. Postal questionnaires will be available for participants who need them. Study follow-up requires no additional hospital visits.

As part of the qualitative study, we will interview up to 20 participants to understand their experience of injury and recovery, and the acceptability of the study procedures and interventions.

See Appendix A for project flowchart and Appendix B for participant flow through the study.

8. PARTICIPANT IDENTIFICATION

For this section, and the remainder of the protocol, "parent" refers to a parent as well as a person with parental responsibility of a patient/participant aged <16 years.

8.1. Study Participants

People aged ≥14 years with an acute first-time or recurrent patellar dislocation.

8.2. Inclusion Criteria

- Aged ≥14 years
- First-time or recurrent patellar dislocation confirmed if:
  - the patellar dislocation was reduced by a healthcare professional **or**
  - 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
- 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

8.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- >21 days from injury
- Previous patellar stabilisation surgery on the affected knee
- Requires acute surgical intervention (e.g., due to concurrent osteochondral fracture)
- Contraindication(s) to participation in the study interventions
- Patient is unable to adhere to study procedures
- Previously randomised into the study

9. PROTOCOL PROCEDURES

9.1. Recruitment

Recruiting 50 or more participants across three study sites over 12 months will require recruitment of 1.4 participants per site per month. We believe this is achievable based on recruitment of 3.9 participants per month in our single-arm single-site feasibility study [15].

Our unit has a network of over 100 sites that have previously worked with us on multicentre RCTs. Study sites will be selected based on track records with regards to efficiency of governance approvals, communication with central research teams, predicted recruitment numbers, and representation of diverse geographical regions, hospital sizes, and socio-demographic characteristics. If necessary, we will advertise the study to sites and potential Principal Investigators (PIs) through professional conferences and networks, with the help of the regional Clinical Research Network and through word of mouth.

An invitation pack which includes a Site Feasibility Questionnaire (SFQ) will be provided to potential sites. The SFQ may be completed by an individual with adequate, authoritative knowledge of the site. The PI or an appropriate deputy must confirm participation and the accuracy of any SFQ submitted to the central study team in Oxford.

The central study team will evaluate returned SFQs to ensure a site is equipped with appropriate resources to deliver the project and meet recruitment targets. Written confirmation of collaboration will be provided to the PI.

9.2. Screening and Eligibility Assessment

Potentially eligible patients will be identified in the Emergency Department/Minor Injuries Unit or via virtual or outpatient trauma and orthopaedic clinics and provided with a Patient Information Sheet (PIS). A member of the responsible clinical team will highlight the study to eligible patients and parents (for patients aged <16 years). For those agreeable, the clinician will introduce a local research team member who will explain the study and answer any questions. For patients aged <16 years, the researcher will explain the study using age-appropriate materials (video and paper formats will be available).

The local research team will approach patients and parents (for patients aged <16 years), in person in the clinical setting or via telephone or video call to discuss the study. Participant eligibility will be confirmed by a suitably qualified and experienced individual. There will be no exceptions regarding eligibility i.e., each participant must satisfy all the approved inclusion and exclusion criteria of the protocol.

Screening logs recording the age, gender and, if provided, reasons for declining participation will be kept at each study site to determine the number of patients assessed for eligibility and reasons for exclusion. The number of eligible patients approached, missed, recruited, and the number of patients who decline consent or withdraw will also be recorded.

9.3. Informed Consent

9.3.1. Patients Aged ≥16 years

For this section “patient” refers to a patient aged ≥16 years.

As the interventions require active self-management, following advice and instructions, and using written/online materials, participants must have sufficient cognitive function to manage a self-guided exercise programme and capacity to consent to participation.

After eligibility confirmation, interested patients will have a discussion with a local research team member. The informed consent discussion may be in person or via telephone/video call, depending on the scenarios as described above and in accordance with the recruitment policy of sites. Patients will be given as much time as required to consider the information and discuss it with family, friends and their General Practitioner (GP) if they choose to do so. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to explain their withdrawal. The person who obtained consent must be suitably qualified and experienced and have been delegated to do so by the PI. Permission from participants will be obtained to inform their GP of their inclusion in the study.

If agreeable, patients will provide their consent using the latest approved version of the online Informed Consent Form (ICF) before any study related procedures or data being collected. Alternatively, consent will be recorded by a local research team member on an online Verbal ICF during the informed consent video/telephone call. A copy of the completed online or verbal ICF will be emailed to participants (a printed copy will be provided to patients who do not have an email address). The local research team will store a further copy in participants' medical notes.

9.3.2. Patients Aged <16 years

For this section, "patient" refers to a patient aged <16 years i.e., aged 14-15 years in this study.

A parent must have capacity to consent to the patient's participation. Patients must have sufficient cognitive function to manage a self-guided exercise programme and provide assent should they wish to do so.

After eligibility confirmation, interested parents and patients will have an informed consent discussion with a local research team member as outlined in section 9.3.1. If agreeable, informed consent will be obtained from the parent as outlined in section 9.3.1. Patients will be invited to complete an online assent form, but a completed assent form is not required for participation. However, if a parent provides consent, but the patient indicates on the assent form they do not want to participate, the patient will not be included in the study. Permission from the parent will be obtained to inform the participant's GP of their inclusion in the study. A copy of the completed ICF and assent form (if completed) will be emailed to parents (a printed copy will be provided to parents who do not have an email address). The local research team will store a copy of the consent and assent form (if completed) in participants' medical notes.

Participants who enter the study aged 15 years and turn 16 years within the 9-month follow-up period will be contacted to have an informed consent discussion. If agreeable, informed consent will be obtained as outlined in section 9.3.1. A copy of the completed online or verbal ICF will be emailed to the participants (a printed copy will be provided to patients who do not have an email address). The local research team will store a further copy in participants' medical notes.

9.4. Randomisation

After providing informed consent and completing baseline questionnaires, participants will be randomised using a 1:1 allocation ratio to “supervised rehabilitation” or “self-managed rehabilitation” by a researcher at the recruiting site using a secure (encrypted) web-based service provided by the Oxford Clinical Trials Research Unit (OCTRU).

Participants will be randomised in the clinical setting i.e., the Emergency Department, Fracture Clinic, or Physiotherapy Department, depending on the treatment pathways and processes for identifying and consenting patients at study sites.

The randomisation sequence will be computer-generated and stratified by study site and first-time/recurrent dislocation of the affected patella with permuted blocks of varying lengths.

On randomisation of a participant the central study office, main site contact, and local study team will be notified. This will take place via an automated email as part of the randomisation process.

9.5. Blinding and Code-breaking

Due to the nature of the interventions, it will not be possible to blind participants and intervention providers to treatment allocation. The local research team reviewing hospital records will also not be blind to the treatment allocation. Most outcomes are self-reported by participants by electronic questionnaires.

9.6. Description of Study Intervention, Comparators and Study Procedures (clinical)

Usual care initial injury management for people with acute patellar dislocations can vary within and between hospitals. Normally, a knee splint is applied and mobility aids, such as crutches, are provided to help people walk. We will not specify the content of usual care initial injury management, but this will be recorded.

Based on feedback from consultations with Patient and Public Involvement (PPI) partners and clinicians, initial physiotherapy treatment sessions will be face-to-face. Initial sessions can be by video only if essential e.g., the local policy of the study site restricts face-to-face appointments due to COVID-19. Video appointments are now widely available in NHS physiotherapy services following the COVID-19 pandemic.

9.6.1. Self-Managed Rehabilitation

This involves a single, one-to-one, face-to-face physiotherapy session, lasting up to 60 minutes. If participants are struggling with exercise technique or progression, they can initiate one follow-up phone/video/face-to-face physiotherapy session, following PPI feedback during the development of this study that this would improve intervention acceptability. Based on available data (see section 5), one physiotherapy session with an optional additional follow-up session is within the range of NHS physiotherapy treatment normally provided for patients with this injury.

Following their normal clinical assessment, physiotherapists will provide advice explaining what a patellar dislocation is, what to expect after injury, self-help strategies, return to activity guidance, and how to maintain long-term knee health. Physiotherapists will then prescribe participants a set of exercises from a pre-specified list. Exercises will aim to restore knee flexibility, lower limb strength, and improve lower limb and trunk neuromuscular control. Behaviour change techniques to facilitate

participants' adherence to prescribed exercise will also be used, such as goal setting, self-monitoring of behaviour (physiotherapists will ask participants to record exercise completion in an exercise diary), instruction on how to perform a behaviour (physiotherapists will advise participants on correct exercise technique), and behavioural practice (physiotherapists will ask participants to practice prescribed exercise). These techniques were chosen based on NHS guidance [28], systematic review evidence [29,30] and findings from our preliminary study [15]. After this initial appointment, participants will continue their recovery independently, progressing to more challenging exercises using the information materials provided. Information materials will be available online with paper copies available for participants that require them.

9.6.2. Supervised Rehabilitation

This involves 4-6, one-to-one, physiotherapy sessions over a maximum of 6 months. Initial sessions will last up to 60 minutes and follow-up sessions up to 30 minutes. A maximum treatment duration of 6 months will be used based on participants' reported preferred treatment duration (median 4 months, range 3-6) in our preliminary study [15] and feedback from a group of physiotherapists with expertise in patellar dislocation rehabilitation. Initial sessions will be face-to-face. Follow-up sessions will be face-to-face/video, depending on participants' preferences, based on PPI and clinician feedback that video was preferable to phone for remote appointments to enable more accurate clinical assessment and exercise prescription (phone appointments will be permitted in instances where scheduled video appointments cannot be conducted e.g., equipment failure).

In addition to their normal clinical assessment, physiotherapists will be encouraged to objectively measure leg strength using a leg press or hand-held dynamometer at each treatment session, if the assessing physiotherapist deems this safe. A recent systematic review identified leg strength recovery, when measured objectively, is often incomplete after patellar dislocation [31]. This could be due to clinicians assessing leg strength manually, which can underestimate strength deficits between legs [32].

Following assessment, physiotherapists will provide the advice described in the "self-managed rehabilitation" intervention. Physiotherapists will then prescribe up to five exercises, limited in number to promote adherence [33], from a pre-specified list. Exercise will aim to restore knee flexibility, lower limb strength, improve lower limb and trunk neuromuscular control, and facilitate return to running based activities where relevant to participants' activity-related goals. Physiotherapists will choose exercises using their clinical judgement and considering participants' preferences and activity-related goals. Restoring leg strength is a key focus, so programmes must include at least one resistance exercise prescribed and progressed following American College of Sports Medicine guidelines [23]. Physiotherapists can prescribe one bespoke exercise, not from the pre-specified list, if considered essential to participants' recovery. In addition to the behaviour change techniques described in section 9.6.1, the follow-up sessions in this intervention will enable physiotherapists to use additional behaviour change techniques to facilitate participant adherence to prescribed exercise, such as reviewing goals and problem solving (if exercise adherence is problematic).

Alongside physiotherapist re-assessment at follow-up sessions, the greater range and difficulty of exercises in this intervention should facilitate prescription of exercises that are progressively challenging and matched to the functional demands of participants' activity-related goals, in keeping with the training principles of 'overload' and 'specificity', respectively [23].

9.6.3. Other Healthcare Treatment

Other aspects of health and social care will continue as normal. Records will be made of additional treatments participants receive due to their patellar dislocation. The manualised intervention delivered by physiotherapists will only be available to those allocated to the study intervention, although usual physiotherapy care would be available for those requiring it. The use of out-of- study physiotherapy will be captured in follow-up questionnaires and will be carefully monitored and reported. Participants' GPs will be notified that their patient is taking part in the study, as GPs can also refer patients to physiotherapy.

9.7. Baseline Assessments

Sociodemographic, height, weight, main pre-injury sport or physical activity, injury and previous injury data, type of splint provided, and weight bearing instructions will be collected in the baseline case report form (CRF). Participants will also be asked to complete the KOOS and EQ-5D-5L questionnaires and percentage return to main pre-injury sport/physical activity level.

9.8. Treatment and Physiotherapist Training Logs

Treatment and physiotherapist training logs will be used to record usual care and details of intervention sessions e.g., the date, participant attendance, duration, session content, clinician's experience details, setting, treatment provided, mode of delivery, and the material and resources issued.

9.9. 3, 6, and 9-month Follow-up

9.9.1. Participants Aged ≥16 years

At 3, 6, and 9 months after randomisation, participants will be sent an email and/or text inviting them to complete electronic questionnaires. Postal questionnaires will be available for participants who need them. See section 6 for data collected at 3, 6, and 9-month follow-up. Participants who do not complete questionnaires within a specified timeframe will be sent automated reminder(s) by email and/or text, or a reminder letter by post, according to their preferences. If questionnaires are not completed, participants will be contacted by email, text, or telephone to encourage follow-up. A maximum of 3 attempts will be made to contact participants to encourage follow-up at each follow-up time point (unanswered phone calls where it is not possible to leave a voice message will not be counted as an attempt). We will also obtain missing data and resolve data queries using these methods, as appropriate.

9.9.2. Participants Aged <16 years

Questionnaires and automated reminders (where necessary) will be sent to participants, as outlined in section 9.9.1, if parental consent has been obtained to do so. All other contact to encourage follow-up, obtain missing data, or resolve data queries will be through the participant's parent(s) as described in section 9.9.1.

The participant does not need to provide assent to receive questionnaires and automated reminders, however if the parent provides consent but the participant indicates on the assent form they do not want to receive questionnaires directly, questionnaires and automated reminders will be sent to the participant's parent only. Where parental consent has not been obtained to send questionnaires to the

participant, questionnaires and automated reminders (where required) will be sent to the participant's parent.

9.10. Sample Handling

No samples will be taken from participants.

9.11. Early Discontinuation/Withdrawal of Participants

Participants and parents (for participants aged <16 years) will be informed participation is voluntary and they can withdraw at any time without explaining why and without affecting the quality of their clinical care.

Participants and/or parents (for participants aged <16 years) will be able to withdraw from treatment but participate in data collection. They will not be able to withdraw data obtained before their withdrawal, as the data will be required for the intention-to-treat (ITT) analysis and analysis of safety. The options for withdrawal will be explained in the PIS.

The type of withdrawal and reason for withdrawal, where participants and/or parents (for participants aged <16 years) are willing to provide a reason, will be recorded in the withdrawal CRF.

9.12. Definition of End of Study

The end of study is when the last participant has completed final follow-up and all queries have been resolved.

10. SAFETY REPORTING

Safety reporting for participants will start when the participant is randomised and end when the participant has reached the final follow-up time point i.e., 9 months after randomisation.

10.1. Definition of Serious Adverse Events

A serious adverse event (SAE) is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect.

Other 'important medical events' may also be considered a SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

10.2. Reporting Procedures for Serious Adverse Events

If an SAE arises in the period between randomisation and the final follow-up visit, the site will complete an SAE form and record the description, date of onset, end date, severity, and assessment of relatedness to the study intervention.

For safety recording for this study, only unforeseeable SAEs potentially related to the intervention will be reported immediately to the central study team. When the local research team becomes aware of an SAE in a study participant, the PI will review the SAE locally and make a decision about the causality (i.e., likelihood of the event to be related/attributed to the intervention). Further details on the grades of causality are available in the *SAE Reporting Guidelines* document in the Investigator Site File. Following the assessment of causality, the PI will assess any related events for expectedness. For any SAEs assessed as unexpected and potentially related, the details of the event will be entered on an SAE reporting form on the database, and the local research team will notify the central study team via email or telephone within 24 hours of the PI becoming aware of the event. Once received, causality and expectedness will be confirmed by the Chief Investigator (CI) or delegate (Nominated Person). If consensus is not reached between the PI and Nominated Person about assessment of causality and expectedness, this will be escalated to the CI for further discussion. However, if no consensus decision is reached about expectedness after further discussion within one working day, and the SAE is judged to be unexpected by any one of either the PI, Nominated Person or CI, the event will be classified as an unexpected event.

A SAE occurring to a participant should be reported to the Research Ethics Committee (REC) that gave a favourable opinion of the study where in the opinion of the CI the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the CI becoming aware of the event, using the Health Research Authority (HRA) report of serious adverse event form (see HRA website). All such events will also be reported to the Trial Management Group (TMG) at their next meeting.

Adverse events (AEs) that are unrelated to the injury, intervention or treatment, will not be reported.

10.3. Reporting Procedures for Foreseeable Serious Adverse Events

Foreseeable SAEs, and injury and treatment related complications not defined as serious will be recorded by participants in follow-up questionnaires or by site staff if they become aware of them but will not need to be reported immediately. These events will be verified with participants (or parents of participants aged <16 years) and/or study sites where necessary to ensure accurate recording and to avoid duplicate reports.

These include:

- Deep vein thrombosis or pulmonary embolism
- Surgery to the injured knee (unless this relates to the interventions in which case this would be an unforeseeable SAE)
- Patellar dislocation of the affected (ipsilateral) or unaffected (contralateral) leg (unless this was related to the interventions and requires inpatient hospitalisation in which case this would be an unforeseeable SAE)

- Increased knee pain or swelling after completing intervention exercises that requires a consultation with a healthcare professional
- new or exacerbated medical condition that started during or after completing the intervention exercises that requires a consultation with a healthcare professional

Recurrent ipsilateral patellar dislocations and contralateral patellar dislocations are expected during this study (four-year recurrent ipsilateral dislocation rate after non-surgical treatment for patellar dislocation rate is 31% [8], two-year contralateral patellar dislocation rate was 14% (10/74) in skeletally immature participants treated either surgically or non-surgically [34]). Patellar dislocations will be defined as those reported by participants during follow-up that required attendance at hospital or their GP, or if there is a documented patellar dislocation diagnosis in a participant's medical records that occurred after the index injury. Because measuring subsequent patellar dislocations and surgery will be important to assess the comparative safety and effectiveness of the interventions in the full-scale RCT, site investigators will also be asked to check the medical records of participants at respective sites to determine if any unreported patellar dislocations or related knee surgery occurred during the 9-month follow-up period.

If a participant indicates during study follow-up questionnaires that they have undergone imaging investigation, the central study team will contact study sites to check if this confirms a concurrent injury at baseline or a subsequent injury.

11. STATISTICS AND ANALYSIS

11.1. Statistical Analysis Plan (SAP)

The plan for the statistical analysis of the study is outlined below. There is not a separate SAP document in use for this study.

11.2. Description of the Statistical Methods

The quantitative feasibility outcomes (i.e., willingness to be randomised, recruitment rate, intervention adherence, and retention) at all time points will be expressed as proportions with 95% confidence intervals, calculated using Wilson's method [29]. All other quantitative data will be analysed using descriptive statistics using appropriate summary statistics (e.g., means and standard deviations and/or medians and interquartile ranges). Categorical data will be expressed as counts and proportions.

As this is a pilot study, no comparative statistical testing or inferences about intervention effectiveness will be made. EQ-5D-5L index scores will be calculated using the EQ-5D-3L crosswalk value set, as recommended by the National Institute for Health and Care Excellence (NICE) [30]. If the new EQ-5D-5L valuation is completed and recommended for use by NICE before our data analysis, EQ-5D-5L index scores will be calculated with both approaches and summarised. Withdrawals from treatment or the study, related complications and SAEs will be reported.

Analyses will be conducted using Stata statistical software.

11.3. Sample Size Determination

Retention of study participants is the main uncertainty of a full-scale trial and was the main driver of sample size for this study. A sample size of 50 will enable us to estimate 80% retention to within a 95% confidence interval of ± 11%.

11.4. Analysis Populations

All randomised participants will be analysed according to the treatment arm they were allocated to, regardless of the treatment they receive i.e., by ITT. No imputation of missing data is planned.

11.5. Decision Points

No interim analyses of efficacy outcomes are planned.

11.6. Stopping Rules

As this is a low-risk pilot RCT that will not make inferences about the comparative effectiveness of the interventions, there are no stopping rules.

11.7. The Level of Statistical Significance

The nominal 5% 2-sided significance level will be used to generate 95% confidence intervals.

11.8. Procedure for Accounting for Missing, Unused, and Spurious Data

Missing data will be minimised by careful data management. Missing data will be described with reasons given where available. The number and percentage of individuals in the missing category will be presented by treatment arm. All data collected on data collection forms will be used, since only essential data items will be collected. No data will be considered spurious in the analysis since all data will be checked and cleaned before analysis.

11.9. Procedures for Reporting any Deviation(s) from the Original Statistical Plan

Any changes or deviations from the original SAP will be described and justified in the protocol, final report, and publications as applicable, depending on the timing of the changes.

11.10. Health Economics Analysis

We will collect data on participants' health resource use (see section 6.2) to assess if key data needed for the health economic analysis for the full-scale trial can be collected. No health economic analysis is planned.

12. QUALITATIVE RESEARCH

The embedded qualitative study aims to understand the acceptability of the interventions and follow-up methods which are key uncertainties of the full-scale trial. The qualitative study will also enhance our understanding of participants' experience of injury, recovery after acute patellar dislocation, and

participation in a rehabilitation RCT. Qualitative findings will be considered alongside quantitative progression criteria when deciding if a full-scale RCT is feasible.

12.1. Qualitative Data Collection

One, face-to-face (or by video/telephone if this is not possible), semi-structured interview will be conducted with up to 20 participants at a mutually agreeable location. Participants will be purposively sampled to obtain a breadth of experience and for variation in treatment allocation, age (aged ≥16 years versus aged <16 years) and completed/lost to follow-up. Eligible patients who declined participation in the study will also be interviewed to explore their experience of injury and recovery. Interviews will be conducted within 9 months of randomisation. A sensitising topic list will be developed with PPI partners drawing on their experience.

12.2. Consent for Qualitative Research

During the consenting process for the pilot RCT, participants or parents (for participants aged <16 years) will indicate if they are happy to be contacted about interview participation. Eligible patients or parents (for eligible patients aged <16 years) who decline to participate in the pilot RCT will also be asked to indicate if they are happy to be contacted about interview participation.

If permission to be contacted has been provided, potential interview participants or parents (for those aged <16 years) will be contacted by a member of the study team to explain the purpose of interviews, provide an interview specific PIS, and answer any questions. Age-appropriate materials will be available for interested participants aged <16 years. Informed consent will be obtained face-to-face or verbally as outlined in section 9.1. Potential participants aged <16 years will be invited to provide their assent, but this is not required for interview participation. However, if a parent provides consent but the potential participant aged <16 years indicates on the assent form they do not want to participate, they will not be included in interviews.

12.3. Qualitative Data Analysis

Interviews will be conducted and analysed concurrently. Interviews will be audio-recorded and transcribed verbatim. NVivo software will be used to help organise the data. Field notes will be taken after interviews to provide additional contextual information, and record reflections on the interviewer's experience and how these might affect data collection and interpretation. Data will be analysed iteratively using thematic analysis. This involves data familiarisation, creating a thematic framework, coding data, arranging codes under themes, and data interpretation. An audit trail of decisions made during the analysis will be kept. Findings will be supported with de-identified direct participant quotations.

13. DATA MANAGEMENT

The data management aspects of the study are summarised here with full details described in the Data Management Plan (DMP).

At enrolment, participants will be asked to indicate their preference for the delivery and completion of follow-up questionnaires – electronic or postal follow-up at 3, 6, and 9 months. Data collected in

electronic format will be done by direct entry onto the study database, including the collection of documentary evidence of consent. Electronic data collection has the major advantage of building "data logic" into forms, minimising missing data, data input errors and ensuring the completeness of consent forms. All data entered will be encrypted in transit between the participants/recruitment site and server. All electronic patient-identifiable information will be held on a server located in an access-controlled server room at the University of Oxford. The data will be entered into a Good Clinical Practice (GCP) compliant data collection system and stored in a database on the secure server, accessible only to the research team based on their role within the study. The database and server are backed up to a secure location on a regular basis.

Identifiable data will be limited to contact details and will be accessed separately from the outcome data obtained from/about the participants and managed within the rules of the clinical database system. In all other data, participants will be identified by a study participant identification number only with the exception of CRFs, where participant initials may be added. Direct access to source data/documents will be required for study-related monitoring and/or audit by the Sponsor, NHS Trust or regulatory authorities as required. Contact details will be retained for 12 months after the last data collection. This excludes research documents with personal information which will be held securely at the University of Oxford for three years after the publication of the study results. An electronic de-identified trial dataset will be retained.

13.1. Source Data

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office charts, laboratory records, diaries, microfiches, radiographs, audio recordings and PROMs that are submitted directly to the sponsor and correspondence.

CRF entries will be considered source data if the CRF is the site of the original recording (e.g., there is no other written or electronic record of data). All documents will be stored safely in confidential conditions. On all study specific documents, other than the signed consent and assent form (where applicable), the participant will be referred to by their study participant identification number, not by name.

13.2. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations. Site staff will have access to the centrally collected patient-reported outcome data for participants that they recruit at their site on REDCap (Research Electronic Data Capture), to ensure that they can download a complete dataset for their patients at the end of the study.

13.3. Data Recording and Record Keeping

Study data will be collected and managed using REDCap electronic data capture tools hosted at OCTRU, University of Oxford.

REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Wherever possible, study data will be entered directly into the study database by site staff or participants. Data on paper forms or captured during phone calls to participants will be entered into the study database by suitably trained central office staff. Full details will be recorded in the DMP. The participants will be identified by a unique study participant identification number in any data extract. Identifiable data will only be accessible by members of the study team with a demonstrated need (managed via access controls within the application) and only used to communicate with the participant or parent (e.g., sending follow-up reminders for online form completion or telephone follow-up).

Qualitative interviews and some intervention sessions (see section 14 Quality Assurance Procedures) will be digitally audio recorded on encrypted devices. Qualitative interviews will be electronically transcribed, and pseudonymised transcriptions will be stored on secure servers at the University of Oxford, identified by a study participant identification number and/or initials only and will only be accessible to the CI and those members of the Oxford research team who have been authorised to do so by the CI. Audio recordings will be retained for 12 months after analysis and then deleted. It is necessary to retain the recordings for this period as they are the source data and help us to interpret participants' responses. Access to them is required in case these are needed to refer back to during analysis and reporting. A confidentiality agreement will be in place between the Sponsor and the transcriber if external transcription services are sought for the qualitative interviews. Any external transcription service used in this study will have been approved by the university's Information Security Service.

14. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures (SOPs).

Intervention delivery will be monitored periodically through site visits and/or audio recordings of treatment sessions. Participants' verbal consent will be required to audio record or observe treatment sessions. Physiotherapists will record participants' verbal consent in their medical notes.

CRFs will also be used to monitor intervention fidelity. Data will be collected on intervention content, delivery, and number of treatment sessions attended to facilitate monitoring and reporting. Sites will receive feedback from quality assurance checks to help maintain and improve fidelity. Additional training will be provided to sites if required.

14.1. Risk Assessment

A risk assessment and monitoring plan will be prepared before the study opens and will be reviewed as necessary over the course of the study to reflect significant changes to the protocol or outcomes of monitoring activities.

14.2. Study Monitoring

The monitoring activities will be based on the outcome of the risk assessment. For this study, AEs and SAEs related to the interventions are likely to be relatively rare. If they occur, they will be reviewed by the TMG. Quality control procedures will be undertaken during the recruitment and data collection phases of the study to ensure research is conducted, generated, recorded, and reported in compliance with the protocol, GCP, and ethics committee recommendations. The CI and the Trial Manager will develop data management and monitoring plans.

14.3. Trial Management Group

Day-to-day management of the study will be the CI's responsibility, as this study is being completed by the CI as part of a DPhil (PhD) project. This will be overseen by the TMG who will meet monthly to assess progress. Four TMG members are supervising the CI's DPhil. A PPI partner is an integral member of the TMG. It will be the responsibility of the CI to undertake training of the research staff at each study site. The study statistician and the information specialist will be closely involved in setting up data capture systems, design of databases, and clinical reporting forms. As this is a low-risk pilot RCT, there will be no Trial Steering or Data and Safety Monitoring Committee. The TMG will maintain robust oversight of study conduct and safety issues.

15. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g., consent process or administration of study intervention) or from GCP or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

16. SERIOUS BREACHES

A "serious breach" is a breach of the protocol or of the conditions or principles of GCP which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

If a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the CI, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within 7 calendar days.

17. ETHICAL AND REGULATORY CONSIDERATIONS

17.1. Declaration of Helsinki

The investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

17.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with GCP.

17.3. Approvals

Following Sponsor approval, the protocol, ICF, PIS and any other study materials will be submitted to an appropriate REC, and HRA for written approval.

The CI will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

17.4. Other Ethical Considerations

The researcher conducting qualitative interviews will adhere to the standards of their professional regulatory authority. This includes disclosing confidential information about a participant when these standards require them to do so, for example if the researcher finds out during interviews that the participant is a harm to others.

We are aware that there may be concern about randomising people aged <16 years to a self-management rehabilitation intervention. In preparation for this study, the CI discussed the study plans with the Liverpool Young Person Advisory group (15 people aged 10-20 years, one parent) and two adults with a previous patellar dislocation. No ethical concerns about the study design were raised by the group. One young person highlighted that attending healthcare appointments can hinder education, particularly during exam years, underlining the importance of establishing whether supervised rehabilitation is the most effective rehabilitation approach. Based on the group's feedback, if participants allocated to "self-managed rehabilitation" are struggling, they can initiate one follow-up physiotherapy appointment. The name of the more intense intervention was also renamed "supervised rehabilitation" because some felt the original name "best-practice physiotherapy", inferred that this intervention was superior.

17.5. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the same parties. The CI will submit progress reports to the funder according to their reporting requirements.

17.6. Transparency in Research

Prior to the recruitment of the first participant, the study will have been registered on a publicly accessible database [ISRCTN registry].

The study team undertakes to keep study data up to date and to make the results publicly available.

17.7. Participant Confidentiality

The participants will be identified only by a study participant identification number on all study documents and any electronic database, with the exception of CRFs, where participant initials may be

added. The authorisation functionality within the data collection system will be utilised to ensure that identifiable data can only be accessed by appropriate members of the study team. All documents will be stored securely and only be accessible to study staff and authorised personnel. The study will comply with the UK General Data Protection Regulation and the Data Protection Act (2018), which requires data to be de-identified as soon as it is practical to do so.

17.8. Expenses and Benefits

Participants will receive the exercise interventions as part of standard treatment for their patellar dislocation, so no expenses will be payable to participants for physiotherapy sessions. If qualitative interviews are in person, we will pay participants standard class travel expenses to attend.

18. FINANCE AND INSURANCE

18.1. Funding

This research is funded by a NIHR Doctoral Fellowship (NIHR301759) awarded to Colin Forde.

18.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided.

18.3. Contractual arrangements

A contract will be drawn up between the Department of Health and the University of Oxford. Appropriate contractual arrangements will be put in place with all third parties

19. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR. Authorship will be determined in accordance with the International Committee of Medical Journal Editor guidelines and other contributors will be acknowledged.

The study protocol and results will be published in open-access peer-reviewed journals. We will publish the embedded qualitative study 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 [37], the Consolidated Standards of Reporting Trials (CONSORT) extension to randomised pilot and feasibility trials [38], and the template for intervention description and replication (TIDieR) guidelines [39].

We will disseminate our findings through presentations at academic conferences, for example the British Patellofemoral Society conference, 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 to reach a wider healthcare and public audience.

20. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of intellectual property generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new intellectual property arising from the trial.

21. ARCHIVING

Documents and electronic systems will be archived as per the appropriate OCTRU SOPs in place at the time of archiving.

22. REFERENCES

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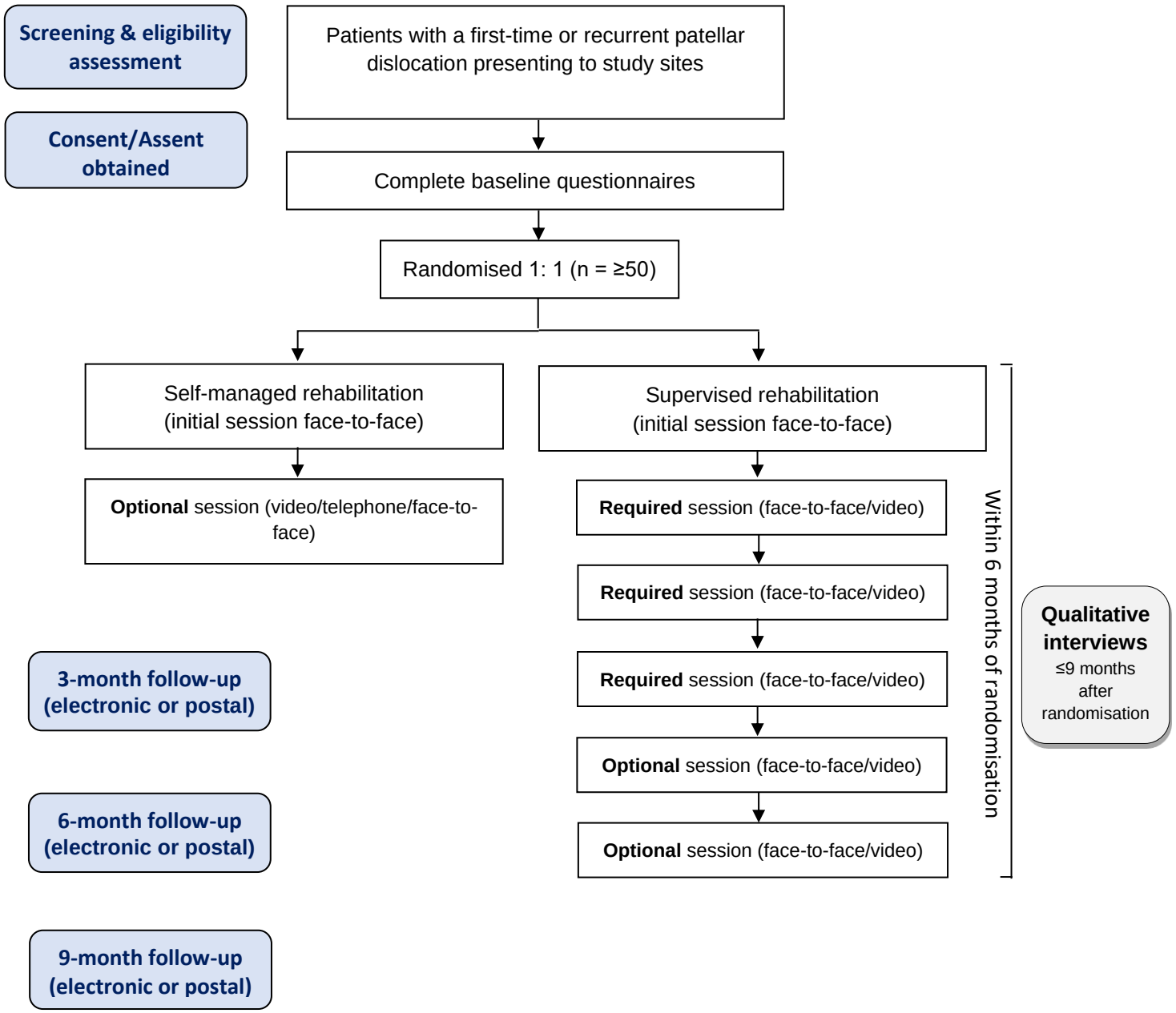
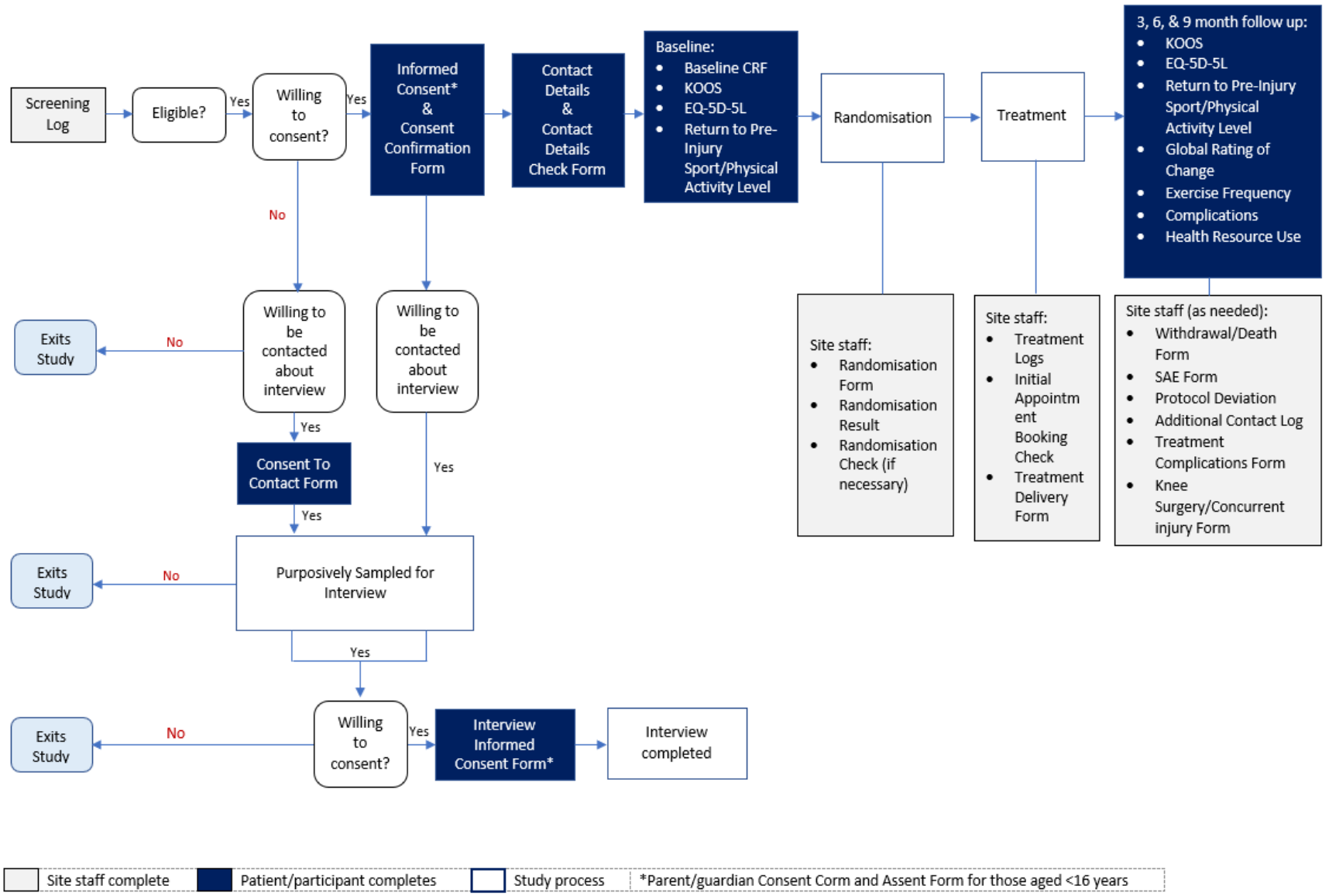
APPENDIX A: STUDY FLOW CHART



APPENDIX B: PARTICIPANT FLOW THROUGH STUDY



23. APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	2	23Aug2022	Colin Forde	To clarify that we will attempt to contact participants who do not complete follow-up questionnaires a maximum of 3 times at each follow-up time point
2	3	03Nov2022	Colin Forde	To amend exclusion criteria (section 8.3), >14 days from injury to >21 days from injury. Section 13 has been amended to be brought in line with the Patient Information Sheet and Data Management Plan