Determining the feasibility of a full-scale randomised controlled trial evaluating rehabilitation for people after acute patellar dislocation

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Abstract

After an acute patellar dislocation, patients are routinely referred for exercise-based rehabilitation to help them recover. Despite this, no high-quality evidence exists to inform rehabilitation practice and patient outcomes vary. A full-scale randomised controlled trial (RCT) evaluating different rehabilitation interventions is needed to inform clinical practice. This thesis aimed to determine if conducting this full-scale RCT was feasible.

First, supervised (four to six physiotherapy sessions of tailored advice and exercise) and self-managed (one physiotherapy session that enabled self-management) rehabilitation interventions were developed, drawing on established intervention development approaches and frameworks.

Next, because there is no consensus on what outcomes should be measured in trials in this area, a systematic review of outcomes reported in patellar dislocation trials was conducted to inform outcome selection for the full-scale RCT. This identified 69 RCTs that used 141 unique outcomes, 42 different patient-reported outcome measures, and variable outcome measurement timepoints.

To investigate the full-scale RCT's feasibility, a multicentre parallel-group external pilot RCT that compared supervised versus self-managed rehabilitation was conducted. Fifty participants aged ≥14 years with an acute first-time or recurrent patellar dislocation were recruited and randomised 1: 1 to the interventions. Follow-up was three, six, and nine months after randomisation. Quantitative feasibility outcome results were 1.) willingness of eligible patients to be randomised: 57% (95% confidence interval (CI) 46% to 67%), 2.) recruitment rate: mean 1.4 (95% CI 0.6 to 1.8) participants per site per month, 3.) nine-month retention: 62% (95% CI 48% to 74%), and 4.) proportion of supervised rehabilitation participants that attended ≥4 physiotherapy sessions and self-managed rehabilitation participants that attended ≥1 session: 72% (95% CI 58% to 83%).

An embedded qualitative study, involving semi-structured interviews with nine pilot RCT participants, found that the experience of patellar dislocation recovery was conveyed through the themes 'coming to terms with the initial injury' and 'regaining my former self'. Findings also

indicated that the pilot RCT interventions and follow-up methods were seen as acceptable, though there was some variation. This suggests that the low retention may have been for reasons other than the outcome measurement instruments and follow-up methods used.

The main finding of this thesis was that a full-scale RCT evaluating rehabilitation is feasible. However refinements are necessary, particularly to improve retention. These refinements should be informed by wider stakeholder consultation.

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Thank you also to the many people who collaborated on various aspects of the studies in this thesis. These people and their contributions are described in Appendix 18.

Finally, I dedicate this thesis to my parents, Ollie and Ber. Thank you for all you have done for me.

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Abbreviations

CERT	Consensus on Exercise Reporting Template
CI	confidence interval
COMET	Core Outcome Measures in Effectiveness Trials
CONSORT	Consolidated Standards of Reporting Trials
COREQ	consolidated criteria for reporting qualitative research
COS	core outcome set
CTIMP	Clinical Trial of an Investigational Medicinal Product
GP	general practitioner
HRA	Health Research Authority
ICF	informed consent form
ICTRP	International Clinical Trials Registry Platform
IQR	interquartile range
ISRCTN	International Standard Randomised Controlled Trial Number
KOOS	Knee injury and Osteoarthritis Outcome Score
MPFL	medial patellofemoral ligament
MRC	Medical Research Council
MRes	Masters in Clinical Research
MRI	magnetic resonance imaging
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OCTRU	Oxford Clinical Trials Research Unit
PIS	patient information sheet
PPIE	patient and public involvement and engagement
PRePPeD	Physiotherapy Rehabilitation Post Patellar Dislocation

PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PROM	patient-reported outcome measure
PROSPERO	International prospective register of systematic reviews
Q-angle	quadriceps angle
RCT	randomised controlled trial
SAE	serious adverse event
SD	standard deviation
SPIRIT	Standard Protocol Items: Recommendations for Intervention Trials
TIDieR	template for intervention description and replication
TMG	trial management group
WHO	World Health Organisation

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Chapter 1 Introduction

This chapter explains what the problems relating to acute patellar dislocation rehabilitation are, why they are important, and how I planned to address some of these problems in this thesis.

Initially, I provide a background to the condition by describing basic patellofemoral joint anatomy and biomechanics, what a patellar dislocation is, and the epidemiology of this condition. Following this, I describe rehabilitation's role in the management of people with an acute patellar dislocation, treatment outcomes, and the limited existing evidence to guide rehabilitation practice. I then discuss why a full-scale randomised controlled trial (RCT) evaluating rehabilitation is needed but that uncertainties remain over whether this full-scale evaluation can be done, and if so, how. I conclude the chapter with the thesis aim and objectives which outline how I planned to assess the feasibility of this future full-scale RCT.

1.1 Background to the condition

1.1.1 Patellofemoral joint anatomy and biomechanics

The patellofemoral joint is the articulation between the patella and the trochlea of the femur (also known as the intercondylar groove or femoral sulcus). This joint's stability is dependent on the shape of these bones, their cartilage surfaces, and the surrounding soft tissues.[1]

The patella's articular surface is located on the upper two thirds of its posterior surface and mainly comprised of a convex-shaped medial and lateral facet separated by a central ridge (Figure 1.1).[2] In contrast, the trochlea is a concave-shaped depression on the anterior surface of the distal femur. The trochlea is formed by a central groove that deepens as it extends distally and a medial and lateral facet.[2] The lateral facet is more prominent and extends more proximally than the medial facet (Figure 1.2). Hence, the lateral facet helps restrain lateral movement of the patella when it is

engaged in the trochlea.[1] Both the patella and trochlea's articular surfaces are covered by thick layers of cartilage with the patellar cartilage the thickest anywhere in the body.[3]

Figure 1.1 Articular surface of the patella. Reproduced from Gray's Anatomy 20th US edition which has now lapsed into the public domain.

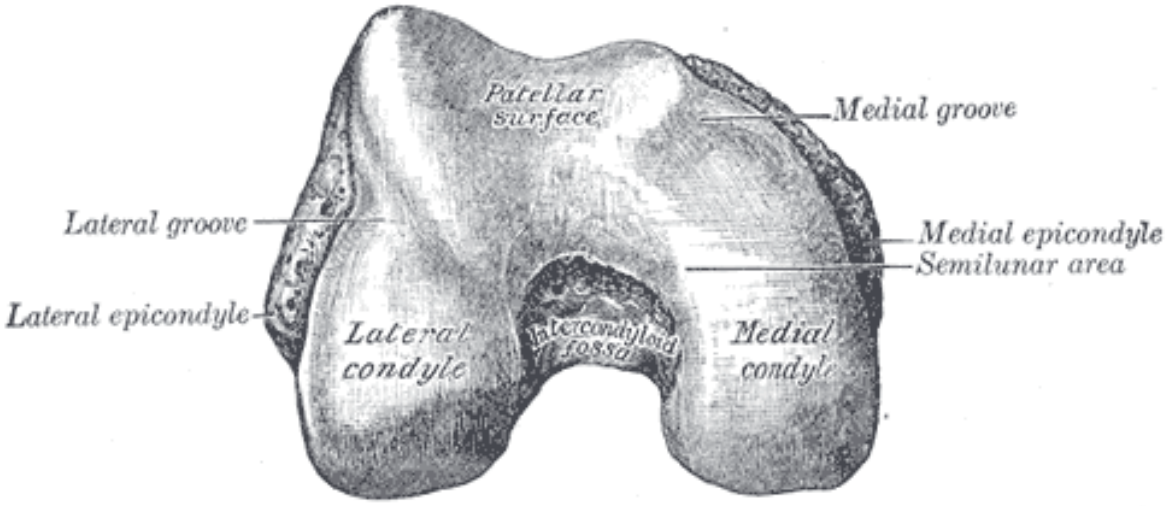


Figure 1.2 Distal end of a right femur. Reproduced from Gray's Anatomy 20th US edition which has now lapsed into the public domain.

When the knee is extended, the patella lies above or slightly overlapping the trochlea.[4] As the knee flexes the patella descends, initially engaging the trochlea at 20º to 30º of knee flexion, then continuing to move distally as the knee flexes.[4] With increased contact between the congruent

surfaces of the patella and trochlea, the patellofemoral joint becomes more stable. Between 0º to 30º of knee flexion there is minimal patellar engagement in the trochlea, so the patellofemoral joint is most mobile in this position.[5] Here, stability is mainly provided by the surrounding soft tissues[2,4] which can be divided into dynamic (contractile) and static (non-contractile) structures.[1]

The most important dynamic soft tissues are the quadriceps muscles: the rectus femoris, vastus lateralis, vastus intermedius, and vastus medialis. Distally, these muscles converge into the quadriceps tendon which inserts into the top of the patella.[6] Fibres of this tendon continue over the patella's anterior surface, exiting at the bottom to create the patellar tendon, which then inserts onto a bony prominence on the tibia called the tibial tuberosity.[7] The quadriceps' main role is to extend the knee and control knee flexion under load. Although the individual quadriceps muscles exert differently directed forces on the patella according to their orientation, the overall quadriceps force on the patella, the so called quadriceps angle (Q-angle), is directed slightly laterally (Figure 1.3).[4] Proximal and distal muscles also influence patellofemoral joint stability through their role in controlling lower limb movement. For example, the hip muscles control femoral rotation and consequently the position of the trochlea relative to the patella in the transverse plane.[8]

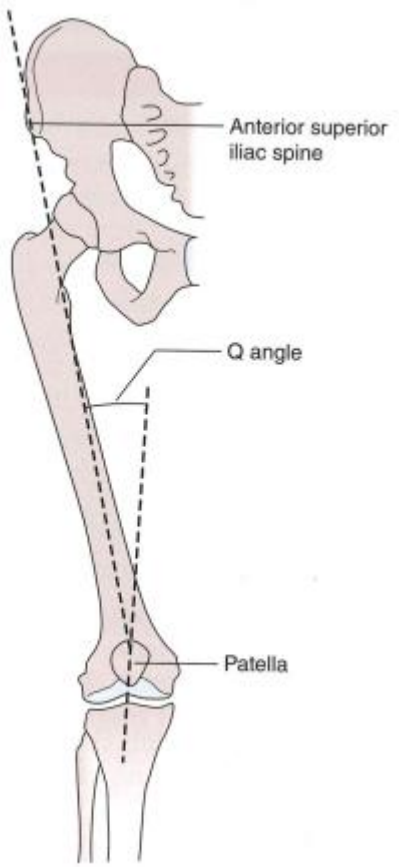


Figure 1.3 Q-angle. The Q-angle is formed by the intersection of a line from the anterior superior iliac spine to the centre of the patella and another line from the centre of the patellar to the tibial tuberosity. Reprinted with permission, from Loudon et al, Clinical Mechanics and Kinesiology, 2013, p290. © Human Kinetics, Inc.

The main static medial soft tissue structures that contribute to patellofemoral joint stability are the medial patellofemoral, patellotibial, and patellomeniscal ligaments (Figure 1.4).[3,9] The most important is the medial patellofemoral ligament (MPFL) which provides 50% to 60% of total restraint to lateral patellar translation between 0-30º of knee flexion.[9,10] Lateral soft tissues that contribute to stability include the lateral retinaculum, the iliotibial band's patellar extension, and the lateral patellofemoral, patellomeniscal, and patellotibial ligaments.[3,4]

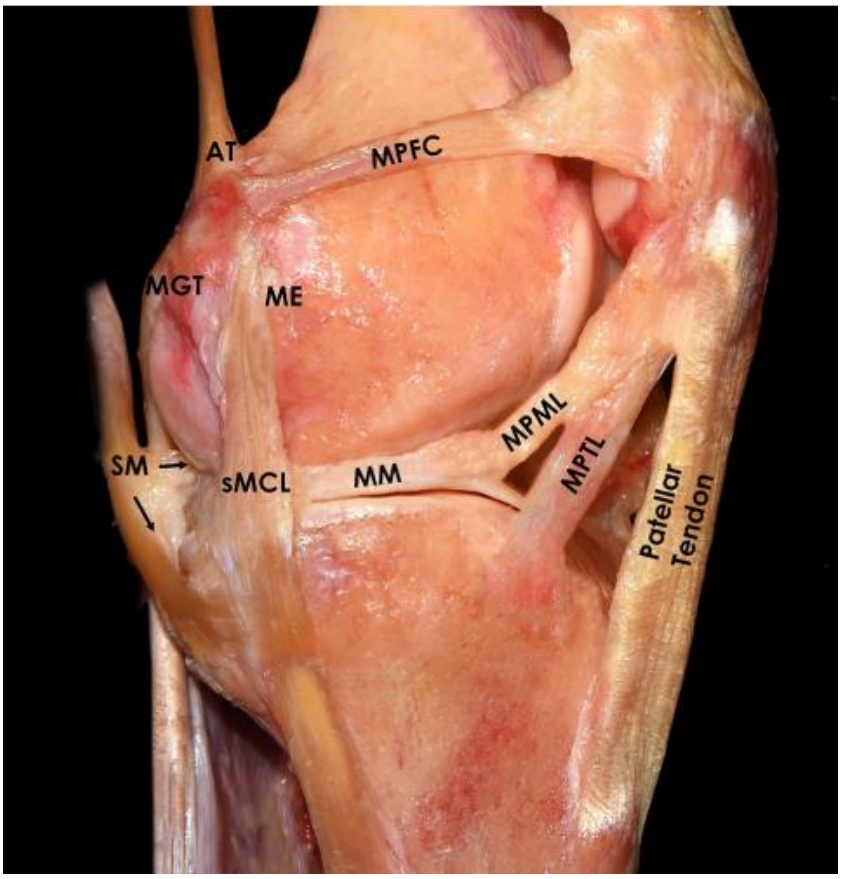


Figure 1.4 Medial view of a left knee. MPFC (medial patellofemoral complex, an alternative term for the medial patellofemoral ligament), MPML (medial patellomeniscal ligament), and MPTL (medial patellotibial ligament). The AT (adductor tubercle), sMCL (superficial medial collateral ligament), ME (medial epicondyle), MGT (medial gastrocnemius tendon), MM (medial meniscus) and SM (semimembranosus) are also shown. From Tanaka et al (2019). Recognition of evolving medial patellofemoral anatomy provides insight for reconstruction, *Knee Surgery Sports Traumatology Sports Arthroscopy*, 27:2537–2550, reproduced with permission from SNCSC.

1.1.2 Patellar dislocations

A patellar dislocation occurs when the patella is forced completely out of the trochlear groove. Normally this happens in a lateral direction. Medial dislocations are extremely rare and usually a complication of a largely outdated procedure for patellofemoral joint pain or instability that involves releasing soft tissues at the lateral knee.[11]

Most dislocations are non-contact injuries[12] and thought to occur when the foot is on the ground, the knee is flexing from an extended position, and the alignment of the lower limb increases the

lateral orientation of the quadriceps force. Implicated alignments include femoral internal rotation and adduction, and tibial external rotation and abduction.[13,14] When the laterally directed force of the quadriceps muscles, which are contracting to control knee flexion, overcomes the restraints to lateral patellar translation, the patella dislocates. The MPFL is nearly always torn,[15] making the joint more unstable and increasing the risk of recurrent dislocation.

While two thirds of patellar dislocations occur during sports,[16] a third occur during everyday activities,[16] most likely in people with a previous dislocation[17] or anatomical variants that predispose them to injury. The main anatomical risk factors are an abnormally shaped trochlea (providing less constraint to lateral patellar translation), a high positioned patella (delaying patellar engagement in the trochlea), and a more laterally positioned tibial tuberosity (increasing the lateral orientation of the quadriceps force).[18,19]

Rare presentations, like patellar dislocations due to significant lower limb deformities or pathological soft-tissue laxity (e.g., in people with Down syndrome[20]) are not the focus of this DPhil because they are usually treated along different pathways. For instance, people with patellar dislocations due to significant coronal or transverse lower limb deformities usually require surgery that is only performed in specialist centres and by select clinicians with specific training or experience.

1.1.3 Epidemiology

The reported incidence of first-time patellar dislocations is 42 per 100,000 person-years at risk.[21] Using 2022 population estimates,[22] that equates to 28,392 new first-time patellar dislocations in the UK each year. The incidence is similar between sexes but highest in the second decade of life with over 80% of first-time dislocations occurring in 10-29 year olds.[16] Within 10 years of a first-time dislocation, the average risk of dislocating the same patella is 23% and the highest risk is 36% which occurs in people aged 10-17 years at the time of injury.[21] This demonstrates that first-time and recurrent patellar dislocations are common injuries, mainly affecting adolescents and young adults.

1.2 The problem and why it is important

1.2.1 Rehabilitation's role in acute patellar dislocation management

When the patella dislocates, it may go back into place itself or it may need to be reduced by a healthcare professional. The medial soft-tissues stabilisers, for example the MPFL, are normally injured[15] creating a local inflammatory response and leading to varying degrees of knee pain, swelling, and impaired function. Therefore, it is generally believed that nearly all people after a first-time dislocation and most people after a recurrent dislocation will attend an acute injury service. There, the patella is reduced if it is still dislocated, a temporary knee splint is applied to support the knee and protect healing soft-tissues, and crutches are provided to help patients walk. Recovery can be slow and usually requires time off education or work. In the acute phase, surgery is usually only performed if there is a significant concurrent injury that requires urgent intervention, such as a large osteochondral fragment (a separated segment of articular cartilage and its underlying bone).

Once the initial injury is managed, most agree that people with an isolated first-time dislocation should be treated non-surgically with rehabilitation guided by a physiotherapist.[23,24] Rehabilitation aims to improve pain, restore function, and reduce re-injury risk by targeting modifiable impairments, such as knee joint stiffness,[25] lower limb muscle weakness,[26] and suboptimal lower limb motor control, usually by providing advice and prescribing home exercises (further details are provided in chapter 2).[27] Recently, international surveys have revealed that some surgeons recommend surgery for patients with a first-time dislocation if they have risk factors for recurrence or plan to return to sport.[28,29] However, this view is not widely held.

The management of recurrent dislocations is more controversial. In the UK, surgery is usually only recommended for these patients if they have persistent symptoms despite undergoing rehabilitation.[23,30] Outside the UK, surgery is more routinely performed for this patient group.[28,31] However, the effectiveness of surgery compared to rehabilitation for people with a recurrent patellar dislocation is unclear.[32] This is currently being investigated in the National Institute for

Health and Care Research (NIHR) funded REPPORT trial.[33] While this trial's results will provide valuable evidence it is unlikely to change acute recurrent dislocation management in the UK National Health Service (NHS). Patellar stabilisation surgery is an elective (non-urgent) procedure and in the preparatory feasibility study for REPPORT, the median time to surgery was 16 weeks.[34] Due to the COVID-19 pandemic current surgical waiting times are likely to be longer. Furthermore, only 25% of assessed patients in the preparatory study were eligible. So, even if the REPPORT trial shows surgery is more effective, the results will only apply to a small subgroup of patients and not guide their management in the acute injury phase. Similarly, if rehabilitation is shown to be as or more effective than surgery, the lack of a comparator rehabilitation group means the optimal rehabilitation intervention will remain unclear. Therefore, initial rehabilitation is likely to remain the standard of care for people with an acute first-time and recurrent patellar dislocation in the UK NHS. The most effective rehabilitation for these patients remains unknown and needs to be determined. This is discussed further below.

1.2.2 Outcomes after rehabilitation

Despite undergoing rehabilitation, patient outcomes are variable and often suboptimal.[35] In some patients the patella continues to feel unstable or it may partially (subluxation) or completely dislocate again.[36,37] This can cause patients to modify or avoid certain physical and social activities due to fear of re-injury.[37] Even in patients who only experienced one dislocation, 56% reported pain during vigorous physical activity at six months[25] and 68% experienced patellar-related activity limitations at three years.[38] The risk of developing patellofemoral joint osteoarthritis is also increased with 49% of patients developing this condition 25 years after the initial injury.[39] As described above, if rehabilitation is unsuccessful, some patients proceed to surgery. However, surgery has a higher risk of serious complications, [32] such as patellar fracture and deep infection. Although these complications are rare, they can have devastating consequences if they occur. Furthermore, the most common surgery, a MPFL reconstruction, has an estimated cost of around £4000 in the NHS (Healthcare Resource Group code: HN23). In comparison, a NHS physiotherapy appointment is much cheaper (between £64 to £113 based on 2023/2024 data).[40] Given this injury

mainly affects young people, improving rehabilitation could have significant benefits for individual patients and wider society by reducing sickness absence and healthcare use, and increasing participation in important physical and social activities.

1.2.3 Existing evidence

Even though rehabilitation is the norm after this injury, a 2018 systematic review of non-surgical treatment by Moiz and colleagues could not recommend any rehabilitation approach because high-quality trials were lacking.[35] Only one RCT of rehabilitation after the initial immobilisation period was included, which was conducted in the UK NHS.[41] This found a statistically significant but likely clinically unimportant difference in function and activity levels between two quadriceps strengthening programmes for adults (aged ≥16 years) with an acute first-time patellar dislocation. However, the results were at high risk of bias as 12-month retention was 48% (24/50).[41] The interventions were also potentially suboptimal: exercises were not tailored to individual participant's physical abilities, goals, and preferences, and exercise prescription did not follow evidence-based guidelines.[41]

I updated the systematic review of non-surgical treatment in April 2022 (see Chapter 2 for further details) and identified one ongoing RCT by Brightwell and colleagues[42] which is evaluating rehabilitation after the initial immobilisation period. This is comparing real versus sham blood flow restriction training (restricting blood flow to the exercised muscles) alongside standard physiotherapy.[42] However, the planned sample size is small (n = 78), only highly active people aged 14 to 40 years are eligible, and the interventions involve 27 physiotherapy sessions over nine weeks.[42] One other RCT has been published since my updated search. Arrebola and colleagues[43] found no clinically important difference between isolated quadriceps muscle strengthening and combined quadriceps and hip muscle strengthening programmes. Again the sample size was small (n = 40), only patients with a non-traumatic lateral patellar dislocation were included, and the interventions involved 16 physiotherapy sessions over 8 weeks. While these new trials evaluating rehabilitation are welcome, their results are unlikely to influence NHS rehabilitation provision.

They are underpowered to detect a realistic treatment effect and only include specific subgroups of patients. The interventions also involve a volume of physiotherapy that is unlikely to be commissioned or feasible to deliver across the NHS due to resource limitations.

The current lack of high-quality evidence is likely contributing to the variability in NHS physiotherapists' reported rehabilitation practice.[27] While physiotherapists reported their treatment for people after a first-time patellar dislocation mainly involved advice and prescribed home exercise, rehabilitation was provided over durations ranging from three to six weeks (reported by 24% of physiotherapists) to more than four months (12%) and delivered in variable formats i.e., one-to-one (51%) or both one-to-one and in a group (48%).[27]

1.2.4 Possible opportunities for better treatment

In the absence of high-quality evidence, some authors have recommended that to restore function and reduce re-injury risk, patellar dislocation rehabilitation should involve initial pain and swelling management and tailored exercise to improve knee joint movement, hip and thigh muscle strength, and lower limb control during functional movements.[13,44] In a preliminary study, completed as part of a NIHR-funded Masters in Clinical Research (MRes), I tested a prototype intervention of up to six physiotherapy sessions of tailored advice and exercise that incorporated these recommendations.[45] Findings indicated the intervention appeared acceptable to adults (aged ≥16 years) with an acute first-time or recurrent patellar dislocation and was deliverable in the NHS.

However there is no evidence that this type of supervised rehabilitation is effective. Attending physiotherapy sessions can also be inconvenient for patients e.g., due to challenges with travelling and disruption to education or work. This patient population's attendance at physiotherapy can also be poor.[34] In addition, rehabilitation trials in other musculoskeletal conditions, such as ankle fracture and shoulder dislocations, have shown that multiple physiotherapy sessions of tailored advice and exercise are not necessarily more effective than one session of advice and provision of materials that enables self-management.[46,47]

1.2.5 Why a full-scale RCT is needed

Rehabilitation with a physiotherapist is routinely provided for people with an acute patellar dislocation. Despite this, limited high-quality evidence exists to inform rehabilitation practice and NHS physiotherapists' treatment and patient outcomes vary. A full-scale RCT comparing a supervised rehabilitation intervention versus an intervention to support self-management would provide high-quality evidence to guide rehabilitation provision for patients with an acute patellar dislocation in the NHS. This would help create clinical guidelines and reduce variation in physiotherapists' treatment.

This RCT would also address a question deemed important by patients and clinicians. Determining the "best ways to deliver physiotherapy services to meet patients' needs and improve outcomes for patients and services" and the "best rehabilitation for common soft-tissue knee injuries" are top 10 research priorities for physiotherapy and first-time soft-tissue knee injuries, respectively.[48,49] From a policy perspective, the NHS Long Term Plan aims to reduce face-to-face outpatient appointments by a third within five years, emphasising that interventions involving multiple outpatient appointments need to demonstrate effectiveness.[50]

1.2.6 Why the feasibility of a full-scale RCT is uncertain

Although needed, the feasibility of a full-scale RCT evaluating different rehabilitation interventions for people after an acute patellar dislocation is uncertain. To my knowledge, only three RCTs in people with a patellar dislocation in the NHS have been published.[34,41,51] As previously discussed, one evaluated exercise-based interventions but experienced low retention,[41] while the others were feasibility studies ($n \leq 20$)[34,51] which under recruited. There are additional uncertainties over patients' willingness to be randomised to a self-management intervention, whether participants would adhere to a supervised and self-management intervention, and whether the interventions and follow-up methods would be acceptable to participants (discussed further in Chapter 4).

Clearly, preparatory work is required to determine whether the full-scale trial can and should be done, and if so, how. Given the nature of the uncertainties outlined above, this preparatory work should include both quantitative and qualitative methods. For example, qualitative research, with its focus on understanding experience and behaviour, is suited to exploring intervention and follow-up method acceptability, whereas other uncertainties, like retention, are best estimated quantitatively. Qualitative research would also add value by helping to interpret and explain quantitative results. This could be particularly important given the unexplained low retention in the only previous RCT of exercise-based interventions.[41] In addition, while qualitative research has been recently published in people treated surgically for patellar instability,[37] none has been conducted in people with an acute patellar dislocation. If conducted, this work would enhance our understanding of patients' experience of this injury. This could lead to refinement of the design and conduct of the full-scale trial, if this is feasible and undertaken.

Given the full-scale RCT's aim would be to inform rehabilitation provision for people with an acute patellar dislocation treated in the NHS, this future RCT should have a pragmatic focus i.e., designed to provide evidence that can be implemented in the clinical settings to which these patients typically present,[52] and the preparatory study designed accordingly. In contrast, purely explanatory (also known as efficacy) trials are less focussed on future implementation and instead aim to answer if an intervention works in ideal conditions,[52] so would not answer the full-scale RCT's primary question. In addition, explanatory trials typically have more intense follow-up. This would make delivering an explanatory trial in this patient population difficult as retention can be challenging.

1.2.7 Why a systematic review of outcomes is needed

A key stage in RCT design is outcome selection. Outcomes measure the effects of treatment i.e., treatment benefits and harms.[53] Outcome selection in RCTs is crucial, because results from these studies inform clinical and policy decision making. Ideally, RCTs evaluating treatments for the same health condition would measure similar outcomes. This would help compare and, more

importantly, synthesise the results from individual studies. Meta-analyses can provide more precise treatment effect estimates and address questions not answerable in individual trials (e.g. treatment effects across participants with different characteristics),[54] providing better evidence to inform healthcare decisions. Despite the benefits of measuring common outcomes, variable outcome selection is common in studies in many clinical areas. For example, a systematic review of outcomes in colorectal surgery studies found 766 different clinical outcomes were reported in the 194 included studies.[55]

Presently, selecting outcomes for RCTs evaluating patellar dislocation treatments is challenging because there is no agreed set of outcomes that should be measured and reported, a so called core outcome set (COS).[56] Recently, systematic reviews have highlighted the need to establish consensus in this area.[32,35] Until consensus is established, a systematic review of outcomes measured in existing trials would be informative by synthesising what has already been done. The findings could be used alongside other work, such as stakeholder consultations, to guide outcome selection for the future full-scale RCT and other RCTs in this area. This systematic review would also the first step in developing a COS if this undertaken in future.

1.3 How I planned to address the problem

1.3.1 Thesis aim, objectives, and outline

The overall aim of this thesis was to determine the feasibility of conducting a full-scale RCT evaluating rehabilitation for people after acute patellar dislocation.

There were five objectives.

1. Develop and describe the rehabilitation interventions for comparison in an external pilot RCT.
2. Conduct a systematic review of the outcomes, outcome measurement instruments, and outcome measurement timepoints in RCTs evaluating treatments for people with a patellar dislocation.

3. Design an external pilot RCT and embedded qualitative study comparing a supervised versus self-management rehabilitation intervention for people with an acute patellar dislocation.
4. Conduct the aforementioned external pilot RCT.
5. Conduct the aforementioned qualitative study.

These five objectives form the five experimental chapters (chapter 2-6) of this thesis. Although these chapters are presented sequentially for ease of reading, the work packages within chapters were not necessarily conducted in this order. The final chapter discusses the strengths and limitations of this thesis, and my plans for future work.

Chapter 2 Intervention development and description

2.1 Introduction

In Chapter 1, I provided the rationale for this thesis. Here, I describe the development of a supervised and self-management rehabilitation intervention for people with an acute patellar dislocation and how these interventions were subsequently delivered in the pilot RCT reported in chapters 4 and 5.

2.1.1 Rationale

In 2021, the UK Medical Research Council (MRC) and the NIHR published an updated framework for developing and evaluating complex interventions.[57] This defined complex interventions as those that may have numerous interacting components, allow some variation in delivery, target a range of settings or groups, and require intervention providers and/or recipients to demonstrate specific behaviours, skills, or expertise.[57] According to this definition, a multi-component intervention delivered by physiotherapists to support recovery after an acute patellar dislocation would therefore be complex.

In this updated framework, complex intervention research involves four phases: developing or identifying an intervention, feasibility testing, evaluation, and implementation.[57] As Figure 2.1 depicts, these phases are not necessarily sequential. Researchers can start at any phase, proceed to different phases, or revisit phases, depending on the uncertainties they have about the intervention(s) and evaluation design.[57]

As outlined in chapter 1, limited evidence exists to inform rehabilitation for people after an acute patellar dislocation. So, first, new rehabilitation interventions need to be developed before they are tested. This development process should be thorough to increase the chances of the new interventions being effective and implemented.[58] How the interventions were developed and subsequently delivered should also be reported to enable critical appraisal, and implementation of the results of a future full-scale evaluation if this is undertaken.[58]

2.1.2 Chapter aim

Chapters 4 and 5 describe the Physiotherapy Rehabilitation Post Patellar Dislocation (PRePPeD) external pilot RCT which compared supervised (four to six physiotherapy sessions) versus self-managed rehabilitation (one physiotherapy session) for people aged ≥14 years with an acute first-time or recurrent patellar dislocation. The aim of this chapter is to describe the development and delivery of these interventions, and the evidence and scientific theory underpinning the main intervention components.

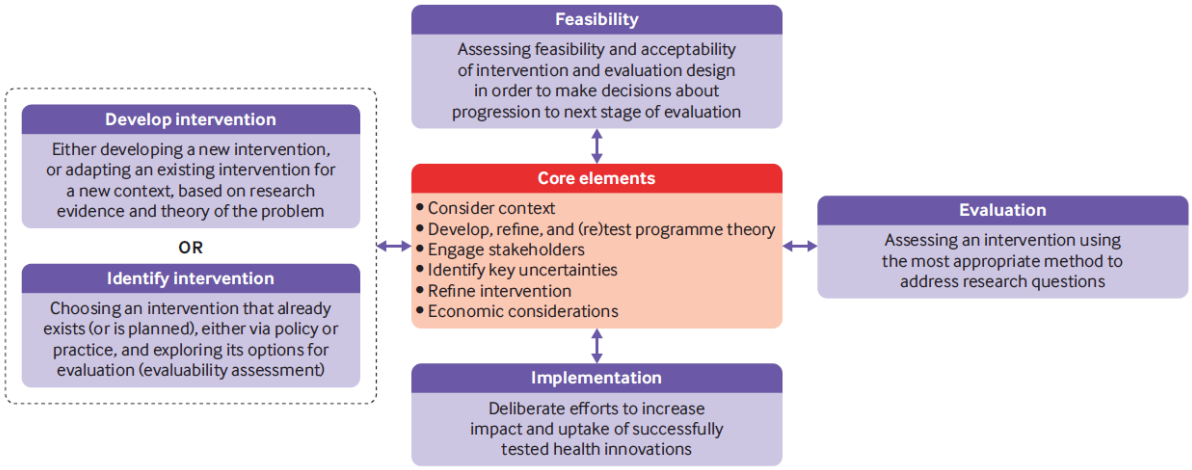


Figure 2.1 NIHR and MRC framework for developing and evaluating complex interventions. Reproduced from Skivington et al[59] under (CC BY 4.0) license in accordance with the terms of the Creative Commons Attribution (CC BY 4.0). See: https://creativecommons.org/licenses/by/4.0/.

2.2 Methods

The PRePPeD interventions were developed by drawing on a range of established intervention development approaches and frameworks.[60] Intervention components were selected after reviewing the existing evidence, clinical guidelines, NHS practice, and relevant scientific theory. Early versions of the interventions were then created and discussed with clinical experts and patient and public involvement and engagement (PPIE) partners. The final interventions were created considering their feedback, my preliminary study's findings, and what would be acceptable to patients and clinicians and deliverable across the NHS. Figure 2.2 shows an overview of the

intervention development process. Although the intervention development phases are presented sequentially, these were conducted in an iterative non-linear manner.

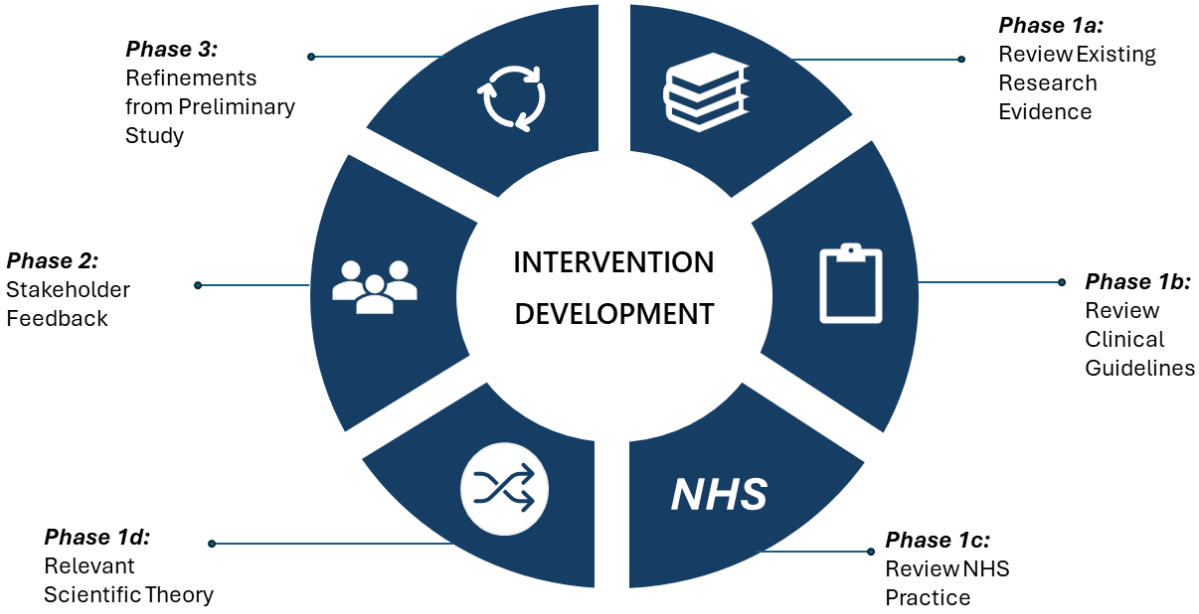


Figure 2.2 Overview of the intervention development process

2.2.1 Intervention development

Phase 1a: review existing evidence

As discussed in Chapter 1, a 2018 systematic review by Moiz and colleagues[35] found a lack of high-quality trials to inform non-surgical treatment and only one RCT that evaluated rehabilitation after initial immobilisation.[41] This study found a statistically significant but clinically questionable difference in function and activity levels between two different quadriceps strengthening exercise programmes, but there were limitations in sample size and retention rates.[41]

To identify new studies reporting non-surgical treatment, I updated this systematic review's MEDLINE and Embase search strategy in April 2022 (see Appendix 1). Seven studies[34,42,61–65] were retrieved (excluding my preliminary study) and data on the non-surgical interventions was extracted and collated. Only one retrieved study was an RCT, the ongoing study of blood flow restriction training by Brightwell and colleagues,[42] which is unlikely to influence NHS

rehabilitation provision for the reasons discussed in Chapter 1. This demonstrates that there is currently insufficient evidence to support any one rehabilitation intervention for people with an acute patellar dislocation after initial immobilisation.

In retrieved studies, non-surgical interventions varied and were often poorly reported, similar to the findings in Moiz and colleagues' review.[35] Where details have been reported, published interventions have mainly involved advice and exercises to improve knee joint movement and lower limb muscle strength. However, no single intervention has prescribed resistance exercises using evidence-based prescription guidelines,[66] retrained movement strategies to reduce reinjury risk, and used behaviour change strategies to support exercise adherence. The evidence and theory supporting the incorporation of these components into a single intervention is described below.

Phase 1b: review clinical guidelines

At the time of intervention development (April 2022), three clinical guidelines published in the English language referred to rehabilitation for people with patellar dislocations/instability. The *British Orthopaedic Association* recommends that rehabilitation after patellar stabilisation surgery should include education/advice, restore knee movement, address lower limb control during functional movements, and involve prescription of a tailored functional exercise programme.[67] The accompanying paper explained that detailed guidance is lacking due to variable practice and insufficient high-quality evidence.[30] Guidance from the *Italian Society of Muscles, Ligaments and Tendons* recommends that initial non-surgical treatment of acute first-time patellar dislocations should include pharmacological pain and inflammation management, temporary immobilisation, and crutch use.[68] Exercise is considered central to recovery, but the lack of evidence to guide exercise prescription is highlighted.[68] Finally, the *American Orthopedic Society for Sports Medicine* and the *Patellofemoral Foundation* consensus statement proposes that lower limb alignment and proximal lower limb muscle strength contribute to patellofemoral stability. However, the only reference to rehabilitation is that investigating the contribution of movement patterns to patellar instability should be a future research focus.[8]

These guidelines demonstrate that exercise is deemed integral to rehabilitation, but specific guidance about exercise type, dose, and mode of delivery is lacking.

Phase 1c: review NHS practice

Physiotherapists' practice

A 2011 UK-wide survey showed that senior NHS physiotherapists' (160 physiotherapists in 160 acute hospitals) treatment for people after first-time patellar dislocation varies, but predominantly involves advice (about rest/activity modification and reassurance) and prescribed exercise (mainly knee joint movement, proprioception, and lower limb muscle strengthening exercises).[27] Treatment lasts from three to six weeks (24% of physiotherapists) to at least four months (12%) and is delivered either one-to-one (51%) or both one-to-one and in a group (48%).[27] These findings demonstrate that advice and exercise are the core aspects of NHS physiotherapists' treatment but there is inconsistency in prescribed exercises, treatment durations, and mode of delivery.

Publicly available information

To enhance my understanding of non-surgical treatment in the NHS, I searched Google (first 10 result pages only, because internet search engines can return an unmanageable number of records[69]) in April 2022 for publicly available NHS information about patellar dislocations. The librarian reviewed search strategy is available in Appendix 2. Sixteen different resources were retrieved from 14 NHS organisations, one private NHS provider, and the NHS website. Retrieved resources focussed on the acute injury phase and mainly contained advice and exercise, underlining that these are the key components of non-surgical treatment in the NHS. Therefore, data on the information/advice and exercises in retrieved resources was extracted and synthesised (Table 2.1). Findings informed the content of acute injury advice and the initial exercises in intervention materials.

Table 2.1 Information/advice and exercises in publicly available NHS information

	Information/advice										Exercise						
											Flexibility		Strengthening/activation				Balance
Organisation	**Explanation of injury**	**Common symptoms**	**Time for healing/recovery**	**Treatment plan**	**Self-help strategies**	**Knee brace/splint**	**Benefits/importance of exercise**	**Return to driving**	**Return to work/school**	**Return to sport**	**Knee**	**Ankle**	**Thigh muscles**	**Hip muscles**	**Hip and thigh muscles**	**Calf/ankle complex**	**Any balance exercise**
Airedale NHS Foundation Trust	✓	✓	-	✓	✓	-	✓	-	-	-	-	-	-	-	-	-	-
Brighton & Sussex University Hospitals NHS Trust[a]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	-	-	-
Bedfordshire Hospitals NHS Foundation Trust	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	-	✓	✓	-	-	-	-
East Sussex Healthcare NHS Trust	✓	✓	-	✓	✓	✓	✓	-	-	-	-	✓	✓	-	-	-	-
Maidstone and Tunbridge Wells NHS Trust	✓	✓	-	✓	✓	✓	✓	-	-	-	-	✓	✓	-	-	-	-
NHS Fife	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓
NHS website	✓	✓	✓	✓	✓	✓	✓	-	-	✓	-	-	-	-	-	-	-
Nuffield Health	✓	✓	-	✓	✓	✓	✓	-	-	-	-[b]	-[b]	-[b]	-[b]	-[b]	-[b]	-[b]
Poole Hospital NHS trust	✓	✓	-	✓	✓	✓	✓	NA[c]	-	-	-	✓	✓	✓	-	-	-
Portsmouth Hospitals NHS Trust	✓	✓	✓	✓	✓	✓	✓	-	-	✓	-	✓	✓	-	✓	-	-
Royal Cornwall Hospitals NHS Trust	✓	-	✓	✓	✓	✓	✓	-	-	-	-	✓	✓	-	-	-	-
Royal United Hospitals Bath NHS Foundation Trust	✓	✓	✓	✓	✓	✓	-	✓	✓	-	-	✓	✓	-	-	-	-

	Information/advice										Exercise						
											Flexibility		Strengthening/activation				Balance
Organisation	**Explanation of injury**	**Common symptoms**	**Time for healing/recovery**	**Treatment plan**	**Self-help strategies**	**Knee brace/splint**	**Benefits/importance of exercise**	**Return to driving**	**Return to work/school**	**Return to sport**	**Knee**	**Ankle**	**Thigh muscles**	**Hip muscles**	**Hip and thigh muscles**	**Calf/ankle complex**	**Any balance exercise**
South Warwickshire NHS Foundation Trust	✓	-	-	✓	✓	-	✓	✓	✓	✓	✓	-	-	✓	-	-	✓
Sussex MSK partnership Central	✓	✓	✓	✓	✓	✓	-	-	-	-	-	-	-	-	-	-	-
University Hospitals Coventry and Warwickshire	-	-	-	-	✓	-	✓	-	-	-	✓	✓	✓	✓	-	-	-
York Teaching Hospital NHS Foundation Trust	✓	✓	✓	✓	✓	✓	✓	-	-	-	-	✓	✓	-	-	-	-

NA: not applicable; NHS: National Health Service

[a]Now named University Hospitals Sussex NHS Foundation Trust.

[b]Resource signposts to a webpage that contains exercises to protect and strengthen the hips and knees.

[c]This was a patient information leaflet for paediatrics.

Phase 1d: scientific theory

Acute injury management

When the patella dislocates, soft tissues at the medial knee, like the MPFL and medial retinaculum, are normally injured.[15] This results in varying degrees of localised pain, swelling, and inflammation, which are normal parts of the acute injury response. However, if these injury sequalae are prolonged or excessive they can delay recovery. Knee pain and swelling, when artificially induced in healthy volunteers, reduces quadriceps muscle strength and activation.[70] This likely occurs through a process called arthrogenic inhibition: the neural inhibition of muscles due to altered sensory receptor discharge from within injured joints.[71] This could impair leg muscle strength restoration with implications for recovery (see next section). Excessive knee swelling can also contribute to secondary ischaemic injury i.e., damage to previously uninjured tissues caused by insufficient blood flow following the primary injury.[72] Knee joint movement is also reduced, impeding function. Therefore, in addition to initial protection then gradual reloading of the injured tissues which are core principles of acute soft-tissue injury management guidance,[73–75] managing pain and swelling were key aspects of acute injury advice.

Exercise – lower limb muscle strength

During dynamic lower limb tasks, external moments act on the lower limb joints. A moment is a rotational force that is the product of the force by its moment arm i.e., the perpendicular distance from the force's line of action to the axis of rotation.[76] External moments are moments acting on the body that are produced by the surrounding environment, whereas internal moments are produced within the body e.g., those produced by skeletal muscle contraction.[77] For instance, when landing from jumping, a mainly external flexion moment acts on the knee. This external moment is primarily resisted by internal moments generated by eccentric contraction of the knee extensors.

Theoretically, if muscles do not have sufficient capacity to resist external joint moments, abnormal movement patterns can occur, and some evidence exists to support this view. Reduced hip strength is associated with increased dynamic knee valgus (movement of the knee medial to the foot

resulting from a combination of femoral internal rotation and adduction, tibial external rotation, and foot pronation) during single-leg landing in healthy females.[78] Reduced quadriceps strength has also been associated with reduced knee flexion during single-leg landing in patients after anterior cruciate ligament injury.[79] Both of these movement strategies are implicated in the patellar dislocation injury mechanism (see below). Improving hip and thigh muscle strength therefore could reduce re-injury risk by preventing movement patterns associated with the patellar dislocation mechanism of injury. Restoring thigh muscle strength may also help maintain long-term knee health. Stronger quadriceps muscles were associated with less patellofemoral cartilage loss in people with knee osteoarthritis.[80] This is relevant for this patient population because they have an increased risk of developing patellofemoral osteoarthritis[39] and normally have long-term knee extensor muscle weakness compared to the unaffected leg.[26]

Exercise – trunk and lower limb alignment

As discussed in chapter 1, most patellar dislocations are non-contact injuries[12] and thought to mainly occur when the foot is planted, the knee is flexing from an extended position, and the alignment of the lower limb increases the lateral orientation of the quadriceps force on the patella. The resultant eccentric quadriceps force overcomes the restraints to lateral patellar translation, dislocating the patella. Figure 2.3 depicts this theorised mechanism of injury. The MPFL, the main soft-tissue restraint to lateral patellar translation in early knee flexion,[9] is normally torn.[15] This makes patients vulnerable to future instability episodes, particularly during high quadriceps demand activities when the knee is near extension.

To reduce re-injury risk, the developed interventions included exercises that retrained movement strategies during functional movements. This mainly involved modifying trunk and lower limb alignment to reduce the magnitude and lateral orientation of the quadriceps force. Appendix 3 is an

example of an intervention exercise that retrains landing from jumping, and shows how this complex information was communicated to participants.

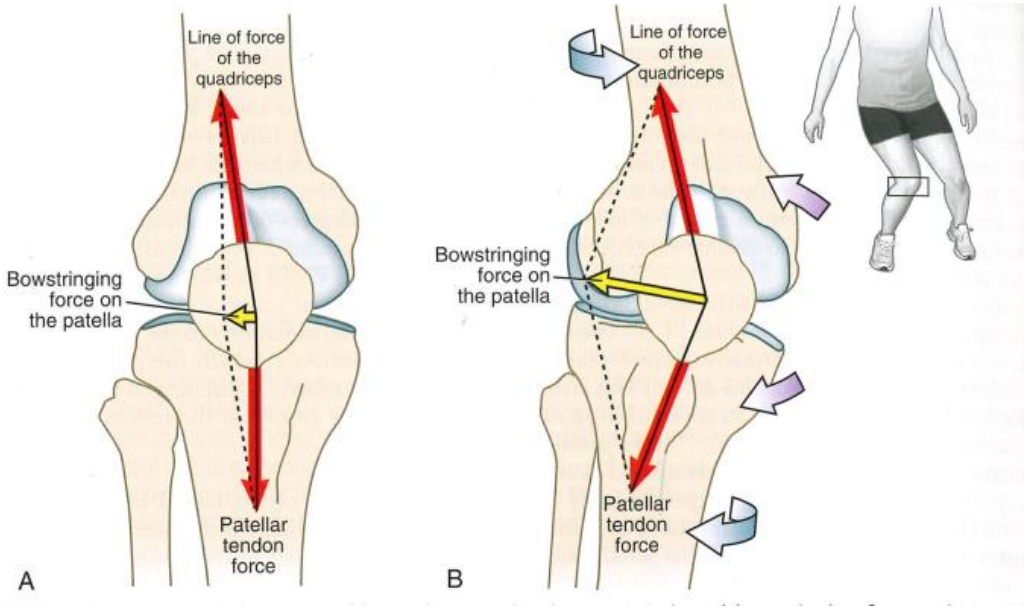


Figure 2.3 Patellar dislocation non-contact mechanism of injury. A Neutral knee alignment showing the normal lateral bowstring effect of the quadriceps force on the patella. B Blue arrows indicate the direction of movement of the of the femur (superiorly) and tibia (inferiorly) which increases the lateral bowstring effect. Purple arrows indicate the forces applied to the medial knee. Used with permission of Elsevier Science & Technology Journals, from *Kinesiology of the musculoskeletal system: foundations for rehabilitation*, Neumann, 2010; permission conveyed through Copyright Clearance Center, Inc.

Behaviour change techniques to facilitate exercise adherence

If exercise interventions are to be effective, participant adherence to prescribed exercise is probably important. This is supported by previous studies which found higher exercise adherence was associated with improved outcomes for people with other musculoskeletal conditions.[81,82] However, patient-reported adherence to prescribed exercise can be poor and is estimated to be 67%.[83] Therefore, the developed interventions used behaviour change techniques to help participants adhere to prescribed exercise. These techniques were based on strategies used in my preliminary study which were associated with high participant-reported exercise adherence.[45] These strategies included providing written information (an information workbook, exercise sheets

with pictures and instructions, and an exercise diary to record exercise performance), physiotherapists demonstrated prescribed exercise, and participants practiced prescribed exercises and received feedback. Participants also set goals, planned where and when they would perform exercise, and physiotherapists assessed participants' confidence to adhere to prescribed exercise. These strategies were informed by systematic review evidence,[83,84] the NHS Health Trainer Handbook,[85] and a previous trial in our research group.[86]

Phase 2: stakeholder feedback

Following phase 1 and drawing on my clinical experience, I created an initial outline of the self-managed and supervised rehabilitation interventions and discussed these with expert physiotherapists and PPIE partners. Given the limited evidence to inform rehabilitation practice, their feedback was important to bring the interventions together into deliverable packages, and increase the chances that these would be acceptable and implementable in the NHS.

Expert physiotherapists

To inform intervention development, I developed a reference group of six clinical and academic physiotherapists (see Appendix 18) with expertise in patellar dislocation rehabilitation. In October 2020, physiotherapists gave feedback on the proposed interventions during an online group (four physiotherapists) or one-to-one meeting (two physiotherapists). Several of their recommendations were implemented. For instance, initial physiotherapy sessions were face-to-face to allow physiotherapists to conduct a physical assessment and build rapport with participants, whereas follow-up sessions could be face-to-face or by video. Physiotherapists also recommended that advice incorporated the negative consequences of fear-avoidance behaviour based on their experience that this was commonly encountered in clinical practice. Although efforts were made to reach consensus on recommendations, no formal consensus process was used, which may be seen as a limitation. During the study set-up phase (September 2022), three physiotherapists from sites participating in the pilot RCT reviewed the intervention workbooks which resulted in minor amendments to the content.

PPIE partners

Between August 2020 and May 2021, two adult males with a previous patellar dislocation and the NIHR GenerationR Liverpool Young Persons Advisory Group (15 people aged 10-20 and one parent) provided a patient's perspective on the proposed interventions. The GenerationR group is comprised of young people who either have taken part in research, have a health condition or disability, or are interested in learning about healthcare and/or research. I did not establish if any of the GenerationR group members who provided feedback had a previous patellar dislocation.

PPIE partners agreed with physiotherapists that initial physiotherapy sessions should be face-to-face, whereas follow-up sessions could be either face-to-face or by video. They also felt that participants allocated to 'self-managed rehabilitation' should be able to initiate one follow-up session if they struggle with their exercises, believing this would increase intervention acceptability. There was also consistent feedback that creating exercise videos could improve exercise adherence. All these suggestions were implemented.

Phase 3: preliminary study refinements

The prototype intervention tested (see section 1.2.4) in my small (n =15) single-site preliminary study[45] was the basis for the supervised rehabilitation intervention in the PRePPeD pilot RCT. Refinements for the pilot included increasing the maximum treatment duration from three to six months based on participants' reported preferences in the preliminary study.[45] The maximum permitted number of sessions remained six, however in the pilot physiotherapists had to offer at least four sessions. This aimed to ensure a clear difference between treatment groups in the number of physiotherapy sessions provided—an issue in a similar rehabilitation trial.[86] An alternative method for setting resistance exercise intensity (described below) was also used, due to poor physiotherapist compliance with a modified Borg scale in the preliminary study. Additional refinements included removing exercise options that were infrequently prescribed and streamlining the exercise adherence strategies for time efficiency e.g., removing an assessment of the participant's confidence to adhere to the prescribed exercise.

2.2.2 Creating intervention materials

The workbook from my preliminary study, which had high participant-reported acceptability,[45] and workbooks from other rehabilitation trials in our group[86,87] informed the design and content of the intervention materials. The wording and formatting of materials was also informed by guidance on producing healthcare information for lay audiences from Cochrane, the NHS digital service manual, and the European Union.[88–90] Examples include using the active voice, short paragraphs and sentences, and images to explain complex information. The online workbooks (described below) were also optimised for mobile phone use as recommended in current NHS guidance for designing digital services.[90]

2.2.3 The interventions

This section describes how the interventions in the PRePPeD pilot RCT were delivered.

A diagram depicting how components of the PRePPeD interventions are thought to work, a so called logic model,[57] is presented in Figure **2.4**. Intervention reporting follows the template for intervention description and replication[91] (TIDieR) and Consensus on Exercise Reporting Template[92] (CERT) guidelines. An overview of the interventions according to the TIDieR criteria is presented in Table 2.2

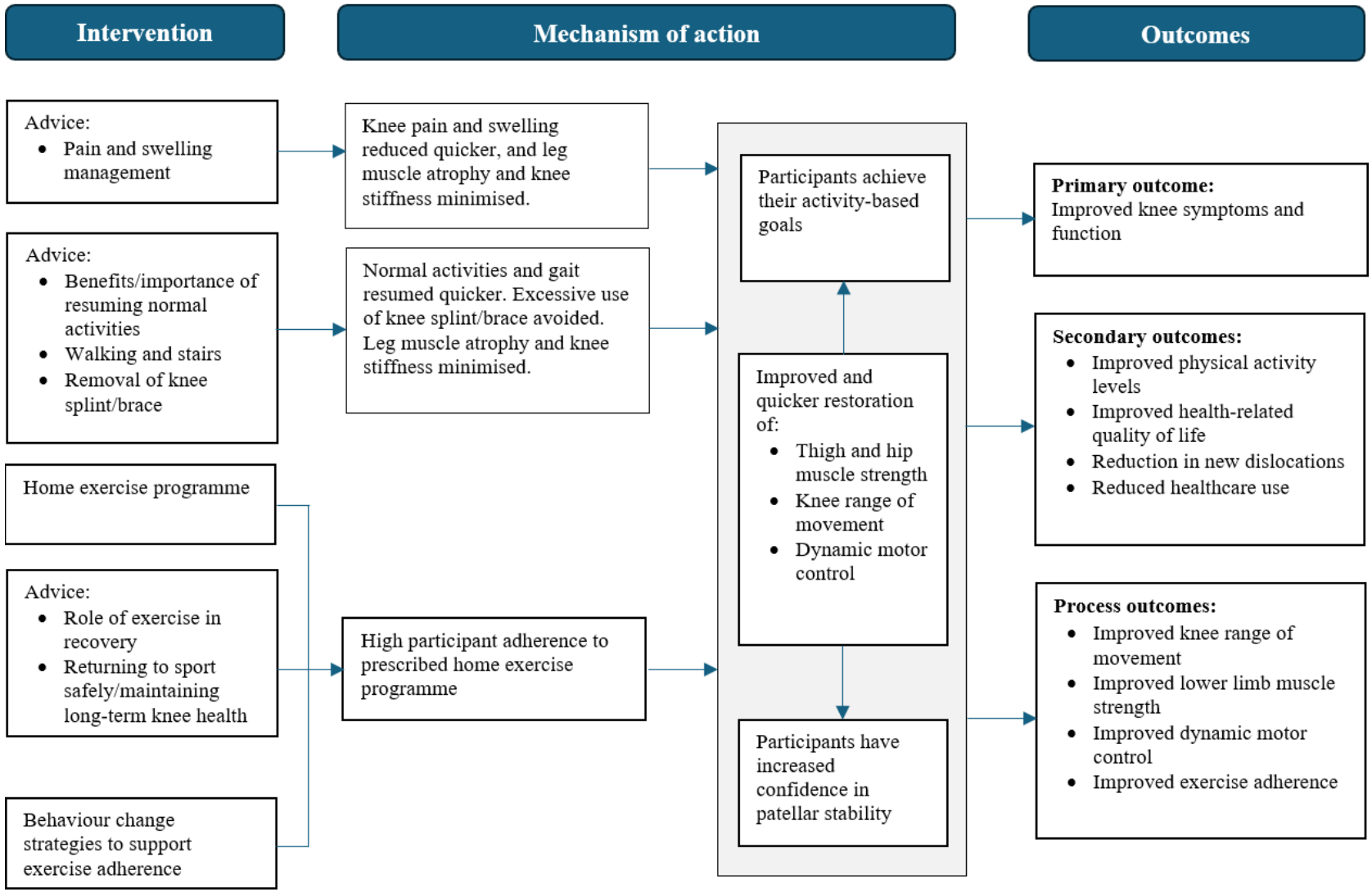


Figure 2.4 Logic model of the PRePPeD interventions

Table 2.2 Overview of the interventions according to the TIDieR criteria

TIDieR item	Supervised rehabilitation	Self-managed rehabilitation
Why	Follow-up sessions enable physiotherapists to review participants and tailor the advice and exercise they provide to individual participants, which could improve outcomes.	Enabling self-management of recovery reduces the burden on patients of attending physiotherapy appointments and could reduce costs to the NHS.
What		
Materials: participants	Paper workbook divided into 2 sections. Section 1 contained advice and basic initial exercises. Section 2 contained additional advice about maintaining long-term knee health and the materials physiotherapists used to deliver the intervention: a goal setting section, an exercise planner, an exercise diary, and a menu of exercises that physiotherapists prescribed exercises from. Exercise sheets had pictures and written instructions. Section 1 of the workbook was also available in an online version.	Section 1 of both workbooks was the same. In section 2 the advice was about how to return to sport for those who wished to, and the exercise programme was a self-guided exercise programme introduced by the physiotherapist (see text). Otherwise, section 2 of the workbook was the same between groups.
Materials: physiotherapists	All physiotherapists received a manual concisely describing intervention delivery.	As for supervised rehabilitation.
Procedures	After randomisation, a healthcare professional or researcher introduced the paper workbook to the participant and encouraged them to implement the advice and exercises in section 1 immediately. The participant was also referred to physiotherapy by a healthcare professional.	As for supervised rehabilitation.
Who provided	A healthcare professional/researcher usually a surgeon, physiotherapist or nurse, introduced the workbook. Fully qualified physiotherapists working in study sites' musculoskeletal physiotherapy services provided the intervention. No specific expertise was required but all treating physiotherapists underwent training in how to provide the intervention.	As for supervised rehabilitation.
How	Workbooks were provided face-to-face or posted if participants were consented remotely. Physiotherapy sessions were one-to-one with initial sessions face-to-face and follow-up sessions face-to-face or by video.	Workbooks were provided as for supervised rehabilitation. The first physiotherapy session was one-to-one and face-to-face. The optional follow-up session could be face-to-face or by video or phone.
Where	Intervention workbooks were provided after randomisation, which normally occurred in outpatient fracture and knee clinics. Face-to-face sessions occurred at study sites' physiotherapy departments. Participants decided where to perform prescribed exercise.	As for supervised rehabilitation.
When and how much	First session was ≤21 days of randomisation depending on local appointment availability. 4-6 physiotherapy sessions were provided over 6 months from the first session. The physiotherapist and participant decided the frequency of sessions.	First session was also ≤21 days of randomisation where feasible. Participants could initiate an optional follow-up session if they were struggling with exercise progression.

TIDieR item	Supervised rehabilitation	Self-managed rehabilitation
Tailoring	Advice: physiotherapists could emphasise any workbook advice or provide any other individual advice judged relevant. Exercise: physiotherapists could prescribe ≤5 exercises per session, but 1 exercise had to be a strengthening exercise and no more than 1 could be a bespoke exercise. Physiotherapists could provide other treatments as long as the core intervention components were delivered.	As for supervised rehabilitation for advice and other treatments. Exercise: only certain participants progressed to different exercise levels within exercise categories (see text).
Modifications	NA	NA
How well		
Planned: physiotherapists	A treatment delivery form recorded if participants received the correct workbook. See quality assurance section in text for monitoring of physiotherapists' fidelity to the intervention.	As for supervised rehabilitation.
Planned: participants	Follow-up questionnaires measured participant-reported exercise frequency 3, 6, and 9 months after randomisation (see section 4.2.10).	
Actual: physiotherapists and participants	Actual intervention fidelity is reported in chapter 5 (see section 5.3.6).	

NA: not applicable; NHS: National Health Service

Intervention delivery

Upon randomisation, which typically occurred in outpatient fracture or knee clinics, a clinician/researcher gave the participant a paper self-managed or supervised rehabilitation workbook according to their allocation. The first section of both workbooks was the same and contained advice (Table 2.3) and initial exercises (Table 2.4) that participants were advised to implement immediately. The participant was then referred to physiotherapy and told to bring their workbook to sessions. Providing intervention materials before the first physiotherapy session aimed to accelerate recovery by minimising pain, swelling, and the consequences of prolonged inactivity.

The second workbook section differed between treatment groups and contained the additional advice, exercises, and exercise adherence materials that physiotherapists used to deliver the interventions at treatment sessions. The differences between the second workbook sections are outlined in Table 2.2 and their rationale is described below. Initial physiotherapy sessions were as

soon as possible after randomisation and ideally within three weeks, so that physiotherapy started within the acute phase of injury (participants were recruited ≤21 days of injury).

Participants who provided an email address as part of their contact details were automatically emailed access to an online version of section 1 of the workbook. The only difference from the paper workbook was the availability of videos on using crutches and performing exercises. I created online materials because I anticipated recruiting a young participant population, and ≥96% of UK 16 to 34 year-olds use a smartphone for private use.[93] An online version of the second workbook section was not created because not all NHS departments can deliver interventions using exclusively online materials. However, videos for all intervention exercises were accessible via a QR code or URL in paper workbooks.

Table 2.3 Overview of the advice in the section one of the intervention workbooks

Section	Contents
Introduction	Explains the contents and purpose of the workbook.
About your kneecap	Explains basic patellofemoral anatomy using text and pictures.
What is a kneecap dislocation?	Describes what a kneecap dislocation is and common injury mechanisms.
What can I expect after a kneecap dislocation?	Common symptoms after injury.
What can I do to help my knee get better?	Why managing pain is important and how to do this (including using medication and cold). Why managing swelling is important and how to do this (including elevating the injured leg). Benefits of restoring normal activities gradually, and the negative consequences of fear-avoidance behaviours. Flare-up management.
Walking and stairs	Explains the benefits of gradually restoring normal gait, weight-bearing, and stair climbing, and how to do this. Pictures/videos and instructions on walking and stair climbing with crutches provided.
Knee splints	Guidance on when any knee splints provided can normally be removed.
Exercise guide	How exercise helps recovery. Guidance on permissible symptoms during and after exercise. The stretching, balance, and strengthening exercises to start before the first physiotherapy session with pictures/videos and instructions on technique and progressions.
Physiotherapy	How the physiotherapy appointment will be arranged, what physiotherapy will involve, and its benefits.
What to do if you have any problems or haven't receive a physiotherapy appointment	Expected timelines for recovery. Advice on who to contact if participants are experiencing problems or have not received their physiotherapy appointment.

Table 2.4 Overview of the initial exercises in section one of the intervention workbooks

Category	Level[a]	Description	Prescription parameters	Progression
Stretching				
Knee bending	1:	Active ROM knee flexion in sitting	3 x 10 reps	Bend knee further using unaffected leg
	2:	Active assisted ROM knee flexion in long sitting using hands	3 x ≥30 s	Bend knee further
Knee straightening	1:	Static quadriceps muscle contractions	3 x 10 reps	Push knee down harder
	2:	Static quadriceps muscle contractions with foot elevated e.g., on rolled up towel	3 x 10 reps	Push knee down harder
Balance	1:	Weight shifting with upper limb support	3 x 10 reps	Increase weight through the affected leg, increase time up to 10 s
	2:	Single leg stand with contralateral upper limb support	3 x 10 reps	Lean on support less, increase time per rep up to 10 s
	3:	Single leg stand without upper limb support	3 x 10 reps	Increase time per rep up to 10 s
Strengthening	1:	Squat to chair	3 x 10 reps, ≥1 min between sets	Increase weight through the affected leg, use lower chair
	2:	Squat to chair split stance (unaffected leg in front)	3 x 10 reps, ≥1 min between sets	Reduce weight on the unaffected leg

Min: minute; Reps: repetitions; ROM: range of movement
[a]Higher level means higher difficulty.

Intervention providers

Reflecting this study's pragmatic focus, physiotherapists who provided the interventions did not require certain experience or expertise, but their characteristics were recorded for results reporting. Before providing the interventions, physiotherapists received two-hour face-to-face or online training covering the study's background, an overview of the interventions, intervention delivery, and study documentation. Where feasible, I conducted intervention training face-to-face to build a rapport with physiotherapists, facilitate interaction, and practice exercise technique. In total, 23 physiotherapists were trained, all except one face-to-face.

Physiotherapists could provide both interventions, but to limit contamination between treatment groups the interventions were manualised and the supervised and self-managed rehabilitation

intervention workbooks were only available to participants allocated to those treatment groups. Intervention fidelity was closely monitored throughout (described below). A previous trial in our group implemented this approach and found no evidence of contamination.[86] All physiotherapists received a manual detailing intervention delivery and were encouraged to contact the trial team with any queries. Throughout the trial, I offered refresher training sessions, focussing on sites with a long duration between training and their first recruited participant. Two sites availed of a one hour face-to-face refresher session.

Supervised rehabilitation

An overview of how physiotherapists delivered the supervised rehabilitation intervention is presented in Figure 2.5.

The key difference in this intervention was the routine follow-up sessions which enabled physiotherapists to re-assess participants. This included, but was not limited to, participants' physical performance, adherence to prescribed exercise, and restoration of function. Physiotherapists also had a greater range of exercises to choose from and more autonomy over exercise prescription parameters than the self-managed rehabilitation intervention. These features aimed to encourage physiotherapists to provide advice and exercises that were informed by their assessment findings and clinical expertise, and tailored to individual participants' physical characteristics, stage of recovery, and activity goals.

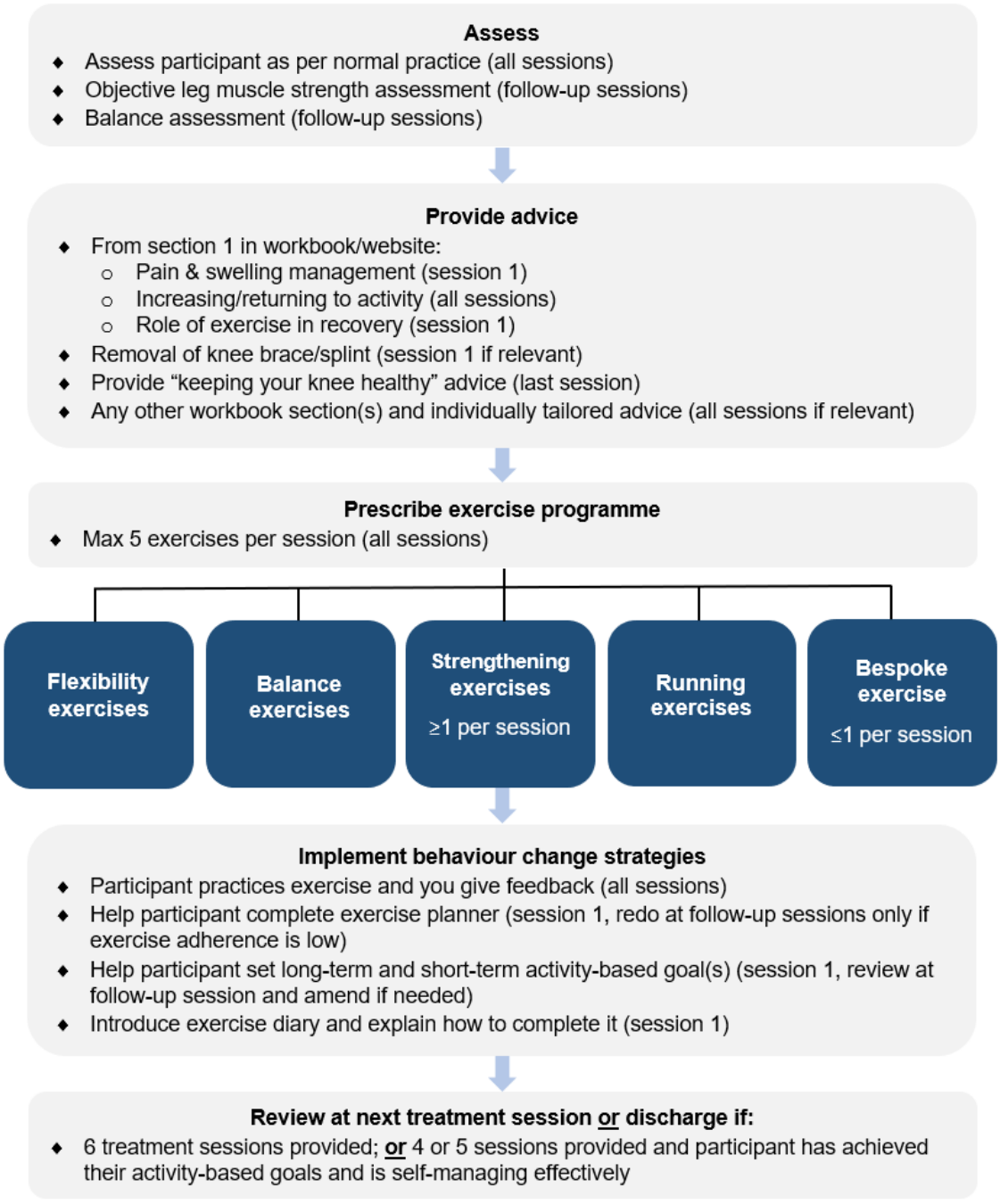


Figure 2.5 Overview of the supervised rehabilitation intervention delivery process

Structure

Participants received four to six physiotherapy sessions over a maximum of six months at a frequency decided between the physiotherapist and participant. Initial sessions were face-to-face and lasted ≤60 minutes and follow-up sessions were ≤30 minutes and face-to-face or by video depending on the physiotherapist's and participant's preferences. Participants were discharged

after six sessions, or after four or five sessions if they had achieved their goals and were self-managing effectively.

Assessment

Physiotherapists assessed participants following their normal practice. At follow-up sessions, physiotherapists also assessed participants' objective leg muscle strength and balance once this was judged safe (the term 'balance' is used hereafter for ease of reference but this could refer to an assessment of static balance or functional movement pattern e.g., single leg landing). This aimed to monitor recovery of these key physical performance variables and guide exercise prescription. Sites were required to assess muscle strength objectively because manual muscle testing underestimates between limb differences.[94] Any balance and objective leg strength assessment method was permitted but these were recorded to inform future intervention iterations. Sites without objective muscle strength testing equipment were provided with a hand-held dynamometer (Lafayette model 001165) and guidance on how to use it. Intervention training encouraged physiotherapists to select a balance assessment method considering participants' stage of recovery, physical capabilities, and the demands of activities they planned to resume.

Advice

At session 1, physiotherapists re-emphasised advice in the workbook about pain and swelling management, resuming normal activities, the role of exercise in recovery, and removing the knee splint/brace (if applicable). At follow-up sessions, the importance of restoring pre-injury activities was emphasised as this was a key focus of the intervention.

On the day of discharge, physiotherapists introduced advice about "keeping your knee healthy " from section two of the workbook, which is based on clinical guidelines for non-pharmacological management of osteoarthritis.[95] This emphasised the benefits of maintaining a healthy weight and having "good" leg muscle strength, balance and flexibility for long-term knee health. To guide longer-term exercise adherence, participants were encouraged to compare physical performance between legs on a challenging leg strengthening, balance, and flexibility exercise prescribed by

their physiotherapist. If exercise performance was more challenging on their affected leg, continuing this exercise three times per week until symmetry was restored was recommended. Performing strengthening exercises one to two times per week was advised to maintain long-term muscle strength based on research that this frequency may be sufficient to stimulate ongoing small strength gains.[96]

The "keeping your knee healthy" advice was included because this patient population have a high risk of recurrent dislocation,[21] an increased risk of developing patellofemoral osteoarthritis,[39] and the physiological adaptations to exercise are reversible if exercise is stopped.[97] Throughout, physiotherapists could highlight any other advice from the workbook or provide any other advice deemed relevant.

Exercise

Physiotherapists prescribed exercises from a menu in the participant's workbook. Exercises were divided into four categories: stretching, balance, leg strengthening, and running (see Appendix 4). Physiotherapists could prescribe up to five exercises per session, because more than five has been associated with reduced exercise adherence.[98]

In keeping with the focus on improving lower limb muscle strength, physiotherapists had to prescribe at least one leg strengthening exercise per session following prescription guidelines to increase muscle strength from the American College of Sports Medicine (1-3 sets by 8-12 repetitions, ≥3 times/week, and ≥2 minutes rest between sets).[66] To ensure strengthening exercises were sufficiently intense to stimulate continued improvements i.e., the progressive overload principle,[66] participants were advised to increase the load if they could perform three sets of 12 repetitions and do two extra repetitions after the last set for two consecutive sessions.[66] For all other exercise categories, physiotherapists prescribed exercise parameters because the optimal dose for flexibility and balance exercises is less well established.[97]

Physiotherapists could prescribe one exercise per session that was not on the exercise menu if deemed important to help participants achieve their goals. This aimed to cater for the anticipated

variability of participants' goals, and to keep the exercise menu concise so it was user friendly. Prescribed bespoke exercises were recorded to inform future intervention iterations.

All exercise sheets (see Appendix 3 for an example) contained written instructions, pictures, and optional sections where physiotherapists could write "make harder by" and "other tips/advice" instructions for additional tailoring. The sheets of prescribed exercises were placed in a plastic pocket in participant's workbook labelled "current exercises" and physiotherapists changed these at subsequent sessions if required.

Strategies to support exercise adherence

At session one, participants wrote in an exercise planner where and when they would do their exercises along with a contingency plan, set short and long-term goals (that were specific, measurable, achievable, relevant, and timely), and physiotherapists introduced an exercise diary where participants recorded exercise performance. At follow-up sessions, physiotherapists reviewed participants' exercise diaries and goals. If adherence to prescribed exercise was low, participants completed the exercise planner again. Similarly, participants amended their goals if the physiotherapist's review indicated this was necessary. Throughout, participants practiced prescribed exercises and received feedback on their technique, and physiotherapists provided any required support with exercise adherence strategies.

Self-managed rehabilitation

An overview of how physiotherapists delivered the self-managed rehabilitation intervention is presented in Figure 2.6.

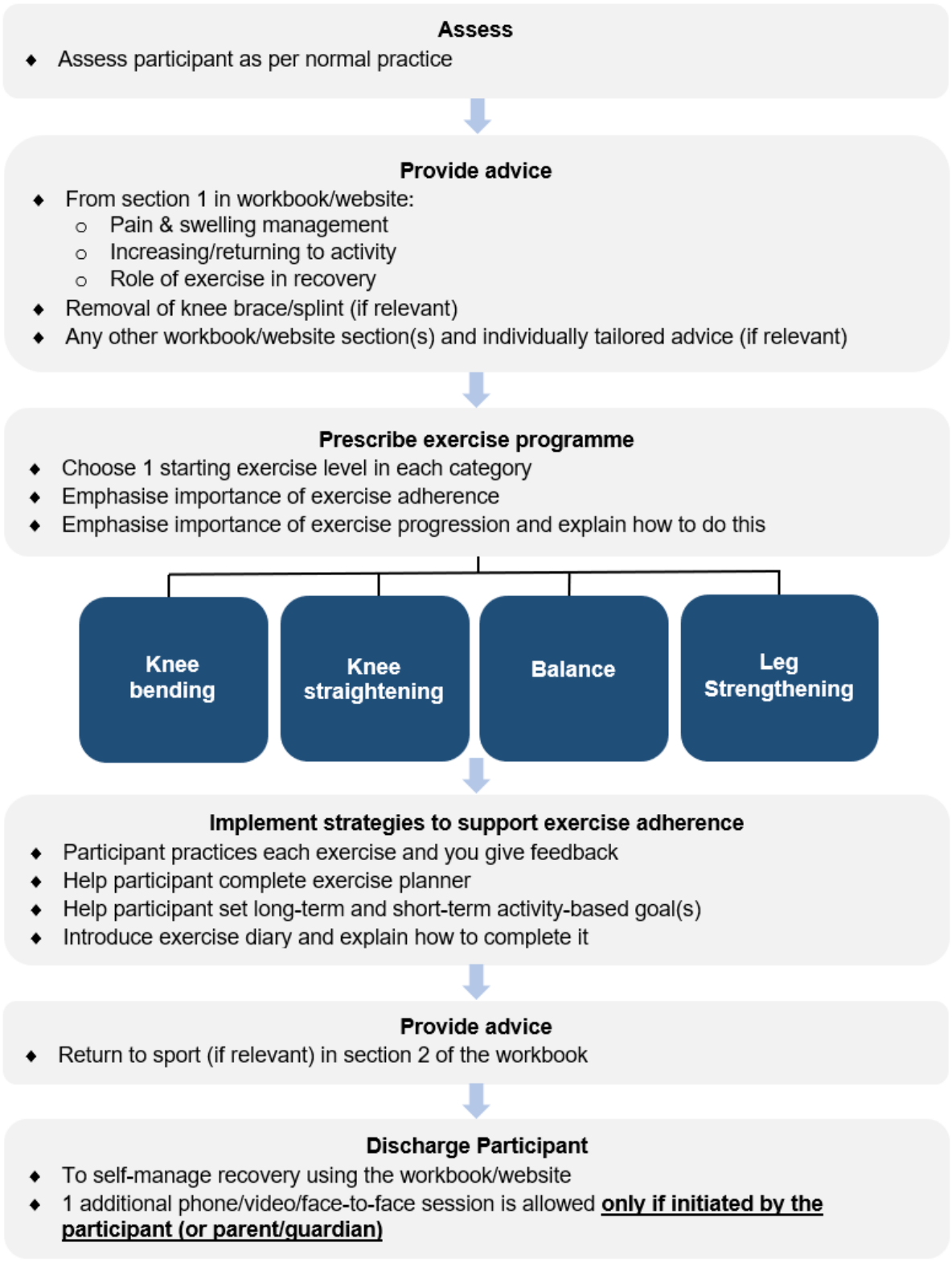


Figure 2.6 Overview of the self-managed rehabilitation intervention delivery process

Structure

Participants received a single, face-to-face, one-to-one physiotherapy session lasting ≤60 minutes. Participants then continued their recovery independently following the advice and exercises in their workbook. Participants who struggled with exercise progression could contact their physiotherapist for advice or to schedule one additional physiotherapy session by phone, video, or face-to-face.

Assessment

Physiotherapists assessed participants as per their normal practice.

Advice

Physiotherapists re-emphasised the same advice in the workbook as described for session one in supervised rehabilitation. If participants planned to return to sport, physiotherapists also introduced advice in section two of the workbook about how to do this safely. This advice was included because these patients are normally young, and two thirds of first-time patellar dislocations occur during sports.[16] This advice explained the benefits of adhering to prescribed exercise and that multidirectional sports have a higher re-injury risk,[16] so require a higher level of balance and muscle strength. Although a specific advice section on maintaining long-term knee health was not included, unlike supervised rehabilitation, the introductory text to the self-guided exercise programme did provide similar guidance on longer-term exercise adherence and the rationale for this.

Exercise prescription

The self-guided exercise programme is comprised of knee bending, knee straightening, balance, and strengthening exercises (see Appendix 4). Each category contains exercises of progressively challenging levels of difficulty (level one is the easiest). Using their assessment findings and clinical judgement, physiotherapists prescribed a starting exercise level in each category i.e., four exercises in total. Physiotherapists then explained the workbook advice on how to progress through the exercise levels until participants reach their desired or pre-injury level and the importance of exercise progression for recovery.

Due to the self-guided nature of the exercise programme, prescription parameters were standardised i.e., three sets of 10 repetitions for strengthening exercises and three repetitions of 30 seconds holds for passive flexibility exercises, in line with the recommended dose for these exercise types.[66,97] The optimal dose for balance exercises is unknown so prescription parameters for these exercises were based on clinical experience. Participants were advised to perform exercises at least three times per week for three months in keeping with the recommended frequency[66] and duration required for neuromuscular adaptation[99] to resistance training. Participants were encouraged to perform exercises more often and for longer if they found this helpful, and told that performing strengthening exercises one to two times per week is necessary to maintain long-term muscle strength.[96]

Strategies to support exercise adherence

The strategies to support exercise adherence were the same as for supervised rehabilitation, except there were no follow-up sessions where adherence and goals were reviewed by the physiotherapist and revisited if necessary.

2.2.4 Other healthcare

Physiotherapists could provide other treatments (e.g., taping) during intervention sessions as long as the core intervention components described above were provided. Additional treatments were recorded in physiotherapist-completed treatment logs to inform future intervention iterations. In keeping with the planned effectiveness perspective of the full-scale evaluation, other healthcare continued as normal, but any patellar-related treatments such as additional physiotherapy sessions, including out-of-trial NHS and private physiotherapy, were recorded and monitored. Sites notified general practitioners (GPs) of their patient's participation because GPs can refer to physiotherapy.

Collecting other healthcare information was important to help interpret the pilot RCT results and assess the feasibility of collecting this data which would be necessary in a full-scale evaluation.

2.2.5 Quality assurance

Intervention fidelity was monitored by reviewing physiotherapist-completed treatment logs which recorded the treatment session number, mode of delivery, duration, and delivery of core intervention components. Treatment sessions were also observed at sites and evaluated against a study-specific quality assurance checklist. At monthly trial management group (TMG) meetings, results from quality assurance checks and a table detailing delivery of core intervention components were reviewed and any necessary actions discussed. Feedback from quality assurance checks was provided to individual physiotherapists along with any advice required to maintain or improve fidelity. This close monitoring and optimisation of intervention delivery may be seen as more characteristic of an explanatory rather than pragmatic trial design. However, understanding how the interventions worked and whether identified problems with delivery were resolvable was considered important at the feasibility stage to identify possible refinements for a full-scale trial.

2.3 Discussion

Adhering to current complex intervention guidance,[58] this chapter describes the development and delivery of the interventions tested in the PRePPeD pilot RCT. This transparent reporting will enable readers to understand the rationale for the interventions, and enhance critical appraisal and interpretation of the PRePPeD pilot RCT results.

While the benefits of clearly reporting trial interventions appear obvious, poor intervention reporting in trials is a longstanding problem. In 2008, Glasziou and colleagues reported key intervention details were missing in roughly 40% of trials in major medical journals.[100] To address this problem, the TIDieR guidelines, which specify the minimum intervention information that authors should report, were published in 2014.[91] Later, the CERT was developed to improve the reporting of exercise interventions.[92] Although these guidelines are freely available, a 2022 overview of systematic reviews found that only 24% of CERT items and 49% of TIDieR items were adequately reported in clinical trials of exercise,[101] with no clear improvement in intervention

reporting over time.[101] This demonstrates the continued importance of clearly reporting exercise-based interventions.

In comparison to intervention description, the reporting of intervention development has received much less focus. This is surprising given that clinical trials are normally time consuming and expensive, yet often find that new interventions are ineffective, potentially due to poor intervention design, acceptability, or feasibility. Clearly reporting how interventions were developed could help future efforts to determine the most effective development approaches[102] which remains unknown.[58] It would also disseminate knowledge of intervention development approaches which other researchers could build upon.[58,102] This could lead to more effective interventions and reduce research waste.[57]

The interventions were developed rigorously and drew on a range of established intervention development approaches, sources of evidence, and stakeholders' opinions. Multiple intervention development approaches exist[60] and could have been used. However, many of these approaches were unsuitable e.g., because they focussed on specific intervention components only, like the behaviour change wheel,[103] or were infeasible to conduct in this context, like the Multiple Optimization Strategy.[104] Therefore, aspects of different intervention development approaches that were deemed relevant and likely to be helpful were used. However, prior to a full-scale evaluation, wider stakeholder input would be beneficial to increase the chances that the most effective intervention could be scaled-up and implemented across the NHS. Further intervention refinements, based on the pilot RCT and embedded qualitative results and any emerging evidence, would also enhance a full-scale RCT.

Physiotherapists could provide both interventions, which raises concerns about treatment contamination between groups and the possible methodological issues this brings e.g., underestimating the between group treatment effects in full-scale trial.[105] To more robustly guard against contamination, I could have stipulated that physiotherapists provide one intervention only. This has been implemented in a high-quality rehabilitation RCT for rotator cuff disorders in the UK NHS.[106] However, this would have raised practical challenges: at least four physiotherapists

would have to have been trained per site (two per intervention) to allow for staff unavailability, and two intervention training sessions would have been required instead of one. A previous similarly designed trial in our group permitted therapists to provide all rehabilitation interventions and found no evidence of contamination,[86] so restricting physiotherapists to providing one intervention appears unwarranted. Furthermore, the main difference between interventions in the PRePPeD pilot RCT is the number of physiotherapy sessions provided, not the content, which is easier to monitor and control. An alternative strategy to limit contamination is a cluster RCT. However, designing and conducting cluster RCTs is challenging and avoiding them is recommended if an individually randomised trial is feasible.[107] Problems include larger sample sizes and possible bias arising from foreknowledge of treatment allocation when patients are recruited after cluster randomisation.[107]

2.3.1 Strengths and limitations

When developing the interventions, I engaged with stakeholders, reviewed the existing published research, and considered the settings in which the interventions could be implemented in future. All these steps are recommended in current complex intervention guidance.[58]

Limitations include no PPIE member reviewed the intervention materials despite multiple attempts to obtain this. The impact of this was mitigated somewhat by drawing on guidance on producing healthcare information for members of the public when designing intervention materials. Going forward, developing a broader PPIE network would be helpful to ensure their input is obtained for all aspects of the study where this is sought. NHS physiotherapy practice was also based on a survey conducted in 2011 which may not reflect current practice. This could be addressed in future by seeking wider physiotherapy input when refining the interventions.

2.3.2 Conclusion

In line with current complex intervention development guidance,[58] this chapter reports how the interventions for the PRePPeD pilot trial were developed and how they were delivered. This will

enable better interpretation and critical appraisal of the pilot RCT results. Before any full-scale evaluation, further intervention refinement may be needed contingent on the pilot RCT and embedded qualitative study results, new evidence, and wider stakeholder input.

Chapter 3 Systematic review of outcomes used in RCTs of patellar dislocation treatments

3.1 Introduction

This chapter describes a systematic review of the outcomes used in RCTs of treatments for people with a patellar dislocation. Due to this DPhil's time constraints, the design and set up of the pilot RCT described in chapter 4 and 5 was initially prioritised. So, this systematic review was not completed in time to inform outcome selection for that study. This chapter is placed here in the thesis as the systematic review's findings are referred to in subsequent chapters.

3.1.1 Rationale

RCTs are widely considered the gold standard for evaluating the effectiveness of treatments.[108,109] Normally, RCTs use multiple outcomes to measure treatment effects, with the primary outcome being the most important. The primary outcome should address the trial's main objective,[110] drive the sample size calculation,[110] and ideally be the outcome deemed most important by relevant stakeholders.[111] Normally, RCTs have one primary outcome and multiple secondary outcomes that measure other important treatment effects.[112] A fully defined outcome has several core components: *what* it measured (i.e., outcome domain), *how* it measured (i.e., outcome measurement instrument), and *when* it measured (i.e., outcome measurement timepoint(s)).[108] The other components, the *specific metric* used and the *method of aggregation*[108] are more concerned with the statistical analysis, so are not the focus of this chapter which aims to inform future RCT outcome selection.

As described in Chapter 1, selecting outcomes for trials evaluating treatments for people with a patellar dislocation is challenging because a COS is lacking despite the recognised need to develop one.[32,35] Until a COS is developed, a systematic review that synthesised *what* was measured, *when*, and *how* in previous RCTs evaluating patellar dislocation treatments could be a helpful resource.

The findings could be used alongside other work, such as stakeholder consultations, to guide outcome selection for a future full-scale RCT and other RCTs of this health condition.

A systematic review of outcomes in existing studies is also the initial step in a COS development process and this was another driver for conducting this systematic review.[53] The development of a COS for patellar dislocations is underway and this systematic review forms part of this work. This is discussed further in Chapter 7.

3.1.2 Chapter aim

To determine what:

- outcomes;
- outcome measurement instruments; and
- outcome measurement timepoints are reported in RCTs evaluating treatments for people with patellar dislocations.

Secondary aims were to determine:

- the primary outcomes; and
- where a new patellar dislocation was as an outcome, how was this defined and measured.

3.2 Methods

Because systematic reviews of outcomes are commonly conducted as part of COS development projects, they are normally registered on the Core Outcome Measures in Effectiveness Trials (COMET) database. So, before undertaking this systematic review, I searched the COMET database and the International prospective register of systematic reviews (PROSPERO) to check no similar review had been conducted or was planned/ongoing. I also emailed COMET directly, as recommended in their handbook,[53] who confirmed they were not aware of any similar planned or ongoing review.

This systematic review's protocol was not eligible for registration on PROSPERO, so the protocol was registered on the Open Science Framework.[113] This enables readers to compare what was planned against what is reported here. To transparently report what was done, reporting follows the current Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline[114] and the extension for reporting literature searches.[69] The completed PRISMA checklist is available in Appendix 5.

3.2.1 Search strategy

I searched MEDLINE (Ovid), Embase (Ovid), CINAHL (EBSCOhost), the Cochrane Database of Controlled Trials (Cochrane Library), and the following trial registries: ClinicalTrials.gov, the International Standard Randomised Controlled Trial Number (ISRCTN) registry, and the World Health Organisation (WHO) International Clinical Trials Registry Platform (ICTRP). I used the Cochrane highly sensitive filter for identifying randomised trials in MEDLINE and Embase, and incorporated the Cochrane filter for identifying randomised trials in CINAHL Plus in the CINAHL search.[115] No date or language restrictions were applied to searches. The search strategy was adapted from a systematic review investigating leg muscle strength recovery after patellar dislocation,[26] and was reviewed by a healthcare librarian. Initial searches were conducted in January 2023 and updated in January 2024. Full database and trial registry searches are presented in Appendix 6.

To identify other potentially eligible studies, I screened all included records and relevant systematic reviews.[32,35,116–119] I also checked my personal files as did another reviewer most familiar with the patellar dislocation literature.

3.2.2 Eligibility

Study design

Only RCTs, including pilot and feasibility RCTs, were included. Studies that claimed to be RCTs but used a pseudorandom participant allocation method (hereafter referred to as quasi RCTs) e.g.,

by odd and even birth year, were also included because this review was not concerned with treatment effectiveness, so this source of bias was considered unimportant. There were no restrictions on study setting, status (i.e., ongoing or completed), publication language, or follow-up duration. Journal articles (both results and protocols), published abstracts, and trial registry records were eligible.

Participants and interventions

Participants could be any age or sex/gender and have received any treatment for a first-time or recurrent patellar dislocation, or persistent patellar instability following a previous patellar dislocation. These broad injury characteristics were used as this review intended to inform outcome selection for all RCTs evaluating patellar dislocations, not just acute injuries. I excluded studies of people with patellar instability without a documented previous patellar dislocation of the affected leg and studies including people with a patellar dislocation following a knee arthroplasty. These were considered separate clinical conditions.

3.2.3 Study selection

In this chapter, I have followed the PRISMA definitions[114] (Table 3.1) when referring to different types of information sources.

Table 3.1 Definitions of the different types of information sources[a]

Report	"A document (paper or electronic) supplying information about a particular study. It could be a journal article, preprint, conference abstract, study register entry, clinical study report, dissertation, unpublished manuscript, government report, or any other document providing relevant information"
Record	"The title or abstract (or both) of a report indexed in a database or website (such as a title or abstract for an article indexed in Medline). Records that refer to the same report (such as the same journal article) are "duplicates"; however, records that refer to reports that are merely similar (such as a similar abstract submitted to two different conferences) should be considered unique"
Study	"An investigation, such as a clinical trial, that includes a defined group of participants and one or more interventions and outcomes. A "study" might have multiple reports. For example, reports could include the protocol, statistical analysis plan, baseline characteristics, results for the primary outcome, results for harms, results for secondary outcomes, and results for additional mediator and moderator analyses"

[a]Content from Page et al.[114]

Retrieved records were exported to Rayyan systematic review software[120] or Microsoft Excel (only the WHO ICTRP records which could not be exported to Rayann), and deduplicated. Trial registry records for the same study that had different titles and/or registration identifiers on different trial registries were not considered duplicates because these can contain different data.[121]

After deduplication, two reviewers independently screened the titles and abstracts for eligibility. The same reviewers then independently screened the full texts of potentially eligible records, or for trial registry records, the source trial registration website to ensure the most current and comprehensive trial registration information was accessed.[121]

Discrepancies

Discrepancies between reviewers were resolved by consensus or consulting supervisor Associate Professor David Keene (DK) if disagreements persisted.

3.2.4 Data extraction

Two reviewers independently extracted the following data into a pilot-tested Microsoft Excel file:

- Study characteristics: authors, publication year, report type (results journal article, trial registry record etc.), study status, study type (RCT, quasi RCT, pilot/feasibility RCT), country, and interventions
- Participant characteristics: sample size, age, gender/sex, and patellar dislocation injury characteristics
- Outcomes: outcomes, outcome definitions, outcome measurement instruments, outcome measurement timepoints, primary outcomes, and primary outcome measurement timepoints

For trial registry records, data was extracted from the most up-to-date trial registry record on the source trial registry website e.g., if a trial registry record was originally retrieved from the WHO ICTRP, but its source registry was the Chinese Clinical Trial Registry, data was extracted from the latter. For pilot/feasibility RCTs, only clinical outcomes were extracted.

Outcomes, outcome definitions, and outcome measurement instruments were extracted verbatim as recommended, to provide an audit trail of how findings were generated from extracted data.[53] For

data extraction, the definitions of an outcome and outcome measurement instrument proposed by Prinsen and colleagues[122] were used (Table 3.2). Outcome related data was extracted regardless of where it was reported in study reports. If the primary outcome was not specified, the outcome informing the sample size calculation was designated the primary outcome. For composite outcomes (i.e., outcomes with multiple components whereby occurrence of a specified event in any component means the outcome occurred[123]), the individual components were separated where relevant. For instance, if recurrent patellar instability was an outcome comprised of patellar dislocation and subluxation, patellar dislocation and subluxation were extracted separately. For outcomes defined by a citation, the cited study was retrieved and the definition extracted.

Due to poor reporting of included reports, rules were developed and refined iteratively to aid consistent data extraction.

Table 3.2 Definitions of an outcome and outcome measurement instrument[a]

Outcome	"*what* is being measured, also referred to as a concept, construct, or (sub)domain. In the context of a clinical trial it refers to any identified result in an outcome arising from exposure to a causal factor or a health intervention"
Outcome measurement instrument	"*how* the outcome is being measured (the tool used to assess the outcome). An outcome measurement instrument can be a single question, a questionnaire, a performance-based test, a physical examination, a laboratory measurement, an imaging technique, and so forth"

[a]Content from Prinsen et al.[123]

Translation

Non-English language records were translated using Google Translate and data extracted from the translated version. This has demonstrated high agreement with data extraction from the original language report by native language speakers.[124] A native German language speaker verified the translation for the one included German-language record.[125]

Discrepancies

Discrepancies were resolved between data extractors unless the error was obvious in which case I corrected this without discussion. If discrepancies could not be resolved by data extractors, DK was consulted. After resolving data queries, I ensured data extraction rules were applied

consistently to all records which resulted in further minor corrections to extracted data. I did not contact study authors for missing data as planned because the number of included studies and amount of missing data was larger than anticipated, so this was considered infeasible to do within the time constraints of this DPhil.

Identifying multiple study reports

Drawing on guidance in the *Cochrane Handbook for Systematic Reviews of Interventions*,[126] I compared the following information (where available) between reports to identify and link multiple reports of the same study:

- authors' names;
- study locations;
- recruitment time periods;
- trial registration, ethics, and funding details;
- participant characteristics;
- intervention characteristics; and
- outcomes.

If uncertainty remained, I emailed the corresponding author or named contact on trial registry records for clarification up to two times. If I received no reply, I decided with DK whether the record was a unique study or multiple report. Eleven people were emailed and two replied providing clarifying information.

Data from multiple reports was extracted separately then combined. If different reports contained additional outcome data, all outcome data was included to account for outcome reporting bias. If outcome data contradicted between reports, the data judged most likely to be correct was included.

3.2.5 Critical appraisal

This systematic review was not concerned with included studies' findings, only their outcomes, so critically appraising included studies was not required.

3.2.6 Data synthesis

Outcomes can be measured or defined differently across studies. So, the first step in data synthesis was to identify the unique outcomes in included studies. Unique outcomes, defined as outcomes with "original meaning and context",[127] were identified following the process described by Young and colleagues.[127] This involved initially comparing extracted verbatim outcomes and their definitions (and outcome measurement instruments where relevant). Identical outcomes or those that differed only by measurement timing and/or minor spelling differences were considered duplicates and deleted. The remaining outcomes were compared and those that were similar and meant the same were grouped under one outcome which was renamed if needed e.g., "thigh hypotrophy" and "quadriceps muscle volume" were grouped together and renamed "thigh muscle mass". Throughout, a guiding principle was that if outcomes would not normally be combined in a meta-analysis they were considered unique. The identification and renaming of unique outcomes was done by two authors independently who resolved discrepancies by discussion.

Originally, I planned to synthesise all outcome measurement instruments in included studies. However, I only synthesised patient-reported outcome measures (PROMs) because these were considered most likely to inform future outcome measurement instrument selection. A patient-reported outcome was defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else".[128] PROMs therefore are instruments that collect patient-reported outcome data. For the synthesis, PROMs were grouped into 'region-specific' (lower limb), 'condition specific' (apply to groups of patients with a specific health condition),[129] 'generic' (measure aspects of health that apply to all people),[129] and 'other' categories. Study-specific PROMs or those deemed unreproducible were excluded from the synthesis because these are unlikely to be used widely in future.

Outcome measurement timepoints were synthesised into time periods adapted from Miller and colleagues,[130] using the measurement timepoints per study e.g., if outcome A was measured at

three months and outcome B was measured at three and six months, only three (counted once) and six months were used for data synthesis.

Results are presented in tables, figures, and text. Quantitative data was analysed using descriptive statistics.

3.2.7 Protocol changes

All protocol changes and the rationale for these are presented in Appendix 7.

3.3 Results

3.3.1 Study selection

The search strategy retrieved 4368 records. After deduplication, the titles and abstracts of 3024 records were screened, 139 records were deemed potentially eligible and underwent full text screening, and 96 reports of 69 studies were included in the review. A flow diagram of the search and screening process is shown in Figure 3.1. A list of the included studies, their status, and any linked reports are presented in Appendix 8, along with the studies excluded at full-text screening and their exclusion reasons.

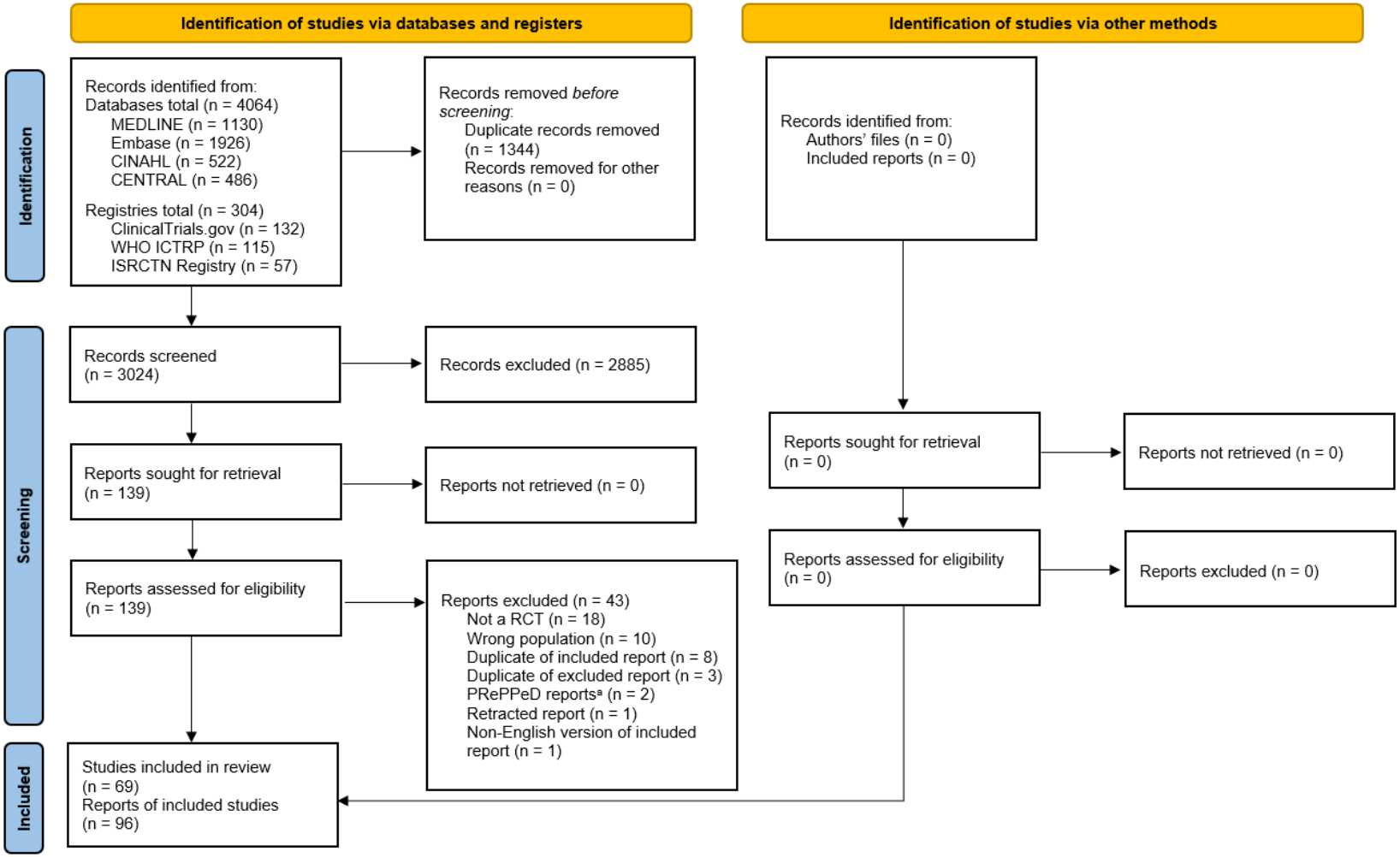


Figure 3.1 PRISMA 2020 flow diagram of the systematic review search and screening process. [a]Reports related to the PRePPeD pilot RCT were excluded for this thesis chapter, but will be included in the manuscript submitted for publication. Reproduced and adapted from Page et al[114] under (CC BY 4.0) license in accordance with the terms of the Creative Commons Attribution (CC BY 4.0). See: https://creativecommons.org/licenses/by/4.0/.

3.3.2 Characteristics of included studies

Of the 69 included studies, 41 were complete and had disclosed results, 14 were judged complete (11 completed >12 months ago) but had no available results, and 14 were ongoing, two of which had published preliminary data.[131,132] In completed studies, the total number of participants was 2487 (data from 44 studies), the median sample size was 60 (interquartile range (IQR) 35 to 80, data from 44 studies), and 63% of participants were women/females (1281/2087 participants, data from 36 studies). Thirty-six (52%) studies evaluated surgical interventions only and 27 (40%, data from 67 studies) studies took place in China. Evaluated participant populations mostly had recurrent (21/39 studies where this was reported) and non-acute (26/61 studies where this was reported) patellar dislocations, mainly driven by the high number of surgical intervention studies including participants with these characteristics. Additional study characteristics are presented in Table 3.3.

Table 3.3 Characteristics of included studies

	Total (N = 69)	Surgical vs surgical (N = 36)	Surgical vs non-surgical (N = 16)	Non-surgical vs non-surgical (N = 12)	Pharmacological vs pharmacological (N = 4)
Study design					
RCT[a]	61 (88)	32 (89)	13 (81)	11 (92)	4 (100)
Quasi RCT	5 (7)	3 (8)	2 (13)	-	-
Pilot/feasibility RCT	3 (4)	1 (3)	1 (6)	1 (8)	-
Publication/registration year[b]					
2020-2024	25 (36)	13 (36)	5 (31)	4 (33)	3 (75)
2015-2019[a]	22 (33)	13 (36)	4 (25)	4 (33)	-
2010-2014	14 (20)	7 (19)	3 (19)	4 (33)	-
2005-2009	5 (7)	1 (3)	3 (19)	-	1 (25)
2000-2004	1 (1)	1 (3)	-	-	-
<2000	2 (3)	1 (3)	1 (6)	-	-
Continent					
Asia (n = 2 countries)	28 (41)				
China[a]	27 (39)	21 (58)	1 (6)	1 (8)	3 (75)
Israel	1 (1)	-	-	-	1 (25)
Europe (n = 11 countries)	23 (33)				
Finland	6 (9)	1 (3)	3 (19)	2 (17)	-
UK	5 (7)	1 (3)	2 (13)	2 (17)	-
Denmark	3 (4)	2 (6)	1 (6)	-	-
Poland	2 (3)	2 (6)	-	-	-
France	1 (1)	1 (3)	-	-	-
Germany	1 (1)	-	1 (6)	-	-
Netherlands	1 (1)	-	-	1 (8)	-
Norway	1 (1)	-	1 (6)	-	-
Sweden	1 (1)	-	1 (6)	-	-

	Total (N = 69)	Surgical vs surgical (N = 36)	Surgical vs non-surgical (N = 16)	Non-surgical vs non-surgical (N = 12)	Pharmacological vs pharmacological (N = 4)
Switzerland	1 (1)	1 (3)	-	-	-
Turkey	1 (1)	1 (3)	-	-	-
North America (n = 2 countries)	7 (10)				
USA	6 (9)	1 (3)	3 (19)	2 (17)	-
Canada	1 (1)	1 (3)	-	-	-
South America (n = 2 countries)	5 (7)				-
Brazil	4 (6)	-	2 (13)	2 (17)	-
Colombia	1 (1)	-	-	1 (8)	-
Australasia (n = 1 country)	3 (4)				-
Australia	3 (4)	2 (6)	-	1 (8)	-
Africa (n = 1 country)	1 (1)				-
Egypt	1 (1)	1 (3)	-	-	-
NR	2 (3)	1 (3)	1 (6)	-	-
Patellar dislocation characteristics: acute or non-acute					
Acute[c]	17 (25)	2 (6)	8 (50)	7 (58)	-
Non-acute[a]	22 (32)	18 (50)	3 (19)	-	-
UC or NR	30 (43)	16 (44)	5 (31)	5 (42)	4 (100)
Patellar dislocation characteristics: 1st time or recurrent					
1st time dislocations	21 (30)	-	12 (75)	8 (75)	1 (25)
Recurrent[a]	26 (38)	20 (56)	3 (19)	1 (8)	1 (25)
1st time and recurrent dislocation	14 (20)	10 (28)	1 (6)	3 (25)	-
UC or NR	8 (12)	6 (17)	-	-	2 (50)

Data are n (%); NR: not reported; RCT: randomised controlled trial; UC: unclear

[a]The interventions of 1 included study was unclear so this study is not counted in the intervention columns.

[b]Where the main study report was a trial registry record this was the date of registration or the date the record was first posted on the registration website.

[c]Defined as ≤6 weeks of injury or if the time since injury was not reported but the term "acute" was used to describe the patellar dislocation.

3.3.3 Outcomes

In total, 141 unique outcomes were identified in included studies (median per study 9, IQR 5 to 14, range 2 to 33). The three most commonly measured unique outcomes were a patellar dislocation of the ipsilateral leg (54/69 studies), the Kujala Patellofemoral Score[133] (50/69 studies) and adverse event(s) (37/69 studies). Eighty-three (59%) unique outcomes were measured only once across included studies. A table containing verbatim outcomes, the corresponding unique outcome, and the number of studies that measured each unique outcome is presented in Appendix 9.

3.3.4 Outcome measurement instruments

Forty-two different PROMs met the criteria for data synthesis. Twenty-eight (67%) of these were measured only once among included studies. The PROMs reported in included RCTs and the frequency they were measured are presented in Table 3.4.

Table 3.4 PROMs in included studies

Categories (no. of PROMs within categories)	Frequency measured in included studies (N = 69)
Region specific (25)	
Kujala Patellofemoral Score	50 (72)
Lysholm Knee Scoring Scale	33 (48)
Tegner Activity Score	25 (36)
IKDC Subjective Knee Form	15 (22)
KOOS knee-related quality of life subscale, KOOS sport and recreation subscale	8 (12)
KOOS activities of daily living subscale, KOOS pain subscale, KOOS symptoms subscale	7 (10)
Lower Extremity Functional Scale	2 (3)
Cincinnati Sports Activity Scale, Fulkerson scale, KOOS4, KOOS-Child pain subscale, KOOS-Child other symptoms subscale, KOOS-Child activities in daily living subscale, KOOS-Child function in sports and play subscale, KOOS-Child knee-related quality of life subscale, KOOS patellofemoral pain and osteoarthritis subscale, modified Cincinnati Knee Rating System, modified Functional Index questionnaire, modified Hughston Clinic Questionnaire, modified Marx activity scale, Oxford Knee Score – Activity and Participation Questionnaire, Pedi-IKDC	1 (1)
Condition specific (6)	
Norwich Patellar Instability Score	8 (12)
Banff Patella Instability Instrument	5 (7)
Banff Patella Instability Instrument 2.0	2 (3)
Anterior Cruciate Ligament Quality of Life score, Larsen and Lauridsen criteria, Victorian Institute of Sport Assessment-Patella	1 (1)
Generic (5)	
EQ-5D-5L, 12-Item Short-Form Health Survey	3 (4)
WHOQOL-BREF	2 (3)
EQ-5D-Y, 36-Item Short-Form Health Survey	1 (1)
Other (11)	
VAS for pain	15 (22)
NRS for pain	6 (9)
Cincinnati Occupational Rating Scale, Donor Site Morbidity questionnaire, Hospital for Special Surgery Pediatric Functional Activity Brief Scale, Inpatient satisfaction questionnaire, VAS for patellar insecurity, PROMIS Depression, PROMIS Pain Interference, PROMIS Physical Function, PROMIS Short Form - Satisfaction with Social Roles and Activities 4a	1 (1)

Data are n (%); IKDC: International Knee Documentation Committee; KOOS: Knee injury and Osteoarthritis Outcome Score; KOOS4: average of four of the five KOOS subscales (pain, other symptoms, function in sports and recreational activities, and knee-related quality of life); KOOS-Child: Knee injury and Osteoarthritis Outcome Score for children; NRS: numeric rating scale; Pedi-IKDC: Modified International Knee Documentation Committee Subjective Knee Form in children with knee disorders; PROM: patient-reported outcome measure; PROMIS: Patient-Reported Outcomes Measurement Information System; WHOQOL-BREF: World Health Organisation Quality of Life-BREF; VAS: visual analogue scale

3.3.5 Outcome measurement timepoints

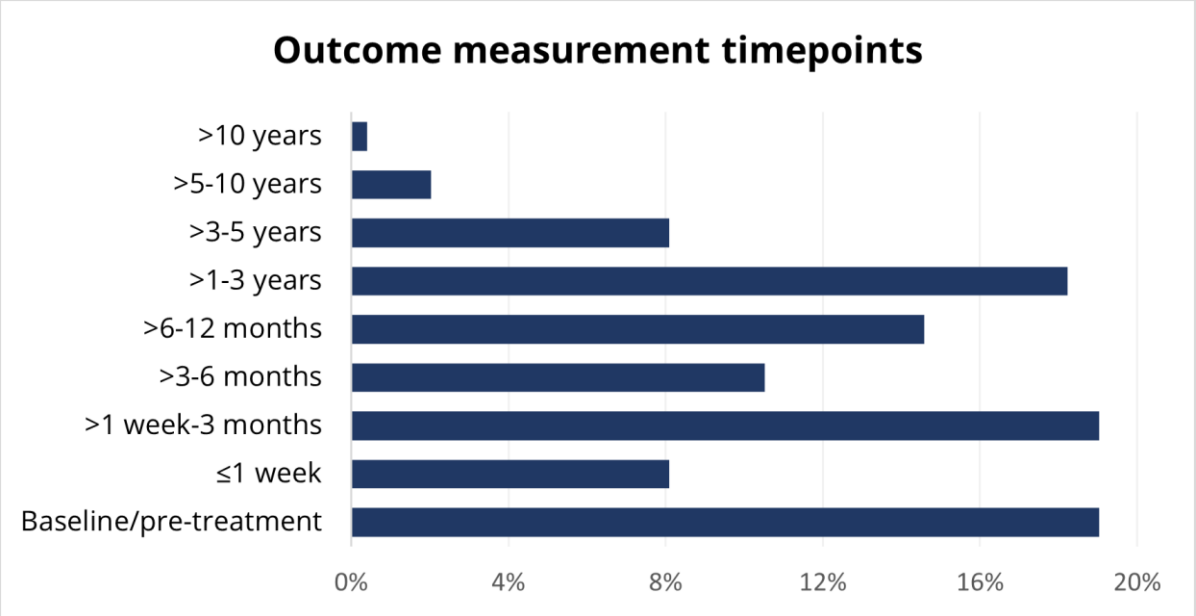


Figure 3.2 Outcome measurement timepoints in RCTs of patellar dislocation treatments

The timepoints that all outcomes were measured in included studies varied, as shown by Figure 3.2. The timing of outcome measurement was not reported in three included studies, all Chinese Clinical Trial registry records. The primary outcome measurement timepoints were also synthesised and are reported separately in the next section.

3.3.6 Primary outcomes

Ninety primary outcomes were identified in 46/69 (67%) included studies. Twenty-eight (61%) of these studies had one primary outcome and 18 (39%) had multiple primary outcomes (median per study 1, IQR 1 to 2, range 1 to 8). Thirty-one different primary outcomes were used with 14 (45%) used only once. The most common primary outcomes were the Kujala Patellofemoral Score (18/46 studies), ipsilateral patellar dislocation (13/46 studies), and the Lysholm Knee Scoring Scale[134] (11/46 studies). Table 3.5 contains the primary outcomes in included studies and the frequency they were measured.

The primary outcome measurement timepoint could be determined in 30/46 (65%) studies and for some but not all primary outcomes in 3/46 (7%) studies. Because the selection of the primary outcome measurement timepoint is likely to be influenced by when the evaluated interventions are anticipated to have greatest therapeutic benefit,[108] Figure 3.3 shows the primary outcome measurement timepoints by evaluated interventions within studies.

Table 3.5 Primary outcomes in included studies

Categories (no. of primary outcomes within categories)	Frequency measured in included studies with an identifiable primary outcome (N = 46)
PROMs (9)	
Kujala Patellofemoral Score	18 (39)
Lysholm Knee Scoring Scale	11 (24)
Tegner Activity Score	5 (11)
IKDC Subjective Knee Form	3 (7)
Norwich Patellar Instability Score, VAS unspecified	2 (4)
Banff Patella Instability Instrument, Banff Patella Instability Instrument 2.0, KOOS4	1 (2)
Adverse events (5)	
Ipsilateral patellar dislocation	13 (28)
Composite outcome of ipsilateral patellar dislocation and subluxation	4 (9)
Ipsilateral patellar subluxation, later surgery	2 (4)
Time to ipsilateral patellar dislocation	1 (2)
Radiological outcomes (5)	
Patellar tilt	3 (7)
Tibial tuberosity to trochlear groove distance, patellar height (Insall-Salvati ratio and Caton-Deschamps index)	2 (4)
Quadriceps angle, surgical femoral tunnel location (distance between the femoral tunnel centre and Schottle's point)	1 (2)
Physical performance test (1)	
Objective knee extensor muscle strength	3 (7)
Biomarkers of cartilage degradation (5)	
MRI T1 rho relaxation times, MRI T2 relaxation times, urinary C-terminal cross-linked telopeptide of type II collagen, neoepitope of type I collagen cleavage, neoepitope of type II collagen cleavage	1 (2)
Other (1)	
Medial retinaculum healing time	1 (2)
Physical examination (2)	
Knee joint swelling, knee flexion and extension passive ROM	1 (2)
Blood biochemistry (2)	
Fibrinogen concentration, fibrin concentration	1 (2)

Data are n (%) unless otherwise stated; IKDC: International Knee Documentation Committee; KOOS: Knee injury and Osteoarthritis Outcome Score; KOOS4: average of four of the five KOOS subscales (pain, other symptoms, function in sports and recreational activities, and knee-related quality of life); MRI: magnetic resonance imaging; PROM: patient-reported outcome measure; ROM: range of movement; VAS: visual analogue scale

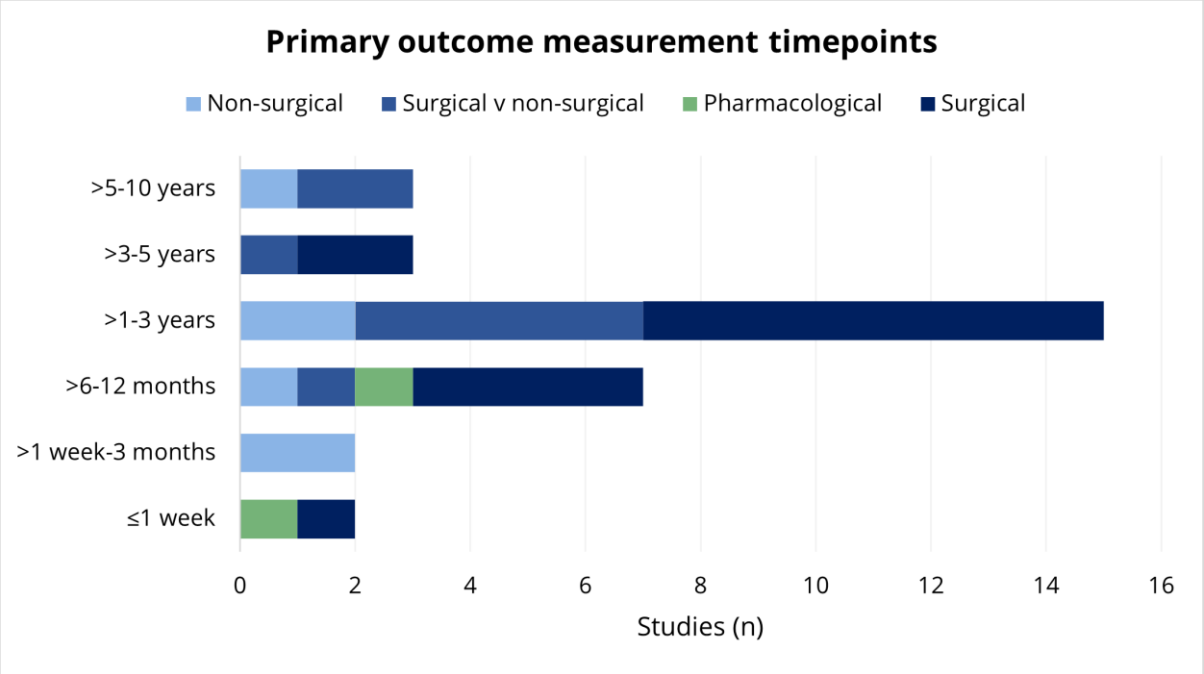


Figure 3.3 Primary outcome measurement timepoints in RCTs of patellar dislocation treatments. One study with different measurement timepoints for different primary outcomes was omitted from this synthesis.

3.3.7 How new patellar dislocations were defined and measured as an outcome

In the 54 studies that measured new ipsilateral patellar dislocations as an outcome (six studies also measured contralateral dislocations), 24 (44%) did not report an outcome definition or measurement method. Of the studies that did not report any details, the main report was a trial registry record for nine studies, an abstract for one, and the remaining 14 were published journal results or protocol articles. In the 30 studies that reported details (see Appendix 10), there was wide variation in how patellar dislocations were defined and measured. The most common measurement method was participant and/or clinician report, used in 14/30 (47%) studies.

3.4 Discussion

This systematic review found high variability in the outcomes, PROMs, outcome measurement timepoints, and primary outcomes used in RCTs evaluating treatments for people with a patellar dislocation. Furthermore, a new ipsilateral patellar dislocation was the most commonly measured outcome, but how this was defined and measured was variable or unreported. This variability in

what is measured, when, and how, highlights the challenges faced by researchers when selecting outcomes for RCTs in this area. The meta-analysis of results from individual studies is also affected. This is particularly important for this condition where RCTs are usually underpowered to detect important but rare events, like new patellar dislocations or later surgery.

Some outcome variability can be reasonably explained by the different evaluated interventions, participant populations, and evaluation focus (i.e., effectiveness versus efficacy) of included studies. However, over half of unique outcomes and two thirds of PROMs were measured in a single study only. This variability appears excessive, even accounting for included studies' different characteristics. These findings are consistent though with many other clinical areas. A similar review of hand fracture and joint injuries identified 639 unique outcomes with 71% of these assessed in only one of the studies included in that review.[135]

Arguably, the variability in primary outcomes is the best indicator that a COS for trials of patellar dislocation treatment is needed. As previously discussed, the primary outcome should ideally be the most important outcome to relevant stakeholders.[111] So, while some variability in primary outcomes in trials of the same health condition is expected, e.g., due to the intended effects of different interventions,[108] some consistency should be expected. However, this review found that the primary outcomes in included RCTs evaluated a wide variety of domains, and nearly half of the primary outcomes were the primary outcome in one study only.

As expected, the most commonly measured outcomes were an ipsilateral patellar dislocation and measures of knee symptoms and/or physical function. In comparison, general health-related quality of life and healthcare resource use outcomes were rare. Even though the most common outcome was a new ipsilateral patellar dislocation, nearly half of the studies that measured this did not report how it was defined or measured. If reported, definitions and measurement methods were often inconsistent between studies or lacked sufficient detail to be reproducible. This poor reporting affects interpretation of results. When different event thresholds are used, such as participant-reported patellar dislocations versus those that require hospital attendance, the number of events recorded will be affected. This is particularly important for this injury where diagnosis

can be challenging and patients do not always seek healthcare after a new dislocation episode (see section 5.3.5). How patellar dislocations are measured can also affect results. Systematic measurement, for instance through standardised questionnaires at set timepoints, will normally capture more events than non-systematic methods like participant initiated self-report.[136] In future, to help interpret the results of individual trials and facilitate meta-analyses, researchers should adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines on reporting outcomes and harms.[108,109]

Though not the focus of this systematic review, the poor design and reporting of included studies deserves comment. Registering studies and making results publicly available is required by the Declaration of Helsinki.[137] Yet, many included studies did not have a corresponding trial registry record. Eleven included studies were judged complete but failed to disclose their results within 12 months of completion, a timeframe commonly recommended by funders and regulatory bodies.[138,139] While I am aware that one of these studies has since been published,[43] it is likely most of the remaining studies have not. When trial results are unpublished, healthcare decisions are not informed by all the available evidence and patient outcomes may be adversely affected. Trials may also be unnecessarily repeated, wasting limited research resources. The primary outcome could also not be determined in one third of included studies. In studies reporting primary outcome details, 39% had multiple primary outcomes even though this is generally not recommended because it makes interpreting results more difficult and increases the risk of false-positive results due to multiple testing.[108,111] Roughly a third of studies with a primary outcome also did not report the corresponding measurement timepoint even though this is a reporting requirement in the CONSORT guidelines.[111]

3.4.1 Strengths and limitations

Although guidance on identifying unique outcomes exists, this remains a largely subjective task. Acknowledging this, the methods and results were transparently reported so that readers can clearly understand what was done. The search strategy was also comprehensive and eligibility

criteria were broad, making this a comprehensive review of outcomes used in RCTs in this area. To minimise errors, record screening, data extraction, and the identification and naming of unique outcomes was completed by two reviewers independently.

The main limitation is that study authors were not contacted for missing outcome related data as intended. However, contacting study authors for missing data for systematic reviews is often unsuccessful.[140] Supporting this finding, only 2/11 people replied to emails about possible multiple study reports in this review. Contacting study authors for missing outcome data would unlikely have added much value when balanced against the amount of time this would have involved. Unlike similar systematic reviews of outcomes,[130,135] observational studies were excluded which could be seen as a limitation. However, preliminary searches of Embase and MEDLINE without Cochrane's filter for identifying randomised trials retrieved 14,209 records. Conducting a systematic review with this number of records was considered infeasible within this DPhil. Instead, this systematic review focussed on RCTs because these were judged most likely to inform outcome selection of future RCTs in this area—the key aim of this systematic review. Finally, I did not examine temporal trends in outcomes, outcome measurement instruments, and outcome measurement timepoints which may have shown important changes over time.

3.4.2 Conclusion

This systematic review found high outcome variability in RCTs evaluating treatments for people with a patellar dislocation. This makes outcome selection for future RCTs challenging and limits the pooling of results from existing RCTs. The findings support current efforts to develop a COS to reduce outcome heterogeneity in RCTs in this area. Until this COS is developed, this review's findings will serve as a useful resource for researchers designing future RCTs. However, the findings likely represent the outcomes deemed most important by researchers which may differ from other stakeholders.[53] Therefore, outcome selection should be informed by other considerations, such as relevant stakeholders' opinions, and guidance on outcome measurement selection.[141]

Chapter 4 Protocol for a pilot RCT and embedded qualitative study

4.1 Introduction

In Chapter 1, I described why a full-scale RCT evaluating rehabilitation for people with an acute patellar dislocation is needed, but that questions remain over this RCT's feasibility. Here, I initially discuss what feasibility studies are, when they should be conducted, and why prospectively registering a complete and accessible trial protocol is important. To demonstrate my understanding of designing and delivering an RCT, I then describe the protocol for the PRePPeD external pilot RCT and embedded qualitative study, explaining the rationale for the uncertainties addressed and the key design decisions made. This chapter details what I planned to do. Any subsequent changes to the protocol are discussed in Chapter 5 (pilot RCT results) and Chapter 6 (embedded qualitative study results).

4.1.1 Rationale

As described in Chapter 2, feasibility testing is one of four phases in the NIHR and MRC framework for developing and evaluating complex interventions.[57] According to this framework, researchers should complete this feasibility phase if important uncertainties remain about the intervention(s) and/or the full-scale evaluation's design.[57]

Feasibility studies are an overarching type of study that assess whether a future full-scale study can be done, should be done, and if so, how.[142] They incorporate a range of study designs, including quantitative and qualitative studies, whatever is judged most appropriate to address the feasibility questions.[143] Pilot studies are a type of feasibility study with a distinguishing feature: they are scaled down versions of all or part of the full-scale evaluation (see Figure 4.1 for the conceptual relationship between feasibility and pilot studies).[143] An external pilot trial is a standalone study that normally does not contribute data to the full-scale trial if this is undertaken.[144] In contrast, an

internal pilot trial takes places at the start and within the full-scale trial to assess if the full-scale trial should proceed to the main recruitment phase, and if so, pilot data is included in the final analysis.[144] Normally, internal trials are conducted when there are few uncertainties and typically these relate to study processes, like recruitment.[144]

As described in Chapter 1, the feasibility of the full-scale RCT is uncertain due to questions over recruitment, patients' willingness to be randomised to the study interventions, retention, intervention adherence, and the acceptability of the interventions and follow-up methods. These uncertainties are discussed further below, but are mentioned here to highlight that they ask fundamental questions about whether the full-scale trial can be done. Given the level of uncertainty, proceeding directly to a full-scale RCT with an internal pilot would be inappropriate. Instead, an external pilot trial and embedded qualitative study is the appropriate study design to address these feasibility questions.

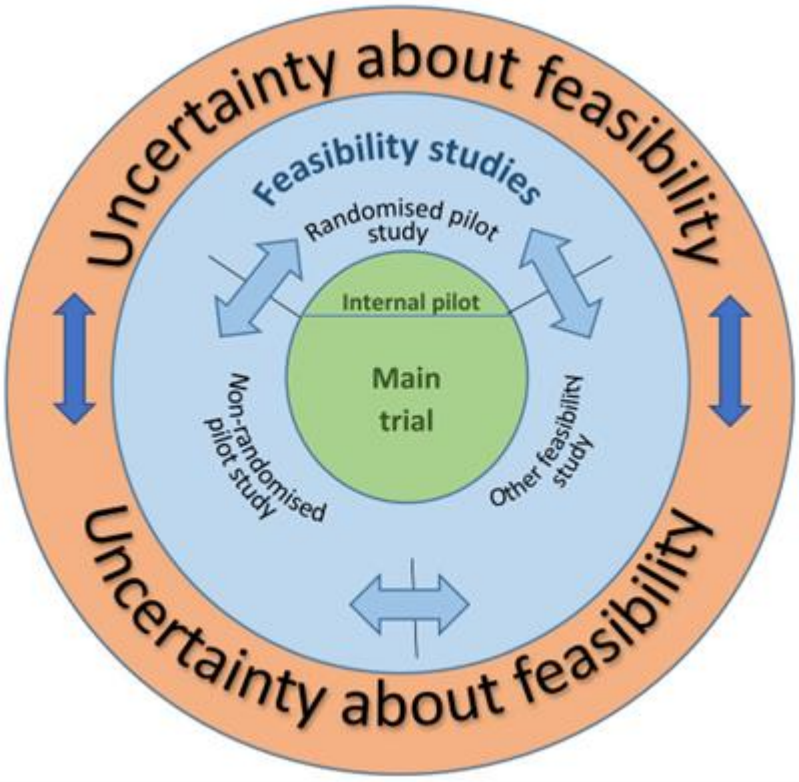


Figure 4.1 Conceptual relationship between types of feasibility studies. Reproduced from Bond et al[144] under (CC BY 4.0) license in accordance with the terms of the Creative Commons Attribution (CC BY 4.0). See: https://creativecommons.org/licenses/by/4.0

4.1.2 The importance of a trial protocol

A study protocol is a document detailing a study's plans from recruitment right through to the dissemination of the results.[145] A complete and accessible study protocol has many benefits, including improved study appraisal, interpretation, and replication.[146] Demonstrating its ethical importance, a study protocol is required by the Declaration of Helsinki.[137] The CONSORT statement and its extension to randomised pilot and feasibility trials also require authors to state where the trial protocol can be accessed.[111,147] Despite this, a review of pragmatic RCTs published between 2014 and 2019 found that only 63% of included studies had an available protocol.[148] Of these, comparison between the protocol and final report showed that one in five RCTs had inconsistent primary outcome information and roughly a third changed the target sample size.[148] This highlights that complete and accessible RCT protocols remain essential to enable readers compare what researchers planned with what they report they did.

4.1.3 Chapter aim

To describe the protocol for the PRePPeD pilot RCT and embedded qualitative study, and explain the rationale for the uncertainties addressed and key design decisions made.

Feasibility objectives

To determine the feasibility of a full-scale RCT comparing supervised versus self-managed rehabilitation for people after acute patellar dislocation by assessing:

- patients' willingness to be randomised;
- the recruitment rate;
- participant adherence to the study interventions;
- retention; and
- by understanding the experience of recovering from a patellar dislocation and the acceptability of the interventions and follow-up methods to pilot RCT participants.

4.2 Methods

No specific guidance for reporting feasibility trial protocols currently exists,[149] so reporting follows the applicable sections of the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) guidance.[145] This external pilot RCT and embedded qualitative study was registered before recruitment of the first participant (to prevent selective reporting[150]) and the sponsored approved protocol deposited on the ISRCTN registry (ISRCTN14235231) on 09 August 2022.

4.2.1 Study design

PRePPeD was a multicentre, parallel, two-group, external pilot RCT and embedded qualitative study comparing supervised versus self-managed rehabilitation for people aged ≥14 years with an acute first-time or recurrent patellar dislocation. Allocation to the study interventions was 1: 1. Planned participant flow through the study is presented in Figure 4.2.

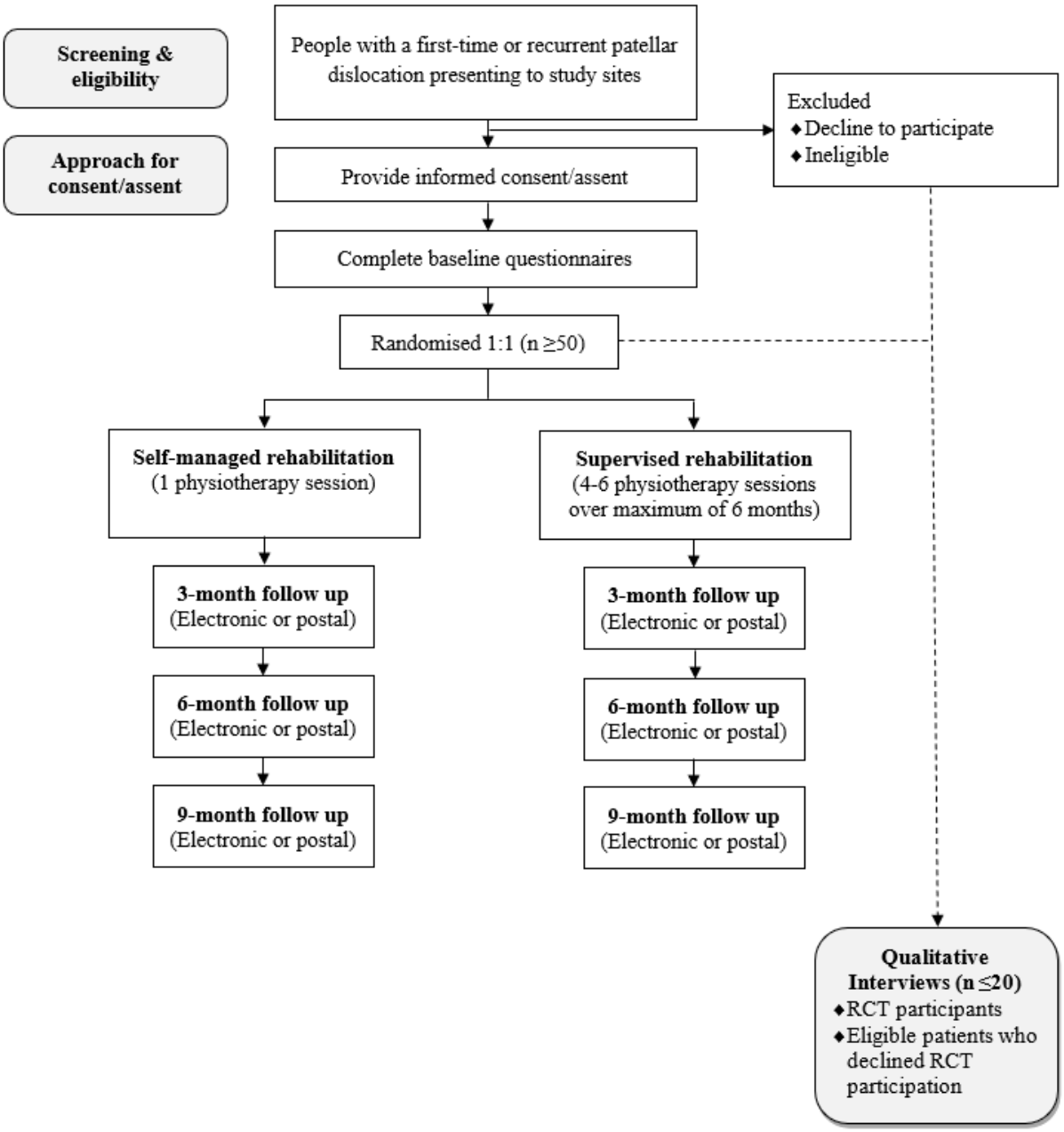


Figure 4.2 Planned participant flow through the study

4.2.2 Study setting

Participant recruitment was planned for ≥3 English secondary care NHS hospitals. To select sites that could deliver the study and be representative of those in a full-scale trial,[151] I considered sites' record with regard the efficiency of governance approvals, previous and predicted recruitment numbers, geographical location, hospital size, research experience, and the local population's socio-demographic characteristics.

4.2.3 Eligibility criteria

For this section and the remainder of this thesis a 'young person' refers to an adolescent aged <16 years and a 'parent' refers to a someone with parental responsibility (e.g., a parent or guardian) for a patient/participant aged <16 years.

The highest incidence of first-time patellar dislocations occurs in 15 year-old females and 16 year-old males (personal correspondence with Gravesen and colleagues[21]). Despite this, UK RCTs[33,34,41,51] have excluded people aged <16 years, probably because young people transition to adult services at this age and certain surgical treatments are contraindicated before skeletal maturity. In the systematic review of non-surgical treatment by Moiz and colleagues,[35] 23/25 included studies also excluded patients with a recurrent patellar dislocation, even though 2019 John Radcliffe Hospital fracture clinic data showed that these represented 42% (32/76) of patients presenting with an acute patellar dislocation. So, broad eligibility criteria were used to help recruit a clinically representative sample.

Inclusion criteria

- Aged ≥14 years
- Have a first-time or recurrent patellar dislocation confirmed if the:
    - patellar dislocation was reduced by a healthcare professional **or**
    - the patient reported a visible lateral patellar dislocation or sensation of the patella 'popping out' of joint followed by reduction **and** the assessing clinician diagnosed a lateral patellar dislocation (reflecting that diagnosis can be challenging as 47% of first-time dislocations reduce before patients present to hospital[12])
- Willing and able to provide informed consent (patients aged ≥16 years), or for patients aged <16 years the parent was willing and able to provide informed consent for their child's participation and the patient was able to provide assent if they wished to do so

Exclusion criteria

- >21 days from injury (physiotherapy was to start ≤3 weeks of randomisation, so this aimed to ensure physiotherapy started in the acute injury phase)
- Previous patellar stabilisation surgery on the affected knee (judged likely to enter a different treatment pathway)
- Required acute surgery e.g., due to concurrent osteochondral fracture
- Contraindication(s) to participation in the study interventions
- Patient was unable to adhere to study procedures
- Previously randomised into the study

4.2.4 Recruitment

Recruiting ≥50 participants across three sites required recruitment of 1.4 participants per site per month over a maximum recruitment duration of 12 months. This was deemed feasible based on recruitment of 3.9 participants per month in my single-group preliminary study[45] and an estimated 178 potentially eligible patients at potential sites (John Radcliffe Hospital, Oxford: 69 patients; Horton General Hospital, Banbury: 59 patients; and Royal United Hospital, Bath: 50 patients). A maximum recruitment duration of 12 months was chosen based on an anticipated nine months for study set-up, nine months for follow-up, and six months for data analysis and thesis write-up.

4.2.5 Screening and eligibility assessment

Potentially eligible patients were identified in Emergency Departments, Minor Injuries Units and fracture or knee clinics. A member of the responsible clinical team highlighted the study to eligible patients and parents (for patients aged <16 years). For those agreeable, a local researcher provided a patient information sheet (PIS), explained the study, and answered any questions. Patients aged <16 years were given an age-appropriate PIS. An animated explainer video, created in collaboration with a private company and PPIE partners (see section 4.2.16), was also available (see: https://prepped.octru.ox.ac.uk/) to ensure that study information was easily understandable.

The researcher could approach patients and parents (for patients aged <16 years) in person, in the clinical setting, or remotely by video or phone.

Each site kept screening logs to record the number and characteristics (age and gender) of patients assessed for eligibility, excluded with reasons, and eligible patients who were missed, declined consent (with reasons if provided to inform recruitment for the full-scale RCT), and were recruited.

4.2.6 Informed consent

Under current UK law, people aged <16 years require a parent's consent to participate in a Clinical Trial of an Investigational Medicinal Product (CTIMP).[152] However, no such legislation exists in the UK for non-CTIMP studies (outside of Scotland). In the absence of legislation or clear guidance,[153] I followed our group's current practice and required the parent's consent for people aged <16 years to participate.[154] I also implemented best practice guidance from the Health Research Authority (HRA)[155] by providing young people with age-appropriate study information (described above), involving them in the decision-making by inviting them to provide assent, and respecting their wishes to decline participation. Further details are described below.

Patients aged ≥16 years

The informed consent discussion was in person or by telephone/video call as described in section 4.2.5. Patients were given as much time as required within eligibility timeframes to consider the information provided and discuss it with their family, friends, and GP if they wanted to. The person obtaining consent had to be suitably qualified and experienced, and delegated to do so by the Chief or Principal Investigator. Because the interventions required sufficient cognitive function to manage a self-guided exercise programme, participants had to have capacity to consent to participation.

Agreeable patients provided consent using the latest approved version of the online Informed Consent Form (ICF) or a local researcher recorded consent on an online verbal ICF during the

informed consent video/phone call. A copy of the ICF was emailed to participants (or sent by post for participants without an email address) and another stored in their medical notes.

Patients aged <16 years

A parent had to have capacity to consent to the patient's participation and the patient had to have sufficient cognitive function to manage a self-guided exercise programme and provide assent if they wished to.

Interested parents and patients had an informed consent discussion with a local researcher, and if agreeable, informed consent was obtained from the parent as for patients aged ≥16 years. All patients were invited to complete an online assent form, but a completed assent form was not required for participation. However, if a parent provided consent, but the patient indicated on the assent form they did not want to participate they were not included in the study. A copy of the completed ICF and assent form (if completed) was given to the parent as described above and another copy was stored in the participant's medical notes.

4.2.7 Randomisation

Participants were randomly allocated 1: 1 to supervised or self-managed rehabilitation by a researcher at the study site using a secure (encrypted) web-based service provided by the UK Clinical Research Collaboration registered Oxford Clinical Trials Research Unit (OCTRU). The randomisation sequence was computer generated and stratified by study site and first-time/recurrent dislocation of the affected patella (deemed the strongest prognostic clinical characteristic[17]). Permuted blocks of varying length were used to balance these characteristics between intervention groups while keeping the allocation sequence unpredictable.[156] Randomisation occurred after participants provided informed consent and completed baseline questionnaires to prevent foreknowledge of treatment allocation affecting whether researchers decided to recruit participants.[111]

4.2.8 Blinding

The nature of the study interventions meant blinding participants, intervention providers, or researchers at study sites was not possible. I conducted the statistical analysis and was also unblinded. However, this was less relevant for this study because it did not make inferences about treatment effectiveness. Most outcomes were also participant reported and collected directly from participants, limiting the impact of the lack of blinding on outcome data collection.

4.2.9 Interventions

See Chapter 2 for a full description of the interventions and their development.

4.2.10 Outcomes

Primary (quantitative) feasibility outcomes

- Willingness to be randomised: defined as the proportion of eligible patients approached who were randomised. It was uncertain what proportion of a mixed sample of adults and young people and their parents would be willing to be randomised to the study interventions. If this proportion was low, the recruited sample would need to be assessed to determine if it was representative, and strategies to increase the proportion of patients willing to be randomised would need to be considered.
- Recruitment rate: defined as the number of participants recruited per site per month. Measuring recruitment would help estimate the number of sites and recruitment duration for the full-scale RCT which is important because 37% of NIHR-funded RCTs do not meet their original recruitment target.[157]
- Intervention adherence: defined as the proportion of participants allocated to supervised and self-managed rehabilitation attending at least four physiotherapy sessions and one physiotherapy session, respectively. This would indicate whether there was sufficient participant engagement with the interventions and an adequately different treatment dose between interventions to justify comparison in a full-scale RCT.

- Retention: defined as the proportion of participants that returned nine-month KOOS4 outcome data which was the planned primary outcome for the full-scale trial. Retention is the main uncertainty of a full-scale trial based on 52% loss to follow-up at 12 months in the only published RCT that compared exercise-based rehabilitation interventions after acute patellar dislocation.[41]

Progression criteria for quantitative pilot outcomes are shown in Table 4.1. A traffic light system was used to guide decision making about the full-scale trial's feasibility (green = feasible, amber = continue with modification(s), and red = stop, not feasible).[151]

Progression criteria thresholds were based on the TMG's expertise in RCT design and conduct, the published literature, and the target population. A willingness to be randomised of ≥50% was judged necessary to ensure the study sample would be clinically representative—a key focus of this pragmatic study. Determining thresholds for intervention adherence was challenging as NHS-based exercise trials in teenagers and young adults that report this data are lacking. A ≥75% threshold was felt to indicate good participant engagement with the interventions and would ensure a clear difference in the number of physiotherapy session provided to treatment groups. Recruiting >1 participant per site per month was based on recruiting >20% of the estimated five potentially eligible patients per site per month (see section 4.2.4). This aligned with the recruitment target of 1.4 participants per site per month, was in keeping with the recruitment rate of other trials in our group, and exceeds the median recruitment rate in NIHR Health Technology Assessment funded trials.[157] Retention of ≥80% was used as loss to follow-up >20% raises questions about the validity of a trial's results.[158] The TMG decided if the full-scale trial was feasible by considering the progression criteria, whether identified problems were resolvable, and the embedded qualitative study's findings.

Although this protocol was developed before recent recommendations on using progression criteria in external pilots RCTs was published,[159] many of the recommendations relating to the study design phase were adhered to: progression criteria were pre-specified, justified, based on pilot

objectives, and follow the intended full-scale trial funder's (NIHR) guidelines.[143] Progression criteria will also be considered alongside qualitative findings and whether identified problems are resolvable when assessing the full-scale trial's feasibility.[159]

Table 4.1 Progression criteria for quantitative pilot outcomes

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			
Supervised rehabilitation	<60%	60% to <75%	≥75%
Self-managed rehabilitation	<60%	60% to <75%	≥75%
Retention			
Supervised rehabilitation	<60%	60% to <80%	≥80%
Self-managed rehabilitation	<60%	60% to <80%	≥80%

Secondary (clinical) outcomes

Collecting clinical outcomes was important to assess if the planned outcomes for the full-scale trial could be collected. It also allowed evaluation of the standard deviation (SD) of the KOOS4, thereby informing the sample size calculation for a full-scale evaluation.

Selecting clinical outcomes was challenging because of the lack of a COS and the apparent inconsistency in outcome selection in published trials, and this was the driver for conducting the systematic review described in Chapter 3. Clinical outcomes were chosen following feedback from PPIE partners that pain and restoring pre-injury activity levels/function were the most important outcome domains to measure (further details in section 4.2.16). Chapter 3 showed that the two most commonly measured PROMs in trials of patellar dislocation are the Kujala Patellofemoral Scale[133] and the Lysholm Knee Scoring Scale.[134] These measures of knee symptoms and function were considered, but disregarded due to recognised problems with ceiling effects[160] and the use of terms in the Kujala Patellofemoral Score that may not be understandable to lay people e.g., "atrophy" and "flexion". Other validated disease-specific (Norwich Patellar Instability Scale[161] and

Banff Patellofemoral Instability Instrument 2.0[162]) and activity level (Tegner Activity Scale[134]) PROMs were reviewed by PPIE members and deemed inappropriate because they were either poorly designed, did not adequately assess acute symptoms, or contained questions not relevant to young people, such as questions related to work.

The assessed domain, the corresponding outcome measurement instruments, and the rationale for selecting these is outlined below. These outcomes align with PPIE feedback and recommendations in the literature that knee-specific, general health, and activity level PROMs should be collected.[163]

- Knee symptoms and function: assessed by the KOOS4, an average of four of the five subscales (pain, other symptoms, function in sports and recreational activities, and knee-related quality of life) of the KOOS,[164] a 42-item knee-specific patient-reported questionnaire. The additional subscale is function in activities of daily living. Individual subscales are scored 0 to 100 (higher scores better) and are reported separately. Assessed at baseline and three, six, and nine months after randomisation. Only current scores were collected at baseline because also collecting pre-injury scores was considered potentially too burdensome for these patients where retention can be an issue. Because the KOOS asks participants about their knee during/in the "last week" and some participants may be randomised ≤1 week of injury, the instructions for the baseline questionnaire specified 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 aimed to ensure no pre-injury scores were included at baseline. Measurement properties are well established,[165] though not specifically in people with patellar dislocations.[160] However, the KOOS4 is the primary outcome for the ongoing NIHR-funded REPPORT trial which is investigating surgical versus non-surgical treatment for recurrent patellar dislocations.[33] A KOOS version for children does exist, but the KOOS can be used in patients aged ≥13 years,[166] and so only the adult version was used for consistency.
- 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% (“not participating at all in your main sport or physical activity”) to 100% (“you have fully returned to your main sport or physical activity”) on a visual analogue scale. Assessed at baseline and three, six, and nine months after randomisation. This study-specific questionnaire was used given the lack of a suitable PROM that measured physical activity.

- Health-related quality of life: assessed by the EQ-5D-5L,[167] a generic patient-reported quality of life questionnaire that would be required for a cost-effective analysis in a full-scale trial. It has five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Domains contain a five-level response: no problems, slight problems, moderate problems, severe problems, and unable/extreme problems. Domain responses can be combined to provide one utility score ranging from -0.594 (worse than dead) to 1 (full health) for the UK population. Participants also rated their overall 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.[168] The EQ-5D-5L was assessed at baseline (current health only), and three, six, and nine months after randomisation.
- Global rating of change**:** participant-reported rating of change in their affected knee compared to when they entered the study, measured on a seven-point Likert Scale (a lot worse, moderately worse, a little worse, no change, a little better, moderately better, a lot better).
- Complications: any Serious Adverse Events (SAEs) would have been processed and reported (where relevant) following OCTRU standard operating procedures. Foreseeable SAEs, and injury and treatment related complications not defined as serious, were collected from participant-reported questionnaires and by sites when they became aware of them. For any complications reported by participants in follow-up questionnaires, the

participant was contacted and the complication verified by me. Foreseeable complications included:

- deep vein thrombosis or pulmonary embolism
- surgery related to patellar dislocation management
- new ipsilateral or contralateral patellar dislocation
- increased knee pain or swelling during or after completing the intervention exercises that required a healthcare professional consultation
- any new or exacerbated medical condition that started during or after completing the intervention exercises that required a consultation with a healthcare professional

New patellar dislocations were defined as those reported by participants in follow-up questionnaires that required hospital or GP attendance, or if there was a documented patellar dislocation diagnosis that occurred after the index injury in a participant's medical records. Sites were asked to check the medical records of participants at their site to determine if any unreported patellar dislocations or related knee surgery occurred during the nine-month follow-up period to assess if this was required for the full-scale trial. These were considered important complications and if retention is low, solely relying on participant-reported complications may underestimate the number of these complications that occur.

To assess if health resource data can be collected and to help develop the health resource use case report forms for the full-scale trial, I also collected health resource use data. Data included the number of physiotherapy sessions (including out-of-study private and/or NHS physiotherapy) and other primary and secondary healthcare appointments. This data was collected from participant questionnaires, physiotherapist-completed treatment logs, and site reporting.

Participants' schedule of events is shown in Table 4.2.

Table 4.2 Participants' schedule of events

	Enrolment	Allocation	Post-allocation		
Timepoint	**-T_1**	**T_0**	**T_1 = 3 months**	**T_2 = 6 months**	**T_3 = 9 months**
Enrolment					
Eligibility screening	**X**				
Informed consent/assent	**X**				
Allocation		**X**			
Interventions					
Supervised rehabilitation		←	—	→	
Self-managed rehabilitation		**X**			
Baseline characteristics					
Sociodemographic information, height, weight, main pre-injury sport/physical activity, current and previous injury details, injury management details	**X**				
Primary pilot outcomes					
Proportion of eligible patients approached willing to be randomised and no. of participants recruited per site per month		**X**			
Proportion of participants adhering to interventions				**X**	
Proportion of participants retained					**X**
Secondary clinical outcomes					
KOOS, EQ-5D-5L, return to main pre-injury sport/physical activity	**X**		**X**	**X**	**X**
Global rating of change, complications, health resource use			**X**	**X**	**X**

KOOS: Knee injury and Osteoarthritis Outcome Score

4.2.11 Data collection

Baseline

Baseline data collection included sociodemographic, height, weight, main pre-injury sport/physical activity, injury and previous injury data, and the type of splint and weight bearing instructions

provided (if any). Participants also completed the KOOS, EQ-5D-5L, and percentage return to main pre-injury sport/physical activity level questionnaires.

Three, six, and nine-month follow-up

For participants aged ≥16 years an email or text or both (according to their preferences) was sent three, six, and nine months after randomisation, inviting them to complete electronic questionnaires. Postal questionnaires were available if required. Participants who did not complete questionnaires within a specified timeframe were sent automated email and/or text message reminders. If questionnaires remained incomplete, participants were contacted by email, text, or phone to encourage follow-up. A maximum of three contacts was allowed at each follow-up timepoint as stipulated by the reviewing Research Ethics Committee. Unanswered phone calls where it was not possible to leave a voice message was not counted as an attempt. These methods were also used to resolve data queries where necessary.

For participants aged <16 years, questionnaires and any automated reminders were sent to participants, as outlined above, if parental consent was obtained. All other contact to encourage follow-up, obtain missing data, or resolve data queries was through the participant's parent. The participant did not need to provide assent to receive questionnaires and automated reminders, however if the parent provided consent but the participant indicated on the assent form they did not want to receive questionnaires directly, questionnaires and automated reminders were sent to the parent only. Where the parent did not consent to questionnaires being sent to the participant, questionnaires and any automated reminders were sent to the parent only.

4.2.12 Withdrawals

During the consenting process, participants and parents (for participants aged <16 years) were informed that participation was voluntary and they could withdraw at any time, without explaining why, and without affecting the quality of their clinical care. Participants or parents (for participants aged <16 years) could withdraw from treatment but participate in data collection. They could not withdraw data obtained before their withdrawal because this data was needed for the intention-to-

treat analysis and analysis of safety. Withdrawal types and reasons were recorded if voluntarily provided for study monitoring and to inform future work. To prevent unnecessary withdrawals by site staff, the distinction between complete and treatment withdrawals was strongly emphasised during intervention training and site initiation visits.

4.2.13 Sample size

Retention was the main uncertainty of a full-scale trial so was the main driver of the sample size calculation. The study aimed to recruit at least 50 participants which enabled an estimate of 80% retention to within a 95% confidence interval of ± 11% using Wilson's method.[169] The sample size of ≥50 was pragmatic, balancing the need to estimate 80% retention to a reasonable level of precision with the number of participants likely to be recruited from study sites within the planned recruitment period.

4.2.14 Statistical analysis

The recruitment rate was summarised as mean participants recruited per month per site and a 95% exact Poisson confidence interval was calculated. Other quantitative pilot outcomes (willingness to be randomised, intervention adherence, and retention) were expressed as proportions with 95% confidence intervals, calculated using Wilson's method.[170] Wilson's method was used because this works well with small numbers and extreme values (i.e., all 0 or all 1). It is also available as a command in STATA (version 17) which was used for the analysis. All other quantitative data was analysed using descriptive statistics using appropriate summary statistics (e.g., means and standard deviations and/or median and interquartile ranges). Categorical data was expressed as counts and proportions.

EQ-5D-5L domains responses were mapped onto the EQ-5D-3L value set as recommended by the National Institute for Health and Care Excellence (NICE)[171] to provide one utility score. The methods by Hernández Alava and colleagues[172] were used, but to account for the lack of a value set for participants aged <16 years, the age of these participants was set to 16 years for the analysis.

No inferences about the comparative effectiveness of the interventions were made because this study was not powered or designed to test treatment effectiveness. All randomised participants were analysed according to their allocated treatment group regardless of the treatment they received (i.e., by intention-to-treat analysis) to maintain the original randomisation in the analysis.[173] This principle should also provide estimates of treatment effects in the full-scale RCT that are more likely reflect those observed in clinical settings where treatment delivery and/or adherence can be suboptimal.[173] Missing data was minimised through careful data management. There was no imputation of missing data and no separate statistical analysis plan.

4.2.15 Embedded qualitative study

Reporting of the embedded qualitative study's methods here, and the results in Chapter 6, was informed by the consolidated criteria for reporting qualitative research (COREQ) checklist.[174]

This qualitative study aimed to explore patients' experience of recovering from a patellar dislocation and participating in a rehabilitation RCT within the context of their everyday lives. This subjective knowledge of participant experience can enhance the refinement of rehabilitation interventions and trial design.[175] This is particularly important in this study because there is limited research about the experience of recovery in acute patellar dislocation and receiving diverse physiotherapy treatments. In addition, understanding what helps and hinders follow-up questionnaire completion could help optimise the follow-up methods for the full-scale trial, potentially improving retention.

Objectives

To understand patient experience of:

- recovery from an acute patellar dislocation;
- acceptability of the intervention; and
- acceptability of the follow-up method.

Researcher's position

To answer the research questions about patients' experience, this research drew on an interpretivist paradigm. This perspective recognises individuality and has a focus on understanding how people make sense of and attribute meaning to their world.[176] This was a different approach to the positivist methods used in the pilot RCT and required learning new skills in interviewing, interpretation, reflection on positionality, and trustworthiness.

Reflexivity

In qualitative research, the researcher is actively involved in the research process. This might include choosing who to interview, acquiring and interpreting data, and so on.[177] Reflexivity refers to being sensitive to how the researcher can influence the research process.[178] This might be due to the researcher's prior experience, biases, characteristics, and relationship with participants.[178,179] To enable readers to interpret how the researcher may have influenced the research process, the characteristics of researchers are described below. Reflexive activities undertaken throughout the research process to examine my role on the research process are also described later. The researcher's relationship with participants is reported in Chapter 6.

Researchers' characteristics

I am a male musculoskeletal physiotherapist. My previous research has mainly involved quantitative methods and this was my first qualitative study. Before this DPhil, I completed modules on qualitative methods during a NIHR-funded MRes, and a five-day "introduction to qualitative research methods" course during a NIHR Oxford Biomedical Research Centre personal research award. All aspects of this qualitative research project were supervised by Dr Elizabeth Tutton (ET), an experienced qualitative researcher, whose work includes understanding the experience of injury and healthcare from the perspectives of patients after orthopaedic trauma injuries.

Data collection

Interviews were selected as the data collection method to elicit participant's in-depth experience of patellar dislocation and recovery. Focus groups could have been used and may have provided valuable insights arising from participants interaction.[180] However, focus groups would have been challenging to arrange given the geographical spread of study sites and if retention was low. Facilitating a focus group comprised of adults and young people would also have been challenging. Similarly, observation, which would have provided value in assessing intervention acceptability, on its own would not have addressed follow-up method acceptability.

I planned to conduct one semi-structured interview with each participant face-to-face at a mutually agreeable time and location. If face-to-face interviews were not feasible, interviews were by video or phone according to participants' preferences. A topic guide, which is a list of questions and prompts on the key issues to explore,[181] was developed to guide interviews. This was used flexibly—the aim was to encourage participants to talk freely about their experiences.[182] The topic guide was based on the qualitative study objectives and used open-ended questions to elicit the participant's experience. A PPIE partner with a previous patellar dislocation reviewed the topic guide and provided feedback, drawing on their injury experience (see PPIE section). Before interviews, I piloted the topic guide with a supervisor (ET) and refined it following her feedback. The ethically approved topic guide is available in Appendix 11.

Field notes were taken immediately after interviews to record additional contextual information (e.g., the participant's non-verbal behaviour), my initial impressions about the interview, and how my own role and experience could have affected the data collection and could affect interpretation. Additional reflections were recorded as they occurred. The initial field journal template was based on published guidance[183] and feedback from ET, and was refined iteratively in response to interview data.

Data collection timing

Collecting qualitative data at different times within an RCT has various implications.[184] After careful consideration, I decided to interview participants shortly after their three-month follow-up which enabled me to explore follow-up method acceptability while also being suitable for exploring intervention acceptability. At this time, participants in supervised rehabilitation would have received most or all of their intervention while those allocated to self-managed rehabilitation should have received their intervention sufficiently recently to have a good recall of intervention details. However, interviews were permitted at any time within nine months of randomisation, so the timing of interviews was modifiable if data indicated this was required.

Sampling strategy

I planned to use a purposive sampling strategy which involves identifying and selecting participants due to the perceived relevance of their characteristics and their experience to the research question.[180] Many purposive sampling strategies exist, but mainly these sample participants for variation or similarity.[185] I planned to sample for variation because no previous qualitative study has been conducted in this specific patient population, so obtaining a breadth of experience was important.[185] Diverse samples are also recommended in qualitative research within feasibility studies to increase the likelihood of identifying problems that can be resolved for the full-scale evaluation.[186]

I planned to sample participants for variation in:

- Age (<16 years and ≥16 years): because young people's experience of recovery and perspectives on the acceptability of the study interventions and follow-up methods could differ from adults. This could help decide whether young people should continue to be recruited in the full-scale RCT. Young people's ability to self-manage an injury is also unknown.
- Treatment allocation: this was necessary to explore the acceptability of both interventions in the pilot RCT.

- Completed/lost to follow-up: retention was the main uncertainty of a full-scale RCT. Interviewing participants who were lost to follow-up could increase understanding of why this occurs and how this could be addressed in future.

I also aimed to interview eligible patients who declined to participate in the pilot RCT because their insights could help recruit a more clinically representative sample in the full-scale RCT.

Sample size

Deciding how many interviews to conduct when designing a qualitative study is challenging.[187] In this study, the main principle that informed the sample size was saturation. Numerous definitions of saturation have been proposed, but here it means the point during data collection when no new themes or explanations are evident in the data.[188] Reflexive discussions with ET (described in the analysis section) were planned to help decide when saturation was reached instead of using specific criteria (e.g., if no new themes were identified in three consecutive interviews as has been proposed[188]).

As saturation is determined during data collection, it is not possible to know in advance how many interviews will be required to achieve it.[189] Numerous factors influence the number of interviews required, for example the richness of the data provided, the breadth of the study's focus, and the researcher's skill and experience.[190,191] I estimated ≤20 interviews would be sufficient based on the relatively narrow scope of this study, the clear nature of the topic being investigated, and the relative similarity of participants (notwithstanding the diversity of characteristics I planned to sample on). A sample size[192,193] of ≤20 was also considered the maximum feasible given the pilot trial's size and the time constraints of this DPhil. A recent systematic review of empirical studies found that 9 to 17 interviews is usually sufficient to reach saturation, particularly in studies with homogenous populations and a narrow scope.[192]

Method of approach and consent/assent

On their consent forms for the pilot RCT, participants or parents (for participants aged <16 years) indicated if they could be contacted about interview participation. Eligible patients or parents (for

eligible patients aged <16 years) who declined to participate in the pilot RCT were also asked to indicate on a consent to contact form if they could be contacted about interviews. Where permitted, I contacted potential interview participants or parents (for those aged <16 years), to explain the purpose of interviews, provide an interview specific PIS, and answer any questions. A young person PIS was available for potential participants aged <16 years.

Analysis

Interviews were digitally audio recorded, transcribed verbatim by an external transcriber, then verified by me for accuracy against the audio recording, as recommended.[180] Transcripts were imported into NVivo 14 which was used to help organise the data.

The analysis method was thematic analysis based on the method described by Braun and Clarke,[193] which looks for patterns of meaning across the data. I chose this analysis method for several reasons. Thematic analysis is flexible,[193] enabling data to be analysed deductively according to pre-specified objectives and inductively (where interpretations are derived from the data[176]). Thematic analysis is also considered the foundation of all other qualitative analysis approaches and has been recommended as the first analysis method qualitative researchers should learn.[180,193] The Framework Method[194] was considered but requires researcher experience,[195] so was discounted.

Data analysis involved the following iterative steps:

1. Initially, the transcripts and field notes from the first few interviews were read and possible codes noted. A code is a "descriptive or conceptual label that is assigned to excerpts of raw data".[195]
2. The remaining interviews were coded and these codes were refined iteratively.
3. Codes related to each other were grouped under broader categories to develop a coding framework. This framework included categories derived from the pre-specified qualitative objectives and categories derived inductively. This coding framework guided the analysis and was also refined iteratively. This process involved constantly comparing the raw data with coded data within categories to check interpretations made sense.[180] A codebook, a

document containing a list of all code names and their descriptions, was kept throughout to ensure data was coded consistently.[196]

4. Categories were subsequently merged where appropriate and arranged into themes i.e., patterns of meaning within the data that capture something important about the research question.[193] This aimed to provide a conceptual explanation of what was going on in the data.
5. Themes were reviewed and refined to ensure they were distinct, accurately reflected patterns of meaning across the data set, and that the data within themes was coherent.[193]

I led all aspects of the analysis, but ET also coded the first two interview transcripts. This provided me with an alternative interpretation of the data and a practical example of coding, which informed my later analysis.

Rigour and reflexive activities during the analysis

Rigour was based on the concept of trustworthiness, as described by Lincoln and Guba.[197] To demonstrate rigour, I recorded my thoughts and key decisions during the analysis to provide an audit trail of how I moved from the raw data to the study findings. This included findings that challenged the developing framework. Regular discussions with ET explored the basis for my developing interpretations[197] and offered an alternative insight into meanings within the data. I did not check my interpretations with participants (known as respondent validation or member checking)[178] as this can be time-consuming[198] and was deemed potentially too burdensome for interview participants who were also participating in a pilot RCT. Instead, I sense checked my overall interpretation of the data with a PPIE partner with a previous patellar dislocation who also provided his thoughts on the meaning within specific data excerpts. Findings were supported by de-identified participant quotations.

4.2.16 Patient and public involvement and engagement

The NIHR GenerationR Liverpool Young Persons Advisory Group and two adults with a previous patellar dislocations helped design this study. Study information was available as an animated

explainer video based on advice from the GenerationR group that this would make study information more understandable. GenerationR members also reviewed the explainer video transcript, young person PIS's, and assent forms, while two adult PPIE members reviewed the adult PIS's. 'Supervised rehabilitation' was originally called 'best-practice physiotherapy' but renamed following feedback from a parent at a GenerationR meeting that the original name inferred this intervention was superior and could affect willingness to be randomised. Clinical outcomes were chosen following unanimous feedback that pain or restoring pre-injury activity levels/function were the most important outcome domains to assess. The study used electronic follow-up (with a paper option for those who needed it) and exercise videos following advice that these would improve retention and exercise adherence, respectively. An adult with a previous patellar dislocation was a member of the TMG. This PPIE partner also reviewed and provided feedback on the qualitative interview topic guide and provided his interpretation of the meaning within qualitative data excerpts. The additional role of PPIE partners in developing the interventions and outcome selection has already been described in chapter 2 (section 2.2.1) and this chapter (section 4.2.10), respectively.

4.2.17 Study monitoring

I was responsible for day-to-day management of the study with support from a senior trial manager as needed. A TMG, which included my four supervisors, met monthly to oversee study design, set-up, and conduct. From April 2023 (three months after opening to recruitment), performance against pre-specified progression criteria was reviewed at TMG meetings as recommended.[159] This enabled actions to address underperforming areas to be implemented and therefore better judgements about whether these problems would be resolvable in a full-scale trial.

I developed data management and monitoring plans. Quality control procedures were also undertaken during recruitment and data collection to ensure the research was conducted, generated, recorded, and reported in compliance with the protocol, Good Clinical Practice, and the Research Ethics Committee's recommendations.

Planned monitoring of intervention delivery was planned and has been described previously (see chapter 2, section 2.2.5).

This was a low-risk pilot study so there was no trial steering, data monitoring, or safety monitoring committees. Any SAEs related to the interventions, which were anticipated to be rare, were to be reviewed by the TMG if they occurred.

4.2.18 Ethics

The East of Scotland Research Ethics Service (Research Ethics Committee reference: 22/ ES/0035) granted ethical approval for this study on 25 August 2022.

4.2.19 Protocol amendments

Substantial protocol amendments required submission to the Research Ethics Committee and HRA for approval. Substantial amendments are described in Chapter 5 and will be included in the published study report.

4.2.20 Dissemination

This protocol has been published open-access in a peer-reviewed academic journal.[199] The pilot RCT and embedded qualitative study will also be submitted for publication in open-access peer-reviewed journals. Authorship will be determined following the International Committee of Medical Journal Editor guidelines[200] and other contributors will be acknowledged. A summary of the study results will be available on the study website for participants. Study updates were shared on social media which will also be used to share future publications. Results have been and will be disseminated regardless of their magnitude or direction. Dissemination activities completed so far are presented in Appendix 15 and Appendix 16.

4.3 Discussion

There were several decisions that required careful thought when designing this study. Broad eligibility criteria were used to try and recruit a clinically representative sample, but the minimum

age of 14 years meant some patients presenting with this injury would be ineligible. However, data collected from the John Radcliffe trauma service between 01 January 2019 and 01 January 2022 indicated that the proportion of patients excluded for this reason would be small (14%, 41/290). Excluding patients aged <14 years was also considered justifiable due to the issues that including younger patients would bring. Issues to overcome would have included dealing with using adult and paediatric versions of the same PROM (EQ-5D-5L and KOOS) and creating intervention materials that would be appropriate for all included age ranges. Patellar dislocations could also be confirmed based on a patient's history combined with a diagnosis by the assessing clinician according to their normal clinical practice, rather that according to specific diagnostic criteria. It is possible this could lead to patients without true patellar dislocations (e.g., subluxations) being recruited. However, this was anticipated to be rare, and if it occurred would reflect what normally happens in clinical practice. In the full-scale trial, randomisation should balance these participants between treatment groups.

I did not use a 'usual care' physiotherapy intervention because survey data[27] and clinical consultations indicated that NHS physiotherapy treatment can vary in content and duration. If a full-scale trial showed no difference between supervised rehabilitation versus usual care physiotherapy, making clinical recommendations to guide rehabilitation practice would be challenging. In contrast, both the self-managed and supervised rehabilitation interventions in the pilot RCT are highly structured enabling them to be reproduced. This should aid future implementation of the intervention shown to be most clinically and cost-effective in a future full-scale trial if this is undertaken.

Feasibility outcomes related to the interventions focussed only on participant attendance at intervention sessions and the acceptability of the interventions to participants. Due to concerns about the time constraints of this DPhil, physiotherapists who provided the interventions were not interviewed. Interviewing intervention providers would have enhanced understanding of the acceptability of the interventions to physiotherapists and how the interventions were delivered in practice. This could have identified important areas of intervention refinement. Furthermore, with

the exception of exercise adherence, I did not collect outcomes that measured the interventions' intended mechanisms of action (see process outcomes in Figure **2.4**). This was due to concerns that assessing knee range of movement, lower limb muscle strength, and dynamic motor control, which would have required face-to-face follow-up, may have affected participant retention. Reliable and valid assessments of lower limb muscle strength and dynamic motor control also require specialist equipment which is not widely available. While not testing the interventions' mechanisms of action is justifiable in this instance, not collecting this data in the full-scale trial would limit understanding of how and why an intervention did or did not work. This could affect uptake of the results by policy makers and clinicians.[201]

The timing of the primary outcome also required careful consideration. Previous RCTs have shown potentially a small change in PROMs data between six and 12 months but no further improvement beyond 12 months in participants with acute dislocations treated non-surgically.[202,203] Intuitively, this makes sense. The resolution of symptoms arising from tissue damage at the time of injury is likely to have mostly plateaued by six months. Most non-surgical interventions for acute patellar dislocation also aim to optimise knee symptoms, function, and physical activity levels by providing advice and exercise. Significant changes in these domains in response to those treatments beyond 12 months is unlikely. Therefore, a primary outcome timepoint of nine months seemed reasonable as this would minimise the adverse effects of longer follow-up on retention and trial costs. A primary outcome timepoint of six months could have been used but would have been problematic because supervised rehabilitation can last up to six months, so some participants may still have been receiving treatment at primary outcome data collection.

4.3.1 Strengths and limitations

This study was rigorously designed and the protocol was reported according to relevant guidelines.[145] An additional strength was the inclusion of both adults and young people, making the study sample more clinically representative, even though this imposed a significant administrative burden. For example, 14 different consent forms were required as part of the document set

submitted for sponsor and ethical review: six for the pilot RCT (a remote and face-to-face version of an adult consent form, a parent consent form, and a young person assent form), six for the qualitative study (as for the pilot RCT), and two for permission to contact patients who declined pilot RCT participation about the qualitative study (one face-to-face and one remote consent form).

A limitation was that physiotherapists who provided the interventions were not interviewed. This limits understanding of the acceptability of interventions to physiotherapists and how the interventions were delivered in practice. However, quality assurance checks and informal feedback from physiotherapists enabled me to identify some possible refinements.

4.3.2 Conclusion

This chapter describes the protocol for the PRePPeD pilot RCT and embedded qualitative study, and the rationale for key design decisions. The results of the pilot RCT and embedded qualitative study are reported in Chapter 5 and Chapter 6, respectively.

Chapter 5 Pilot RCT results

5.1 Introduction

This chapter reports the results of the external pilot RCT. The methods for this pilot RCT were described in the previous chapter, so only any changes from those methods and other relevant details are included in the methods section here.

5.1.1 Chapter aim

To describe the results of the PRePPeD pilot RCT.

5.2 Methods

This pilot RCT is reported in accordance with the CONSORT extension to randomised pilot and feasibility trials.[147] The completed CONSORT checklist is presented in Appendix 12.

5.2.1 Substantial protocol amendments

There was one substantial protocol amendment. Participants or parents (for participants aged <16 years) who provided an email address as part of their contact details for the pilot RCT were sent an automated email with instructions on how to access an online version of their intervention workbook. Due to an oversight, this participant-facing email was not part of the original document set submitted to the Research Ethics Committee. When this oversight was discovered an amendment was submitted which the sponsor classified as substantial.

5.3 Results

5.3.1 Trial sites

This pilot was conducted in five English secondary care NHS hospitals. Originally, opening three sites was planned, but due to delays in study set-up, two additional study sites were opened to reduce the study's recruitment duration. Selected sites varied in size and research experience (one

participating physiotherapy department had no experience delivering trial interventions), and were located in a mix of large and small urban centres across England. This increases the chances that study sites and the patients invited to participate were representative of those that would be in a full-scale trial, and so provided a good assessment of feasibility.

In total, 23 physiotherapists were trained to provide the study interventions and 15 physiotherapists provided at least one intervention session. The characteristics of the participating sites and the physiotherapists who provided the interventions are presented in Table 5.1.

Table 5.1 Characteristics of participating sties and physiotherapists

Site	Start date	Months of recruitment[a]	No. of physiotherapists[b]				
			Provided intervention(s)	Band 5	Band 6	Band 7	Band 8a
Leeds Teaching Hospitals Trust	01 Feb 2023	7	3	0	1	2	0
Horton General Hospital, Oxford University Hospitals NHS Foundation Trust	09 Jan 2023	8	3	0	2	1	0
John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust	09 Jan 2023	8	4	0	3	1	0
Royal United Hospitals Bath NHS Foundation Trust	20 Feb 2023	6	2	0	0	1	1
South Tyneside and Sunderland NHS Foundation Trust	03 Jan 2023	8	3	1	0	1	1

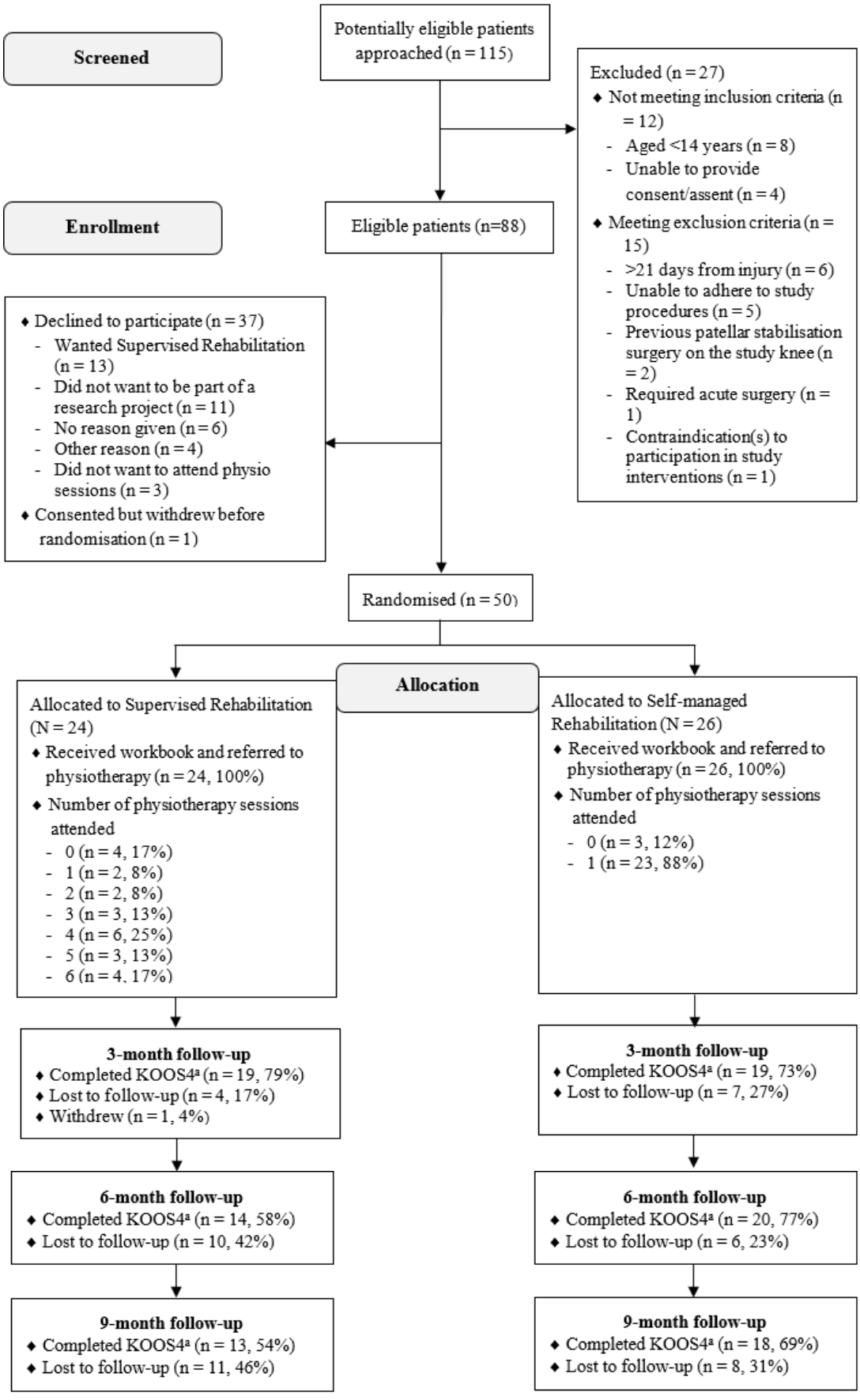
[a]Recruitment ended on 29 August 2023.
[b]NHS pay bands at the time of intervention training.

5.3.2 Recruitment

Recruitment started in January 2023 and closed in August 2023 when the recruitment target was reached. Of the 115 potentially eligible patients approached, 88 were eligible, and 50 eligible patients agreed to participate and were randomised (see Figure 5.1). Recruiting more than 50

participants was permitted, which would have increased the precision of the estimates for the quantitative feasibility outcomes. However, when the 50th participant was recruited their last day within range for nine-month follow-up was 13 July 2024. So, recruitment stopped when this participant was recruited to allow enough time for data analysis and write-up.

Of the patients who were ineligible, the main reason was being <14 years, but this represented only 7% (8/115) of patients assessed for eligibility. One patient initially provided consent but later declined to participate before randomisation due to concerns about the impact of physiotherapy attendance on school commitments.


Screened
Potentially eligible patients approached (n = 115)
Excluded (n = 27)
♦ Not meeting inclusion criteria (n = 12)
- Aged <14 years (n = 8)
- Unable to provide consent/assent (n = 4)
♦ Meeting exclusion criteria (n = 15)
- >21 days from injury (n = 6)
- Unable to adhere to study procedures (n = 5)
- Previous patellar stabilisation surgery on the study knee (n = 2)
- Required acute surgery (n = 1)
- Contraindication(s) to participation in study interventions (n = 1)
Enrollment
Eligible patients (n=88)
♦ Declined to participate (n = 37)
- Wanted Supervised Rehabilitation (n = 13)
- Did not want to be part of a research project (n = 11)
- No reason given (n = 6)
- Other reason (n = 4)
- Did not want to attend physio sessions (n = 3)
♦ Consented but withdrew before randomisation (n = 1)
Randomised (n = 50)
Allocation
Allocated to Supervised Rehabilitation (N = 24)
♦ Received workbook and referred to physiotherapy (n = 24, 100%)
♦ Number of physiotherapy sessions attended
- 0 (n = 4, 17%)
- 1 (n = 2, 8%)
- 2 (n = 2, 8%)
- 3 (n = 3, 13%)
- 4 (n = 6, 25%)
- 5 (n = 3, 13%)
- 6 (n = 4, 17%)
Allocated to Self-managed Rehabilitation (N = 26)
♦ Received workbook and referred to physiotherapy (n = 26, 100%)
♦ Number of physiotherapy sessions attended
- 0 (n = 3, 12%)
- 1 (n = 23, 88%)
3-month follow-up
♦ Completed KOOS4[a] (n = 19, 79%)
♦ Lost to follow-up (n = 4, 17%)
♦ Withdrew (n = 1, 4%)
3-month follow-up
♦ Completed KOOS4[a] (n = 19, 73%)
♦ Lost to follow-up (n = 7, 27%)
6-month follow-up
♦ Completed KOOS4[a] (n = 14, 58%)
♦ Lost to follow-up (n = 10, 42%)
6-month follow-up
♦ Completed KOOS4[a] (n = 20, 77%)
♦ Lost to follow-up (n = 6, 23%)
9-month follow-up
♦ Completed KOOS4[a] (n = 13, 54%)
♦ Lost to follow-up (n = 11, 46%)
9-month follow-up
♦ Completed KOOS4[a] (n = 18, 69%)
♦ Lost to follow-up (n = 8, 31%)

`

Figure 5.1. CONSORT diagram. [a]Planned primary clinical outcome for the full-scale trial. Reproduced from Eldridge et al[147] under (CC BY 3.0) license in accordance with the terms of the Creative Commons Attribution (CC BY 3.0). See: https://creativecommons.org/licenses/by/3.0/

Of the 37 eligible patients who declined to participate, 23 (62%) were male, the median age was 17 (IQR 15 to 28) years, and 14 patients were aged <16 years. This indicates that patients who declined participation differed from participants (see next section) in age and gender. Of the 20 eligible patients aged <16 years, 30% (6/20) were recruited. In comparison, 65% (44/68) of eligible adult patients were recruited. The most common reason for declining participation (Table 5.2) was a preference for supervised rehabilitation.

Table 5.2 Reasons for declining to participate

Reason	Adults (N = 23)	<16 years (N = 14)	Total (N = 37)
Does not want to be part of a research project	6 (26)	5 (36)	11 (30)
Wants supervised rehabilitation only	7 (30)	6 (43)	13 (35)
No reason given	5 (22)	1 (7)	6 (16)
Other	2 (9)	2 (14)	4 (11)
Does not wish to attend physiotherapy sessions	3 (13)	0 (0)	3 (8)

Data are n (%)

5.3.3 Baseline data

Participants' characteristics

The groups were well balanced at baseline on most characteristics, including previous ipsilateral patellar dislocations (stratification variable), indicating that randomisation was successful (Table 5.3). As expected, most participants were young adults. For 42% of participants their injury was a recurrent dislocation and 18% of participants had experienced a previous contralateral patellar dislocation. Half of participants were given a knee splint that restricted knee movement and roughly one third had been advised to limit their weight bearing.

One participant had a significant concurrent knee injury not affecting their patellofemoral joint. The results of the magnetic resonance imaging (MRI) scan which diagnosed this injury were received after the participant had attended their single self-managed rehabilitation session and were discharged from physiotherapy. This participant's results were included in the analysis to reflect real-life clinical practice where decisions about referral to physiotherapy are sometimes made before all clinical information, such as MRI results, are known.[204] In a full-scale trial, excluding such participants would be misleading and reduce statistical power.[204]

Baseline PROMs

KOOS subscale scores showed that participants had a moderate impairment in knee symptoms and function at baseline. Similar to other trials of people with soft-tissue knee injuries,[205,206] the lowest scoring (lower scores worse) KOOS subscales were knee-related quality of life and function in sports and recreational activities.

There was a baseline imbalance between groups in the KOOS subscales (pain, function in activities of daily living, and function in sports and recreational activities) and in the return to pre-injury sport/physical activity level questionnaire. This is not uncommon is RCTs with small sample sizes and would be less likely to occur in a full-scale trial assuming the randomisation process is implemented correctly. Should they occur, baseline imbalances can be adjusted for in the analysis but ideally these should be pre-specified in the study protocol and described in the results report according to reporting guidelines.[111]

During the study, routine data checks detected near perfect baseline KOOS scores for three participants recruited within one week of injury at one site. This suggested that these participants answered questions based on their pre-injury rather than post-injury symptoms. The researcher who recruited these participants could not confirm if this was the case. The KOOS scores of these three participants remained relatively consistent over follow-up timepoints, so it could not be definitively determined whether their baseline score represented their pre-injury symptoms, but this was likely. This indicates that the instructions about the recall period in the baseline KOOS (see

section 4.2.10) were not sufficiently clear or that the training provided to researchers at sites was inadequate, or both.

For one participant aged <16 years, their parent completed the baseline PROM questionnaires. Once this was detected, the parent was contacted and the participant completed their baseline PROM questionnaires, as originally intended, five days after randomisation.

Baseline PROM scores are reported as median (IQR) regardless of their distribution for ease of comparison. The distribution of baseline PROMs and aspects of their measurement properties are discussed in section 5.3.5.

Table 5.3 Participants' baseline characteristics

Characteristic	Supervised rehabilitation (N = 24)	Self-managed rehabilitation (N = 26)	All participants (N = 50)
Age (years), median (IQR)	20.0 (18.0 to 27.0)	26.0 (17.0 to 31.0)	22.0 (18.0 to 29.0)
<16 years, n (%)	1 (4)	5 (19)	6 (12)
Gender, n (%)			
Male	10 (42)	11 (42)	21 (42)
Female	14 (58)	15 (58)	29 (58)
Index of multiple deprivation decile,[a] median (IQR)	5.5 (2.8 to 8.0)	6.0 (4.3 to 8.0)	6.0 (4.0 to 8.0)
BMI (kg/m^2), median (IQR)	24.8 (22.1 to 31.5)	27.1 (19.7 to 32.0)	25.4 (20.9 to 32.0)
Ethnicity, n (%)			
White	23 (96)	21 (81)	44 (88)
Asian or Asian British	1 (4)	3 (12)	4 (8)
Black, African, Caribbean, or Black British	0 (0)	1 (4)	1 (2)
Mixed or multiple ethnic groups	0 (0)	1 (4)	1 (2)
Other ethnic group	0 (0)	0 (0)	0 (0)
Education,[b] n (%)			
Higher professional or university education	13 (54)	12 (46)	25 (50)
Secondary education	11 (46)	14 (54)	25 (50)
Employment, n (%)			
Full-time employed	10 (42)	12 (46)	22 (44)
Full-time student	8 (33)	8 (31)	16 (32)
Part-time employed	5 (21)	6 (23)	11 (22)
Unemployed	1 (4)	0 (0)	1 (2)
Affected knee, n (%)			
Left	16 (67)	15 (58)	31 (62)

Characteristic	Supervised rehabilitation (N = 24)	Self-managed rehabilitation (N = 26)	All participants (N = 50)
Right	8 (33)	11 (42)	19 (38)
Duration from injury to randomisation (days), median (IQR)	10.0 (5.0 to 14.0)	9.5 (2.0 to 16.0)	10.0 (5.0 to 15.0)
Mechanism of injury, n (%)			
Sporting activity (yes)	6 (25)	8 (31)	14 (28)
Direct blow to knee (yes)	4 (17)	5 (19)	9 (18)
Main pre-injury sport or physical activity, n (%)			
Walking or none	12 (50)	12 (46)	24 (48)
Multidirectional sport	9 (38)	10 (39)	19 (38)
Linear sport	3 (13)	4 (15)	7 (14)
Previous ipsilateral patellar dislocation (yes),[c] n (%)	10 (42)	11 (42)	21 (42)
1	1 (4)	3 (12)	4 (8)
2	4 (17)	1 (4)	5 (10)
3	2 (8)	1 (4)	3 (6)
4	0 (0)	1 (4)	1 (2)
5	0 (0)	2 (8)	2 (4)
6	0 (0)	1 (4)	1 (2)
7	1 (4)	0 (0)	1 (2)
≥10	2 (8)	2 (8)	4 (8)
Physiotherapy for any previous ipsilateral patellar dislocation (yes), n (%)	7 (70)	6 (55)	13 (62)
Previous contralateral patellar dislocation (yes), n (%)	5 (21)	4 (15)	9 (18)
1	2 (8)	2 (8)	4 (8)
2	2 (8)	2 (8)	4 (8)
≥10	1 (4)	0 (0)	1 (2)
Previous surgery on the affected knee (yes), n (%)	0 (0)	1 (4)	1 (2)
Medial growth plate arrest for valgus knee	0 (0)	1 (4)	1 (2)
Concurrent knee injury (yes),[d] n (%)	0 (0)	2 (8)	2 (4)
Complete ACL tear, grade 2 MCL sprain, and lateral meniscus tear	0 (0)	1 (4)	1 (2)
Lateral meniscus tear	0 (0)	1 (4)	1 (2)
Splint,[e] n (%)			
Knee immobiliser/cricket pad splint	14 (58)	20 (77)	34 (68)
Laterally stabilising soft knee brace	5 (21)	3 (12)	8 (16)

Characteristic	Supervised rehabilitation (N = 24)	Self-managed rehabilitation (N = 26)	All participants (N = 50)
Hinged knee brace, angle not fixed	0 (0)	1 (2)	1 (2)
Other	1 (4)	0 (0)	1 (2)
None	4 (17)	2 (8)	6 (12)
Weight-bearing advice,[e] n (%)			
Full weight-bearing/weight-bearing as tolerated	11 (46)	14 (54)	25 (50)
Partial weight-bearing	6 (25)	7 (27)	13 (26)
Touch weight-bearing	0 (0)	1 (4)	1 (2)
Non weight-bearing	1 (4)	3 (12)	4 (8)
None	5 (21)	1 (4)	6 (12)
Not specified	1 (4)	0 (0)	1 (2)
KOOS4, median (IQR)	48.2 (31.9 to 61.7)	52.2 (35.5 to 64.7)	48.6 (32.4 to 64.7)
KOOS symptoms, median (IQR)	50.0 (42.9 to 57.1)	53.6 (46.4 to 64.3)	50.0 (24.9 to 60.7)
KOOS pain, median (IQR)	59.8 (50.0 to 81.9)	73.6 (55.6 to 83.3)	66.7 (55.6 to 83.3)
KOOS ADL, median (IQR)	65.4 (42.6 to 83.1)	75.0 (54.4 to 91.2)	72.1 (44.1 to 88.2)
KOOS sport/rec, median (IQR)	30.0 (10.0 to 62.5)	40.0 (5.0 to 65.0)	30.0 (5.0 to 65.0)
KOOS QoL, median (IQR)	43.8 (25.0 to 59.4)	40.6 (18.8 to 62.5)	43.8 (25.0 to 62.5)
% return to pre-injury physical activities, median (IQR)	50.0 (24.5 to 77.5)	10.0 (0.0 to 75.0)	50.0 (0.0 to 75.0)
EQ-5D-5L utility score, median (IQR)	0.63 (0.46 to 0.74)	0.63 (0.44 to 0. 73)	0.63 (0.44 to 0.73)
EQ-5D-5L VAS, median (IQR)	80.0 (50.0 to 87.5)	72.5 (50.0 to 80.0)	75.0 (50.0 to 85.0)

ACL: anterior cruciate ligament; BMI: body mass index; EQ-5D-5L; EuroQol 5 dimensions 5 levels; IQR: interquartile range; KOOS: Knee injury and Osteoarthritis Outcome Score; MCL: medial collateral ligament; VAS: visual analogue scale
[a]Lower scores mean higher deprivation.
[b]Highest level participant is completing or has completed.
[c]Stratification variable used in randomisation.
[d]Concurrent knee injuries not affecting the patellofemoral joint.
[e]Provided at baseline or most recently.

Withdrawals

One participant in the supervised rehabilitation group completely withdrew because they were unhappy with the delay in scheduling their initial physiotherapy session, so sought private care.

5.3.4 Primary quantitative feasibility outcomes

Results for the primary quantitative feasibility outcomes according to pre-specified progression criteria are presented in Table 5.4.

Table 5.4 Primary quantitative feasibility outcome results

Pilot objectives	Stop, not feasible	Continue with modifications	Continue, feasible	Results (95% CI)
Willingness to be randomised	<20%	20% to <50%	≥50%	57% (46% to 67%)
Recruitment rate	<1 per month per site	1 per month per site	>1 per month per site	1.4 (0.6 to 1.8)
Intervention adherence				72% (58% to 83%)
Supervised rehabilitation	<60%	60% to <75%	≥75%	54% (35% to 72%)
Self-managed rehabilitation	<60%	60% to <75%	≥75%	88% (71% to 96%)
Retention				62% (48% to 74%)
Supervised rehabilitation	<60%	60% to <80%	≥80%	54% (35% to 72%)
Self-managed rehabilitation	<60%	60% to <80%	≥80%	69% (50% to 83%)

CI: confidence interval

Willingness to be randomised

Of the 88 eligible patients approached, 50 (57%, 95% confidence interval (CI) 46% to 67%) were randomised.

Recruitment rate

The recruitment rate, averaged over the duration all sites were open, was 1.4 (95% CI 0.6 to 1.8) participants per site per month. All sites recruited ≥1 participant per month (Table 5.5), indicating the strategies used to promote site engagement and facilitate recruitment were helpful. Examples of the strategies used included:

1. Designating a surgeon and physiotherapist co-Principal Investigator at each site because surgeons are normally the key decision-makers in clinics where participants are recruited, while physiotherapists coordinate and provide rehabilitation.

2. Offering participation in the NIHR Associate Principal Investigator scheme to site staff because evidence of research activity can be important for aspiring clinical academics and the continuing professional development portfolios of healthcare staff. One physiotherapist availed of the scheme.
3. Offering collaborative authorship on the published results manuscript to site Principal Investigators and staff who performed a certain number of study-specific tasks. Collaborative authorship with clear criteria on how to achieve it is recommended to enhance collaborative research.[207]

Table 5.5 Participant recruitment by study site

Site	Jan	Feb	Mar	Apr	May	June	July	Aug	Mean	Total
South Tyneside and Sunderland	0	1	4	2	1	4	1	1	1.8	14
Horton General Hospital	1	3	1	1	2	0	0	3	1.4	11
John Radcliffe Hospital	0	0	0	4	2	4	0	0	1.3	10
Leeds Teaching Hospitals	-	3	2	2	0	0	1	1	1.3	9
Royal United Hospitals Bath	-	-	2	1	0	0	1	2	1.0	6
	1	7	9	10	5	8	3	7		

- indicates a month the site was not open to recruitment

Intervention adherence

Intervention adherence, the proportion of participants allocated to supervised rehabilitation attending at least four physiotherapy sessions and participants allocated to self-managed rehabilitation attending at least one physiotherapy session, was 72% (95% CI 58% to 83%). However, this relatively high proportion was mainly driven by the high intervention adherence in the self-managed rehabilitation group (Table 5.6).

In total, seven (14%) participants did not attend any physiotherapy session despite the efforts of site teams to contact them to arrange treatment. Of participants allocated to supervised rehabilitation, 54% attended at least four physiotherapy sessions as intended. For 6/7 participants

who partially completed supervised rehabilitation treatment, defined as attending at least one session but fewer than four, this was because the participant did not attend or wanted to stop treatment due to work or moving out of area. Attending face-to-face appointments may be challenging for this young patient population due to work and/or education commitments. Some study sites are also located in large urban centres which can be inconvenient and time consuming to travel to. To facilitate physiotherapy attendance, physiotherapy sessions by video were allowed in this study, but these were not used in any instance. Whether there was no uptake of video appointments because of participant preferences, physiotherapists failing to offer them, or other reasons is unclear as data on this was not collected.

Six participants, all allocated to self-managed rehabilitation, had an additional contact with the site physiotherapy team. For four of these participants, the additional contact was related to their patellar dislocation: three due to a lack of progress and one for rehabilitation after a subsequent tibial tuberosity osteotomy. The other additional contacts were for the participant with the concurrent anterior cruciate ligament tear who was re-referred for physiotherapy, and another participant who sought advice by phone for an unrelated injury that occurred after their single treatment session.

While there are areas for improvement, certain intervention components worked as intended. Initial physiotherapy sessions were normally within three weeks of randomisation, so occurred in the acute phase of injury as planned. No participant in supervised rehabilitation attended more than six physiotherapy sessions or received treatment for more than six months, as intended. The duration of initial and follow-up physiotherapy sessions were also normally not longer than the pre-specified maximum of 60 and 30 minutes, respectively.

Further analysis of the delivered interventions are described in section 5.3.6.

Table 5.6 Adherence to the allocated interventions

	Supervised rehabilitation (N = 24)	**Self-managed rehabilitation (N = 26)**
Completed physiotherapy treatment,[a] n (%)	13 (54)	23 (88)
Partially completed physiotherapy treatment,[b] n (%)	7 (29)	NA
Participant wished to stop sessions due to work/moving out of area	3 (15)	NA
Did not attend and/or unable to contact	3 (15)	NA
Clinician decided that no further treatment required	1 (5)	NA
Attended no physiotherapy intervention session, n (%)	4 (17)	3 (12)
Did not attend and/or unable to contact	4 (17)	3 (12)
Total no. of physiotherapy intervention sessions attended, n	78	23
Mode of intervention session, n (%)		
Face-to-face	76 (97)	23 (100)
Video	0 (0)	0 (0)
Phone	2 (3)	0 (0)
Physiotherapy intervention sessions attended, median (IQR)	4 (3 to 5)	1 (1 to 1)
Max no. of physiotherapy intervention sessions attended, n (%)		
1	2 (8)	23 (89)
2	2 (8)	NA
3	3 (13)	NA
4	6 (25)	NA
5	3 (13)	NA
6	4 (17)	NA
Participants receiving additional physiotherapy sessions at site,[c] n (%)	0 (0)	6 (23)
Days from randomisation to first treatment session, median (IQR)	15.0 (5.5 to 22.5)	16.0 (11.0 to 27.0)
Days from injury to 1st physiotherapy session, median (IQR)	21.5 (15.5 to 36.0)	29.0 (18.0 to 41.0)
1st treatment session duration (mins), median (IQR)	45.0 (42.5 to 60.0)	45.0 (40.0 to 50.0)
Follow-up session duration (mins), median (IQR)	30.0 (30.0 to 30.0)	NA
Physiotherapy duration (days), median (IQR)	88.0 (46.3 to 116.5)	NA

IQR: interquartile range; Max: maximum; Mins: minutes; NA: not applicable
[a]Attending ≥4 physiotherapy sessions for supervised rehabilitation or attending ≥1 physiotherapy session for self-managed rehabilitation.
[b]Attended ≥1 but <4 physiotherapy sessions.
[c]Some participants received more than one additional contact session.

Retention

Retention, the proportion of participants that returned nine-month KOOS4 outcome data, was 62% (31/50, 95% CI 48% to 74%). Retention at three months was 76% (38/50) and at six months was 68% (34/50).

Retention was similar between groups at three months (self-managed rehabilitation: 73% (19/26), supervised rehabilitation: 79% (19/24)) but higher in the self-managed group at six months (self-managed rehabilitation: 77% (20/26), supervised rehabilitation: 58% (14/24)) and nine months (self-managed rehabilitation: 69% (18/26), supervised rehabilitation: 54% (13/24)).

One participant returned nine-month KOOS data three days outside their pre-specified follow-up window but this data was included following discussion with statistician and supervisor Professor Jonathan Cook (JC). Another participant provided nine-month KOOS data by phone, but this data did not record on REDCap because the participant accessed their questionnaire link during this phone call. Attempts to re-obtain this data from the participant, which would have increased nine-month retention to 64%, were unsuccessful.

In January 2024, to address the fall in retention after the three month follow-up timepoint, several actions were implemented which appeared to improve follow-up rates.

- The wording of emails, text messages, and letters sent with questionnaires were amended drawing on a theory-informed letter shown to improve retention.[208]
- Guidance on optimising data collection by phone from Trial Forge, an initiative that aims to improve trial efficiency, was followed.[209]
- Participants were posted a newsletter to update them about the study's progress and to explain why completing questionnaires was important. This was based on a theory-informed proposal that retention could be improved by informing participants that completing questionnaires contributes to the study's results and knowledge about management of the investigated condition.[210]

- A postal questionnaire and prepaid return envelope was sent to participants who had not completed nine-month follow-up despite receiving electronic invitations and automated reminders. The rationale was that postal follow-up might be successful if electronic follow-up was not. Sixteen participants were posted a questionnaire. Two of these completed nine-month questionnaires which was electronic in both instances, and for one of these two participants was in response to a phone call encouraging follow-up. This suggests that postal follow-up methods may not be helpful in a future full-scale RCT.

The Cochrane review of retention strategies found some evidence that monetary incentives improve retention[211] and these were considered by the TMG in December 2023. However, implementing this would have required a substantial protocol amendment, additional funds, and created an additional administrative burden. Given the time constraints of this DPhil, it was decided not to use monetary incentives.

5.3.5 Secondary (clinical) outcomes

PROMs

Table 5.7 shows that clinical PROM scores steadily improved from baseline to six months then largely plateaued. Overall, PROM scores indicated that participants on average did not recover fully. This was most notable in the KOOS subscales knee symptoms and knee-related quality of life, potentially because some questions within these subscales ask about aspects of recovery that may not be fully modifiable with rehabilitation. For instance, the frequency of knee swelling and the modification of activities to avoid re-injury.

Histograms depicting the distribution of the KOOS4, the planned full-scale trial primary outcome, at each measurement timepoint are shown in Appendix 13. Although scores clustered near the upper end of the scale at follow-up timepoints, there was no obvious ceiling effect. In contrast, for the study-specific return to pre-injury sport/physical activity questionnaire, 11/34 (33%) participants scored the maximum of 100 at six months as did 12/29 (41%) participants at nine

months. This indicates this questionnaire cannot detect further important improvements in recovery of physical function in some participants.[212]

Table 5.7 Clinical outcomes at each measurement timepoint

	Supervised rehabilitation (N = 24)		Self-managed rehabilitation (N = 26)		All participants (N = 50)	
	n	Median (IQR)	**n**	Median (IQR)	**n**	Median (IQR)	Mean (SD)
KOOS4							
Baseline	24	48.2 (31.9 to 61.7)	26	52.2 (35.5 to 64.7)	50	48.6 (32.4 to 64.7)	50.2 (21.0)
3 months	19	73.6 (53.1 to 84.5)	19	64.1 (44.6 to 87.3)	38	65.2 (51.0 to 86.0)	66.3 (19.8)
6 months	14	74.5 (69.4 to 86.6)	20	76.9 (53.7 to 85.6)	35	75.0 (55.9 to 85.7)	70.4 (19.4)
9 months	13	84.3 (68.4 to 88.8)	18	64.7 (49.6 to 89.4)	31	79.4 (52.2 to 89.4)	70.5 (21.1)
KOOS symptoms[a]							
Baseline	24	50.0 (42.9 to 57.1)	26	53.6 (46.4 to 64.3)	50	50.0 (42.9 to 60.7)	51.9 (11.2)
3 months	19	53.6 (42.9 to 67.9)	19	60.7 (46.4 to 67.9)	38	57.1 (42.9 to 67.9)	54.9 (13.3)
6 months	14	57.1 (53.6 to 67.9)	21	60.7 (50.0 to 71.4)	35	60.7 (50.0 to 71.4)	58.1 (11.6)
9 months	13	67.9 (60.7 to 67.9)	18	58.9 (50.0 to 67.9)	31	60.7 (50.0 to 67.9)	60.1 (10.5)
KOOS pain[a]							
Baseline	24	59.7 (50.0 to 81.9)	26	73.6 (55.6 to 83.3)	50	66.7 (55.6 to 83.3)	66.1 (22.7)
3 months	19	80.6 (66.7 to 100)	19	83.3 (75.0 to 97.2)	38	83.3 (69.4 to 100)	81.6 (16.8)
6 months	14	91.7 (83.3 to 100)	21	88.9 (80.6 to 94.4)	35	91.7 (80.6 to 97.2)	84.8 (17.7)
9 months	13	94.4 (88.9 to 100)	18	88.9 (66.7 to 100)	31	91.7 (72.2 to 100)	84.2 (18.4)
KOOS ADL							
Baseline	24	65.4 (42.6 to 83.1)	26	75.0 (54.4 to 91.2)	50	72.1 (44.1 to 88.2)	66.7 (25.8)
3 months	19	91.2 (72.1 to 100)	19	92.6 (70.6 to 100)	38	91.2 (72.1 to 100)	85.2 (15.8)
6 months	14	94.9 (88.2 to 100)	20	95.6 (81.6 to 100)	34	95.6 (83.8 to 100)	88.1 (17.7)
9 months	13	98.5 (85.3 to 100)	18	88.2 (67.6 to 100)	31	95.6 (80.9 to 100)	86.4 (18.2)
KOOS sport/rec							
Baseline	24	30.0 (10.0 to 62.5)	26	40.0 (5.0 to 65.0)	50	30.0 (5.0 to 65.0)	37.8 (33.2)
3 months	19	75.0 (50.0 to 95.0)	19	70.0 (40.0 to 100)	38	70.0 (45.0 to 100)	67.2 (29.2)
6 months	14	80.0 (60.0 to 100)	20	82.5 (62.5 to 100)	34	80.0 (60.0 to 100)	74.0 (27.8)
9 months	13	90.0 (70.0 to 100)	18	72.5 (50.0 to 100)	31	85.0 (55.0 to 100)	74.0 (28.6)

		Supervised rehabilitation (N = 24)		Self-managed rehabilitation (N = 26)		All participants (N = 50)	
KOOS QoL							
Baseline	24	43.8 (25.0 to 59.4)	26	40.6 (18.8 to 62.5)	50	43.8 (25.0 to 62.5)	45.0 (27.9)
3 months	19	68.8 (43.8 to 93.8)	19	50.0 (31.3 to 81.3)	38	62.5 (37.5 to 87.5)	61.5 (28.5)
6 months	14	71.9 (56.3 to 100)	20	65.6 (37.5 to 93.8)	34	71.9 (43.8 to 93.8)	65.8 (28.5)
9 months	13	81.3 (56.3 to 93.8)	18	50.0 (37.5 to 87.5)	31	75.0 (37.5 to 93.8)	63.7 (32.5)
EQ-5D-5L utility score[b]							
Baseline	24	0.63 (0.46 to 0.74)	26	0.63 (0.44 to 0.73)	50	0.63 (0.44 to 0.73)	0.55 (0.29)
3 months	18	0.87 (0.76 to 0.98)	18	0.75 (0.61 to 0.98)	36	0.81 (0.63 to 0.94)	0.79 (0.19)
6 months	14	0.93 (0.73 to 0.98)	20	0.73 (0.54 to 0.93)	34	0.84 (0.63 to 0.98)	0.75 (0.27)
9 months	13	0.98 (0.76 to 0.98)	17	0.80 (0.68 to 0.98)	30	0.85 (0.69 to 0.98)	0.78 (0.24)
EQ-5D-5L VAS							
Baseline	24	80.0 (50.0 to 87.5)	26	72.5 (50.0 to 80.0)	50	75.0 (50.0 to 85.0)	68.1 (21.1)
3 months	18	76.5 (70.0 to 95.0)	18	75.0 (52.0 to 91.0)	36	75.0 (63.0 to 92.0)	74.3 (20.7)
6 months	14	85.0 (74.0 to 90.0)	20	75.0 (68.5 to 86.5)	34	77.5 (70.0 to 90.0)	75.9 (19.2)
9 months	13	82.0 (79.0 to 95.0)	16	82.5 (72.5 to 88.5)	29	82.0 (75.0 to 94.0)	79.4 (17.6)
% Return to main pre-injury sport/physical activity							
Baseline	24	50.0 (24.5 to 77.5)	26	10.0 (0.0 to 75.0)	50	50.0 (0.0 to 75.0)	40.7 (35.5)
3 months	18	80.0 (50.0 to 99.0)	18	50.0 (30.0 to 85.0)	36	75.5 (34.5 to 90.0)	61.9 (34.2)
6 months	14	75.0 (50.0 to 100)	20	71.0 (32.5 to 100)	34	73.5 (35.0 to 100)	66.6 (33.9)
9 months	13	91.0 (87.0 to 100)	16	85.0 (25.0 to 100)	29	91.0 (70.0 to 100)	74.0 (36.4)

EQ-5D-5L; EuroQol 5 dimensions 5 levels; IQR: interquartile range; KOOS: Knee injury and Osteoarthritis Outcome Score; SD: standard deviation

[a]1 participant allocated to self-managed rehabilitation only completed the KOOS symptoms and pain subscales at 6 months, so the number of participants in self-managed rehabilitation that completed the other KOOS subscales is different at this timepoint.

[b]1 participant allocated to self-managed rehabilitation only completed the domains section of the EQ-5D-5L questionnaire at 9 months, so the number of participants in self-managed rehabilitation that completed the EQ-5D-5L VAS is different at this timepoint.

Participants also rated the overall change in their injured knee since they entered the study on a seven-point Likert scale (Table 5.8). At nine months, there was a spread of responses, but 21/30 (70%) participants who provided data reported their knee was “a lot better”.

Table 5.8 Global rating of change at each follow-up timepoint

	Supervised rehabilitation (N = 24)	**Self-managed rehabilitation (N = 26)**	**All participants (N = 50)**
3 months	**n = 18**	**n = 17**	**n = 35**
A lot worse	0 (0)	0 (0)	0 (0)
Moderately worse	0 (0)	0 (0)	0 (0)
A little worse	0 (0)	1 (6)	1 (3)
No change	0 (0)	0 (0)	0 (0)
A little better	3 (17)	5 (29)	8 (23)
Moderately better	3 (17)	6 (35)	9 (26)
A lot better	12 (67)	5 (29)	17 (49)
6 months	**n = 14**	**n = 20**	**n = 34**
A lot worse	0 (0)	0 (0)	0 (0)
Moderately worse	0 (0)	0 (0)	0 (0)
A little worse	0 (0)	0 (0)	0 (0)
No change	0 (0)	1 (5)	1 (3)
A little better	1 (7)	3 (15)	4 (12)
Moderately better	3 (21)	4 (20)	7 (21)
A lot better	10 (71)	12 (60)	22 (65)
9 months	**n = 14**	**n = 16**	**n = 30**
A lot worse	0 (0)	0 (0)	0 (0)
Moderately worse	1 (7)	0 (0)	1 (3)
A little worse	0 (0)	2 (13)	2 (7)
No change	0 (0)	1 (6)	1 (3)
A little better	2 (14)	1 (6)	3 (10)
Moderately better	0 (0)	2 (13)	2 (7)
A lot better	11 (79)	10 (63)	21 (70)

Data are n (%)

Complications

No SAEs or complications that were not pre-specified were reported to the trial team. The occurrence of verified pre-specified complications are presented in Table 5.9. All complications except one occurred in participants allocated to self-managed rehabilitation, likely influenced by

the higher retention and so higher number of follow-up complication questionnaires completed by these participants.

Participants reported eight new ipsilateral and one contralateral dislocation in follow-up questionnaires, but only three of these met the pre-specified definition of a new patellar dislocation i.e., required hospital or GP attendance or was documented in the participant's medical notes. The fourth patellar dislocation was identified by the medical notes review performed by sites to check for any unreported patellar dislocations or related knee surgeries that occurred during the follow-up period.

Table 5.9 Verified pre-specified complications

Complication	**Supervised rehabilitation (N = 24)**		**Self-managed rehabilitation (N = 26)**		**All participants (N = 50)**	
	Events	Participants	Events	Participants	Events	Participants
Increased knee pain or swelling after completing the intervention exercises that required a healthcare professional review[a]	1	1	4	3	5	4
New or exacerbated medical problems that started or worsened during or after completing intervention exercises that required a healthcare professional review	0	0	1	1	1	1
New ipsilateral patellar dislocation	0	0	4	3	4	3
New contralateral patellar dislocation	0	0	0	0	0	0
Subsequent patellar related surgery	0	0	1	1	1	1
Tibial tuberosity osteotomy	0	0	1	1	1	1
DVT or PE	0	0	0	0	0	0

DVT: deep vein thrombosis; PE: pulmonary embolism
[a]This complication was not verified with 1 participant in each treatment group. For these participants, the number of events of this complication was therefore counted as 1.

5.3.6 Additional analyses

Intervention delivery

Physiotherapists reported high fidelity to delivering the key components of self-managed rehabilitation (Table 5.10). The most challenging knee bending and straightening exercise were prescribed for 20% to 30% of participants at this one-off session. These represent high difficulty exercises, so probably indicates that the knee movement of these participants was nearly or fully restored. Few participants were prescribed the most challenging balance and leg strengthening exercises, suggesting that these categories contain a sufficiently challenging range of exercises to enable progression.

Table 5.10 Delivery of core components of self-managed rehabilitation

Self-managed rehabilitation	
Session 1 (N = 23)	
Participant using the workbook before the session? (yes)	20 (87)
All core advice in the workbook provided?[a] (yes)	23 (100)
Strategies to support exercise adherence	
Participant completed the exercise planner? (yes)	21 (91)
Participant set goals? (yes)	23 (100)
Exercise diary explained? (yes)	23 (100)
Participant practiced prescribed exercise? (yes)	90 (98)
Physiotherapist gave feedback on technique? (yes)	90 (98)
Prescribed exercise[b]	
Knee bending, n	23
1 Sitting active ROM knee flexion	7 (30)
2 Supine/long sitting active ROM knee flexion (+/- active assisted ROM)	8 (35)
3 Quadriceps stretch	3 (13)
4 Kneeling passive ROM knee flexion	5 (22)
Knee straightening, n	23
1 Static quadriceps muscle contractions	6 (26)
2 Static quadriceps muscle contractions, foot elevated	10 (44)
3 Passive ROM knee extension using hands in sitting	7 (30)
Balance, n	23
1 Weight shifting with upper limb support	5 (22)
2 Single leg stand with contralateral upper limb support	4 (17)
3 Single leg stand without upper limb support	9 (39)
4 Single leg squat	4 (17)
5 Single leg hop from unaffected to affected leg forward and laterally	1 (4)
Leg strengthening, n	23
1 Squat to chair	13 (57)
2 Squat to chair in split stance (unaffected leg in front)	8 (35)
3 Single leg squat to chair	1 (4)
4 Single leg squat to chair weighted	1 (4)

Data are n (%) unless otherwise stated; ROM: range of movement
[a]Sections on pain and swelling management, increasing/returning to activity, and the role of exercise in recovery.
[b]Numbers correspond to exercise levels (higher levels indicate greater difficulty).

There was also high physiotherapist-reported fidelity to delivering the core supervised rehabilitation components (see Table 5.11). Of note, there was good implementation of the strategies to support exercise adherence, and physiotherapists routinely assessed leg strength objectively at follow-up sessions. These are key differences from self-managed rehabilitation but may not be part of physiotherapists' routine practice. Strengthening exercises were also prescribed

in 92% of sessions demonstrating that physiotherapists usually prescribed at least one leg muscle strengthening exercise per session as intended.

Table 5.11 Delivery of core components of supervised rehabilitation

Supervised rehabilitation	
Session 1 (N = 20)	
Participant using workbook before session? (yes)	14 (70)
All core advice sections provided?[a] (yes)	19 (95)
Participant completed exercise planner? (yes)	16 (80)
Participant set goals? (yes)	20 (100)
Exercise diary explained? (yes)	20 (100)
Follow-up sessions (N = 58)	
Exercise planner reviewed? (yes)	50 (86)
Exercise diary reviewed? (yes)	47 (81)
Goals reviewed? (yes)	56 (94)
Leg strength assessed objectively? (yes)	46 (79)
Balance assessed? (yes)	52 (90)
All sessions (N = 78)	
No. sessions where exercise within categories prescribed	
Flexibility	39 (50)
Balance	67 (86)
Strengthening	72 (93)
Running	8 (10)
Bespoke	15 (19)
All exercises prescribed (N = 315)	
Proportion of all exercises prescribed	
Flexibility	52 (17)
Balance	76 (24)
Strengthening	160 (51)
Running	10 (3)
Bespoke	17 (5)
Participant practiced prescribed exercise?[b] (yes)	265 (89)
Physiotherapist gave feedback on technique?[b] (yes)	264 (89)

Data are n (%) unless otherwise stated
[a]Sections on pain and swelling management, increasing/returning to activity, and role of exercise in recovery.
[b]Not recorded for bespoke exercises, so the denominator is 298.

Participant-reported adherence to exercise

In follow-up questionnaires, participants were asked to report if they were currently doing any exercises provided as part of the study, and if so, how often. Responses are in Table 5.12. Of the

participants who replied, the proportion that reported they were completing any prescribed exercise at three, six, and nine months was 66%, 47%, and 45%, respectively.

Table 5.12 Participant-reported adherence to prescribed exercise

	Supervised rehabilitation (N = 24)	**Self-managed rehabilitation (N = 26)**	**All participants (N = 50)**
3 months	**n = 18**	**n = 17**	**n = 35**
No	3 (17)	9 (53)	12 (34)
Yes	15 (83)	8 (47)	23 (66)
Every day	2 (11)	0 (0)	2 (6)
6 days/week	1 (6)	0 (0)	1 (3)
5 days/week	3 (17)	1 (6)	4 (11)
4 days/week	2 (11)	2 (12)	4 (11)
3 days/week	4 (22)	2 (12)	6 (17)
2 days/week	2 (11)	1 (6)	3 (9)
1 day/week	1 (6)	2 (12)	3 (9)
6 months	**n = 14**	**n = 20**	**n = 34**
No	6 (43)	12 (60)	18 (53)
Yes	8 (57)	8 (40)	16 (47)
Every day	1 (7)	1 (5)	2 (6)
6 days/week	0 (0)	0 (0)	0 (0)
5 days/week	1 (7)	0 (0)	1 (3)
4 days/week	0 (0)	1 (5)	1 (3)
3 days/week	2 (14)	4 (20)	6 (18)
2 days/week	3 (21)	0 (0)	3 (9)
1 day/week	1 (7)	2 (10)	3 (9)
9 months	**n = 13**	**n = 16**	**n = 29**
No	6 (46)	10 (63)	16 (55)
Yes	7 (54)	6 (38)	13 (45)
Every day	0 (0)	0 (0)	0 (0)
6 days/week	1 (8)	0 (0)	1 (3)
5 days/week	1 (8)	1 (6)	2 (7)
4 days/week	0 (0)	0 (0)	0 (0)
3 days/week	2 (15)	2 (13)	4 (14)
2 days/week	3 (23)	2 (13)	5 (17)
1 day/week	0 (0)	1 (6)	1 (3)

Data are n (%)

Health resource use data

The proportion of participants that returned health resource use questionnaires at three, six, and nine months was 78%, 68%, and 58%, respectively. In questionnaires, two participants allocated to supervised rehabilitation and three participants allocated to self-managed rehabilitation reported attending private physiotherapy. Two participants allocated to self-managed rehabilitation (including one of those who reported attending private physiotherapy) also reported attending NHS community physiotherapy.

Baseline characteristics of specific participant subgroups

Table 5.13 presents the key baseline characteristics of participants who were 1.) retained at nine months versus those that were not, and 2.) adhered to the interventions versus those who did not. This aimed to identify if there were any differences between these sub groups of patients, and if so, potentially guide strategies to improve retention and intervention adherence in the full-scale trial. This showed that most participants aged <16 years were retained and adhered to the interventions, and those with a previous ipsilateral patellar dislocation who did not adhere to the interventions were more likely to have had previous physiotherapy. However the numbers are small so these may represent chance findings.

Table 5.13 Baseline characteristics of specific participant subgroups

Characteristic	Retained[a] (N = 31)	Not retained (N = 19)	Adhered to intervention[b] (N = 34)	Did not adhere to intervention (N = 16)
Age (years), median (IQR)	22.0 (16.0 to 31.0)	23.0 (18.0 to 28.0)	22.0 (17.0 to 29.0)	21.5 (18.0 to 29.5)
<16 years, n (%)	5 (16)	1 (5)	5 (15)	1 (6)
Gender, n (%)				
Male	11 (35)	10 (53)	14 (41)	7 (44)
Female	20 (65)	9 (47)	20 (59)	9 (56)
Index of multiple deprivation decile,[c] median (IQR)	6.0 (3.3 to 8.0)	6.0 (4.0 to 8.0)	6.0 (4.0 to 8.0)	4.5 (2.8 to 8.0)
BMI (kg/m^2), median (IQR)	25.0 (19.7 to 32.4)	25.7 (19.0 to 35.1)	25.1 (19.7 to 32.0)	25.4 (23.4 to 32.1)
Ethnicity, n (%)				
White	27 (87)	17 (89)	30 (88)	14 (88)
Asian or Asian British	3 (10)	1 (5)	3 (9)	1 (6)

Characteristic	Retained[a] (N = 31)	Not retained (N = 19)	Adhered to intervention[b] (N = 34)	Did not adhere to intervention (N = 16)
Black, African, Caribbean, or Black British	1 (3)	0 (0)	1 (3)	0 (0)
Mixed or multiple ethnic groups	0 (0)	1 (5)	0 (0)	1 (6)
Other ethnic group	0 (0)	0 (0)	0 (0)	0 (0)
Education,[d] n (%)				
Higher professional or university education	15 (48)	10 (53)	19 (56)	6 (38)
Secondary education	16 (52)	9 (47)	15 (44)	10 (63)
Employment, n (%)				
Full-time employed	11 (35)	11 (58)	14 (41)	8 (50)
Full-time student	11 (35)	5 (26)	11 (32)	5 (31)
Part-time employed	8 (26)	3 (16)	8 (24)	3 (19)
Unemployed	1 (3)	0 (0)	1 (3)	0 (0)
Main pre-injury sport or physical activity, n (%)				
Walking or none	17 (55)	7 (37)	18 (53)	6 (38)
Multidirectional sport	9 (29)	10 (53)	13 (38)	6 (38)
Linear sport	5 (16)	2 (11)	3 (9)	4 (25)
Previous ipsilateral patellar dislocation (yes), n (%)	13 (42)	8 (42)	13 (38)	8 (50)
1	1 (8)	3 (38)	3 (23)	1 (13)
2	4 (31)	1 (13)	3 (23)	2 (25)
3	2 (15)	1 (13)	1 (8)	2 (25)
4	1 (8)	0 (0)	1 (8)	0 (0)
5	1 (8)	1 (13)	1 (8)	1 (13)
6	1 (8)	0 (0)	1 (8)	0 (0)
7	1 (8)	0 (0)	1 (8)	0 (0)
≥10	2 (15)	2 (25)	2 (15)	2 (25)
Physiotherapy for any previous ipsilateral patellar dislocation (yes), n (%)	7 (54)	6 (75)	6 (46)	7 (88)
Previous contralateral patellar dislocation (yes), n (%)	7 (23)	2 (11)	6 (18)	3 (19)
1	3 (43)	1 (50)	3 (50)	1 (33)
2	4 (57)	0 (0)	3 (50)	1 (33)
≥10	0 (0)	1 (50)	0 (0)	1 (33)

BMI: body mass index; IQR: interquartile range
[a]Returned 9-month KOOS data.
[b]Attended ≥4 supervised rehabilitation sessions or attended ≥1 supervised rehabilitation session and did not attend out-of-trial NHS physiotherapy.
[c]Lower scores mean higher deprivation.
[d]Highest level participant is completing or has completed.

Per-protocol analysis

A per-protocol analysis was not pre-specified in the study protocol but is performed here for the KOOS (see

Table **5.14**) and global rating of change questionnaire (

Table 5.15) to demonstrate what this could look like for the full-scale trial and to investigate if there is a potential signal of effectiveness. In the full-scale trial, the per-protocol population would likely exclude participants who do not meet the definition of intervention adherence (i.e., participants allocated to supervised rehabilitation who attend at least four interventions sessions and participants allocated to self-managed rehabilitation who attend at least one intervention session, and those who do not access out-of-trial NHS physiotherapy).

Results showed that at three and nine months, participants who adhered to their intervention had higher KOOS4 scores and a higher proportion reported they were "a lot better" than participants who did not adhere to their intervention.

Table 5.14 Per-protocol analysis for the KOOS at each follow-up timepoint

		Adhered to supervised rehabilitation[a] (N = 13)		**Adhered to self-managed rehabilitation[b] (N = 21)**
	n	Median (IQR)	**n**	Median (IQR)
KOOS4				
Baseline	13	57.4 (48.2 to 70.2)	21	55.3 (38.3 to 68.3)
3 months	12	75.9 (60.5 to 85.3)	15	64.1 (44.6 to 87.5)
6 months	11	80.8 (70.3 to 87.7)	19	81.3 (57.4 to 87.2)
9 months	11	86.4 (59.8 to 90.2)	16	74.1 (51.5 to 89.5)
KOOS symptoms[c]				
Baseline	13	57.1 (50.0 to 60.7)	21	57.1 (46.4 to 67.9)
3 months	12	64.3 (46.4 to 67.9)	15	60.7 (53.6 to 67.9)
6 months	11	57.1 (53.6 to 71.4)	19	60.7 (50.0 to 71.4)
9 months	11	67.9 (60.7 to 67.9)	16	60.7 (50.0 to 69.6)
KOOS pain[c]				
Baseline	13	72.2 (58.3 to 86.1)	21	75.0 (61.1 to 86.1)
3 months	12	87.5 (72.2 to 100)	15	88.9 (75.0 to 100)
6 months	11	97.2 (83.3 to 100)	19	91.7 (80.6 to 97.2)
9 months	11	91.7 (72.2 to 100)	16	91.7 (65.3 to 100)
KOOS ADL				
Baseline	13	82.4 (61.8 to 83.8)	21	75.0 (57.4 to 95.6)
3 months	12	91.9 (80.9 to 100)	15	92.6 (70.6 to 100)
6 months	11	100 (92.6 to 100)	18	95.6 (83.8 to 100)
9 months	11	100 (80.9 to 100)	16	93.4 (71.3 to 100)
KOOS sport/rec				
Baseline	13	50.0 (30.0 to 65.0)	21	30.0 (0.0 to 65.0)
3 months	12	77.5 (67.5 to 97.5)	15	80.0 (40.0 to 100)
6 months	11	85.0 (75.0 to 100)	18	87.5 (65.0 to 100)
9 months	11	95.0 (70.0 to 100)	16	80.0 (37.5 to 100)
KOOS QoL				
Baseline	13	50.0 (43.8 to 68.8)	21	50.0 (25.0 to 75.0)
3 months	12	75.0 (59.4 to 93.8)	15	50.0 (37.5 to 100)
6 months	11	75.0 (56.3 to 100)	18	78.1 (43.8 to 93.8)
9 months	11	87.5 (50.0 to 100)	16	65.6 (37.5 to 90.6)

KOOS: Knee injury and Osteoarthritis Outcome Score; IQR: interquartile range
[a]Attended ≥4 supervised rehabilitation sessions did not attend out-of-trial NHS physiotherapy.
[b]Attended ≥1 self-managed rehabilitation session and did not attend out-of-trial NHS physiotherapy.
[c]1 participant allocated to self-managed rehabilitation only completed the KOOS symptoms and pain subscales at 6 months, so the number of participants in self-managed rehabilitation that completed the other KOOS subscales is different at this timepoint.

Table 5.15 Per-protocol analysis for the global rating of change at each follow-up timepoint

	Adhered to supervised rehabilitation[a] (N = 13)	**Adhered to self-managed rehabilitation[b] (N = 21)**
3 months	**n = 12**	**n = 14**
A lot worse	0 (0)	0 (0)
Moderately worse	0 (0)	0 (0)
A little worse	0 (0)	1 (7.1)
No change	0 (0)	0 (0)
A little better	1 (7.7)	4 (28.6)
Moderately better	2 (15.4)	5 (35.7)
A lot better	9 (69.2)	4 (28.6)
6 months	**n = 11**	**n = 18**
A lot worse	0 (0)	0 (0)
Moderately worse	0 (0)	0 (0)
A little worse	0 (0)	0 (0)
No change	0 (0)	1 (5.6)
A little better	1 (9.1)	2 (11.1)
Moderately better	2 (18.2)	4 (22.2)
A lot better	8 (72.7)	11 (78.6)
9 months	**n = 11**	**n = 14**
A lot worse	0 (0)	0 (0)
Moderately worse	0 (0)	0 (0)
A little worse	0 (0)	1 (7.1)
No change	0 (0)	1 (7.1)
A little better	2 (18.2)	1 (7.1)
Moderately better	0 (0)	2 (14.3)
A lot better	9 (81.8)	9 (64.3)

Data are n (%)

[a]Attended ≥4 supervised rehabilitation sessions and did not attend out-of-trial NHS physiotherapy.
[b]Attended ≥1 self-managed rehabilitation session and did not attend out-of-trial NHS physiotherapy.

5.3.7 Quality assurance

In addition to reviewing physiotherapist-completed treatment logs, four treatment sessions provided by four different physiotherapists at three study sites were observed. In all instances, intervention delivery was judged satisfactory with only minor deviations from the intended intervention noted. Attempts to audio record a treatment session at two sites, Leeds Teaching Hospitals Trust and South Tyneside and Sunderland NHS Foundation Trust, were unsuccessful so quality assurance was limited to treatment log review at these sites.

Quality assurance checks identified that the most common intervention delivery issues were 1.) sites not keeping spare intervention workbooks, so if a participant did not bring their workbook to a session some intervention components could not be delivered, 2.) strengthening exercises were prescribed outside the target set and repetition range in supervised rehabilitation, and 3.) participant performance of prescribed exercises was not reviewed for supervised rehabilitation. On 19 June 2023, an infographic detailing the delivery of core intervention components was sent to sites to address these deviations and in response to a physiotherapist's feedback that this would be useful. Observing treatment sessions was also an opportunity to see how the interventions worked in practice and to hear physiotherapists' views on how the interventions could be improved which were noted for future reference. For example, a physiotherapist suggested colour coding exercise categories in the supervised rehabilitation workbook to make identifying exercises in the workbook easier.

5.4 Discussion

This pilot RCT's results indicate that a full-scale RCT evaluating rehabilitation for people with an acute patellar dislocation is feasible with modifications. These modifications should prioritise improving retention and the proportion of participants that attend the intended number of intervention sessions.

In this study, follow-up data collection methods were designed with the foreknowledge that retention could be a problem. To facilitate retention, follow-up was remote and could be completed electronically, as recommended by PPIE partners. Despite this, retention was 62%, which would seriously hinder the credibility of the results if reproduced in the full-scale evaluation. While the actions implemented during the study to improve follow-up appeared to work, these were selected in part based on intuition, due to the lack of high-certainty evidence about what improves trial retention.[211] Potential explanations for the low retention in this study are discussed in the qualitative results chapter and potential strategies to improve retention are discussed in the Chapter 7. Retention was higher in the self-managed rehabilitation group at six and nine months, which was

unexpected given that these participants had less interaction with healthcare staff after randomisation. However, the number of participants are small so this may simply be a chance finding.

The other main area for refinement is intervention adherence. In total, 14% of participants did not attend any physiotherapy session, which exceeds the 5% to 10% observed in comparable RCTs.[86,106] The initial physiotherapy session was scheduled soon after randomisation, so this raises questions about participants' understanding of what study participation involved. Another possible explanation is that having received their intervention workbook upon randomisation, some participants felt that attending physiotherapy was then unnecessary.

In the supervised rehabilitation group, 54% of participants attended at least four intervention sessions as planned. Although this proportion was lower than intended, it is comparable to the number of physiotherapy sessions attended by participants in similarly designed RCTs of musculoskeletal injury rehabilitation.[47,106] Nevertheless, increasing the proportion of participants in supervised rehabilitation that attend a minimum of four sessions will be important to ensure the results of a full-scale RCT are seen as credible and taken up by the clinical community. This will be particularly important if the higher dose intervention is shown not to be more effective. To improve adherence to both interventions, the PIS should clearly explain what study participation involves and researchers should check patients understanding of this during the initial consent discussion. Only giving participants intervention materials covering basic advice and exercises upon randomisation and providing the remaining materials at the first physiotherapy session could also help. For supervised rehabilitation, encouraging sites to offer remote follow-up appointments may also improve session attendance.

A high proportion of patients assessed for eligibility were eligible indicating that a representative patient sample was invited to take part. However, sites' screening practices varied e.g., some sites appeared to only screen patients likely to be eligible, so this proportion should be interpreted cautiously. Despite efforts to recruit a representative sample, patients who declined participation were more often male and younger than participants. The reasons for the former are unknown, but

the latter was mainly driven by the large proportion of patients aged <16 years and their parents who declined participation, most commonly due to a preference for supervised rehabilitation. Potentially, some parents believed this higher dose intervention was more likely to facilitate recovery. Alternatively, this finding could suggest a different intervention is needed for this patient group. Including patients aged <16 years alongside adults in the full-scale RCT would require a significant amount of extra work. Whether this is worthwhile needs to be considered as results may not be generalisable to these patients if only a minority participate and these participants represent a small proportion of the study sample.

In future, capturing other patient characteristics on screening logs, like ethnicity and index of multiple deprivation data, will enable a better comparison between patients who declined to participate and those who were recruited. This would facilitate more informed judgements about the study sample's representativeness. This is important because limited data exists on the characteristics of people with a patellar dislocation in the UK. Another trial in our group is collecting patients' ethnicity and socioeconomic characteristics on screening logs, indicating this can be done.[175]

PROMs data showed that participants' recovery had largely plateaued by six months. Arguably, a primary outcome measurement timepoint of six months after randomisation should therefore be used in the full-scale trial, particularly as retention can be an issue. However, the full-scale trial's main objective would be to determine which intervention was most clinically and cost-effective in improving knee symptoms and function. Supervised rehabilitation lasts up to six months based on the belief that this intervention can improve knee symptoms and function up to that time. Therefore, selecting a primary outcome timepoint before the intended effects of this intervention are fully realised would not answer the full-scale trial's primary question, which is not recommended.[108] Furthermore, the numbers in this study are small. Further recovery or different recovery trajectories between groups beyond six months in a larger cohort of patients cannot be ruled out. As discussed in the previous chapter 4 (section 4.3), some participants could also still be receiving supervised rehabilitation at six months, which might affect their follow-up questionnaire

responses. Retaining a primary outcome measurement timepoint of nine months therefore seems prudent.

Only a third of new patellar dislocations reported by participants met this study's definition of a new patellar dislocation. This definition was used because distinguishing between subluxations and dislocations can be challenging, so including participant-reported new dislocations could lead to overreporting. Whether patients feel the threshold used for a new dislocation in this study is appropriate is unclear as their input was not sought. In future, obtaining patients' views on how new patellar dislocation should be defined would help ensure all important recurrence events are captured. As part of the systematic measurement of complications, sites checked their participant's medical records for any unreported patellar dislocations or related knee surgery that occurred during the follow-up period. One unreported patellar dislocation was identified this way. Sites responded relatively promptly to requests for this data indicating this would be feasible to implement in a full-scale RCT where the number of participants per site would be small, so checking medical records should not be too burdensome. An additional refinement for the full-scale trial would be to ensure complications were verified by someone blinded to treatment allocation, or if this is not possible, at least someone without a material interest in the trial outcome which was not the case in this study.

Sites also recorded data on concurrent knee injuries not affecting the patellofemoral joint. However, significant co-occurring knee injuries were rare, so collecting this data in a future RCT is probably unnecessary as such small numbers would not meaningfully affect the results.

5.4.1 Strengths and limitations

Strengths of this pilot RCT were the large number of physiotherapists who provided interventions and the inclusion of five study sites that varied in size, research experience, and geographical location. This increases confidence that many of the issues that would have arisen in the full-scale trial were detected. Physiotherapists also reported high fidelity to the interventions indicating that these are feasible to deliver within the NHS. However, some refinements may be needed, for

instance, making the initial intervention session more time efficient as 60 minute sessions may not be feasible to implement in some NHS physiotherapy departments.

The main limitations were the low retention and relatively low proportion of participants allocated to supervised rehabilitation that attended at least four physiotherapy sessions. Interpretating recovery was also limited by the lack of baseline pre-injury KOOS scores (see section 4.2.10 for justification) which were unlikely to be perfect in participants with a previous ipsilateral dislocation. Nevertheless, this is only relevant for determining overall recovery. It would not affect the comparison of effectiveness between groups in a full-scale RCT as participants with a previous ipsilateral dislocation would be balanced between groups. No treatment session was observed or audio recorded at two sites as part of planned quality assurance checks. Increasing the proportion of sites where this is done will be important to ensure quality assurance is more robust for the full-scale trial. As discussed previously, I also did not conduct qualitative research with physiotherapists to understand their experience of providing the interventions. However, regular email contact and site visits were opportunities to obtain physiotherapists' feedback about what aspects of the interventions worked well and what could be improved. When qualitative feedback is not possible, such informal feedback in an external pilot RCT can be valuable.[159]

5.4.2 Conclusion

This chapter reports the results of a multicentre external pilot RCT that compared supervised versus self-managed rehabilitation for people aged ≥14 years after an acute patellar dislocation. Findings indicated a full-scale trial is feasible with modifications to improve participant attendance at physiotherapy sessions and retention. However, decisions about the feasibility need to consider the findings from the embedded qualitative study which are described in the next chapter.

Chapter 6 Embedded qualitative study results

6.1 Introduction

This chapter describes the results of the qualitative study embedded within the PRePPeD pilot RCT. The planned methods for this qualitative study were described in Chapter 4, so only changes to those methods are reported in this chapter. The brief methods section is followed by the results and then a discussion of the implications and limitations of the study findings.

6.1.1 Chapter aim

To report the results of the qualitative study embedded within the PRePPeD pilot RCT.

6.2 Methods

6.2.1 Sampling strategy

I intended to purposively sample participants for variation (see section 4.2.15), but because participant recruitment was more challenging than anticipated, I changed to a convenience sampling strategy which involves recruiting those participants who are available and willing to be interviewed.[213]

6.2.2 Method of approach

Initially, potential interview participants were emailed an interview invitation (see section 4.2.15). If there was no reply, one follow-up email was sent one to two weeks later. The only exception was potential participants who were being chased for follow-up in the pilot RCT, who were not emailed again due to concerns that this additional contact could affect retention.

Due to the low number of replies, I changed to phoning potential participants who did not reply to the initial email invitation. Physiotherapists at sites were also asked to remind patients who had been sent invites about the opportunity to participate in interviews. Furthermore, pilot RCT

participants who were contacted by phone for follow-up questionnaire completion and who had previously been sent invites, were reminded about the opportunity to participate in interviews.

6.3 Results

In total, 52 people (48 RCT participants and four patients who declined to participate in the pilot RCT) provided permission to be contacted and 36 were approached, three of whom were patients who declined pilot RCT participation. Nine people, all pilot RCT participants, agreed to participate and were interviewed.

Informed consent was obtained before interviews as described in Chapter 4. One pilot RCT participant agreed to be interviewed by phone, but could not be reached at the scheduled interview time and attempts to rearrange this interview were unsuccessful. A parent of a pilot RCT participant aged <16 years also agreed for their child to take part, but attempts to schedule this interview were unsuccessful. The other 25 people invited either declined or did not reply to interview invitations.

6.3.1 Participants

I conducted interviews between July 2023 and January 2024. The median interview duration was 29 minutes (range 22 to 42) and the median time from randomisation to interview was 112 days (range 98 to 211). Participants were from four of the five pilot RCT sites and had a median age of 22 years (range 16 to 49). Other participant characteristics are presented in Table 6.1.

Four participants were offered face-to-face interviews and five a video or phone interview due to their remote geographical location. Three participants decided to be interviewed face-to-face, three by phone, and three by video. Face-to-face interviews took place in a private room in a hospital physiotherapy department and remote interviews were at a location of the participant's choosing e.g., their home. The participant's mother was present in two face-to-face interviews and in one video interview.

During interviews, I introduced myself to participants as a researcher with the PRePPeD study in case disclosing I was a physiotherapist affected participants' willingness to criticise the study interventions. However, some participants were recruited with the aid of their physiotherapist who may have told them I was also a physiotherapist. The first two interview transcripts were reviewed by my qualitative supervisor (ET) who provided suggestions on how to improve my interview technique e.g., using shorter questions. Closeness to the data, through conducting interviews and verifying transcripts, allowed me to pursue unexpected topics in later interviews e.g., follow-up questionnaires offered an opportunity to reflect on progress.

Generally, there was meaningful interaction in remote interviews. In some instances this format appeared to encourage participants to talk more freely about their physiotherapy treatment than participants interviewed face-to-face, potentially because face-to-face interviews occurred in a physiotherapy department and after the participant's treatment session. For remote interviews, video seemed a better format than phone for building a rapport with participants while also allowing me to observe non-verbal reactions.

Table 6.1 Characteristics of interview participants

Interview ID	Age (years)	Treatment allocation	Lost to follow-up at time of interview?	Gender	1st time/recurrent patellar dislocation	Time from randomisation (days)
P1[a]	19	Supervised	No	Female	1st time	111
P2[a]	17	Supervised	No	Female	Recurrent	106
P3	16	Supervised	No	Male	1st time	98
P4	22	Self-managed	No	Male	Recurrent	199
P5	16	Self-managed	No	Male	1st time	129
P6	36	Supervised	No	Female	Recurrent	103
P7	36	Supervised	No	Female	Recurrent	128
P8[a]	33	Supervised	No	Female	Recurrent	112
P9	50	Self-managed	No	Male	Recurrent	211

ID: identification
[a]Participant's mother was present during the interview.

6.3.2 Themes

The experience of recovery after an acute patellar dislocation was conveyed through the themes of 1) 'coming to terms with the initial injury' with categories of the physical response to the initial injury and the emotional response to the initial injury, and 2) 'regaining my former self' with categories of getting better and looking to the future. Two other themes addressed pre-specified objectives: 1) 'acceptability of the interventions to participants' with categories of supervised and self-managed rehabilitation, and the intervention workbooks, and 2) 'acceptability of the follow-up methods to participants', with categories of a straightforward process and an opportunity for reflection on recovery.

A table containing the themes, categories within themes, and additional participant quotations within categories is available in Appendix 14.

Theme 1: coming to terms with the initial injury

Coming to terms with the initial injury involved the physical symptoms of initial severe pain at the time of dislocation followed by impaired mobility which affected participants' ability, albeit to varying degrees, to perform their normal activities. The emotional response to the injury was initial disbelief that the injury could happen so easily followed by concern for the potential disruption to everyday life.

Category: physical response to the initial injury

Pain was the predominant physical symptom experienced by participants which was highest while the patella was dislocated. Others described feeling nauseous or vomiting, sensing they were having a panic attack, or fainting in response to their patellar dislocation.

P7 (36 year-old female with a recurrent dislocation) Yes it was painful, it was more painful every time I was trying to move it, like trying to move. Yeah, no, it was, and I remember I was sick as well, because I think it was just the shock.

When the patella was relocated, there was relief, mainly due to the reduced pain that this brought. Although participants continued to experience pain and other physical symptoms like knee

swelling and stiffness after the initial injury episode, these were no longer participants' primary concern. Instead, the impact of impaired mobility on participants' ability to perform their normal daily activities was their main worry.

There was variation in the duration and extent that mobility was impaired in the early recovery period, but for most it resulted in difficulty with routine everyday tasks like personal care, food preparation, driving, or caring for children. For those in employment, the injury meant a period of enforced absence from or modification to their work. During this acute injury phase, family and partners were important sources of support that was mainly practical in nature.

P1 (19 year-old female with a first-time dislocation) I couldn't shower myself because obviously I needed help getting in and out of the shower and we bought a shower chair to help with that. I obviously couldn't go downstairs and make myself food. It was very debilitating because obviously you use your legs every day and you don't realise until something bad happens that you can't actually do a lot.

However, for one participant, the disruption to their everyday life was relatively minor and short lived, reflecting a generally smaller impact on those whose daily tasks and responsibilities were less dependent on higher physical function. For example, people who could work from home, young people in education, and those without caring responsibilities.

P3 (16 year-old male with a first-time dislocation) So, I obviously struggled to walk when I first did it, so I got the crutches and the crutches were fine, but they were more just inconvenient than actually like troubling I guess. Then I got off the crutches pretty quickly and then I was fine after that. I couldn't really bend my knee, straighten my knee fully for quite a while but it didn't really affect me that much.

Category: emotional response to the initial injury

The patella dislocated during simple low energy day-to-day activities in all participants except one where it occurred while changing direction during sport. Often, participants were unsure what exactly caused their injury, reflecting their sense that there was no obvious precipitating event.

P2 (17 year-old female with a recurrent dislocation) It's silly really. I was carrying some shopping with my mum to take up to the flat and there was this scaffolding pole, I was nowhere near it, and I went round it and then it sort of, I must have went round it wrong and then it popped out.

The sudden and unexpected nature of the injury during activities perceived as safe and routine often resulted in feelings of shock or disbelief.

P4 (22 year-old male with a recurrent dislocation) I was kind of in disbelief because the first time I didn't know what happened, whereas this time because obviously it had happened before, so I knew that I'd dislocated my knee, but I was like, I couldn't believe it had happened. I was just playing sport, so yeah I was just kinda shocked.

Following the initial injury, there was concern and frustration over the potential disruption to daily life in terms of work, family life, and the impact on others. These feelings were driven either by uncertainty over the injury management process, knowledge of the recovery experience for those with a previous patellar dislocation, or initial advice received in the Emergency Department which suggested prolonged knee immobilisation and non-weightbearing may be required.

P7 (36 year-old female with a recurrent dislocation) I'd understand if I was doing some sort of high impact exercise or sport, but emm, so yeah it took me by surprise and yeah, I remember feeling gutted because I was like oh no, I've got to go through this whole recovery process. It affects work and family life.

While some participants also described fear of re-injury in this early stage, this appeared more pronounced during the later stages of recovery (discussed below), indicating that activity restriction in the early recovery period was mainly driven by physical impairments. Of note, one participant reported the injury had minimal emotional impact.

Theme 2: regaining my former self

Getting better was the experience of wanting to return to normal life and actively pursuing this by progressively testing the physical capacity of their knee and performing rehabilitation exercises which built confidence. Looking to the future was participants' experience of considering the injury's impact on their life going forward: would they be able to return to all valued activities, could they prevent the injury from recurring, and dealing with the potential that the injury could recur.

Category: getting better

Participants were motivated to get better by a desire to return to their normal pre-injury lives. Participants wanted to regain their independence, not have to rely on others, and be able to fulfil their normal responsibilities, such as working and caring for children.

P6 (36 year-old female with a recurrent dislocation) I refused to sit down and rest to be fair. I was pushing myself to do things more on my own.

CF Where did that come from, why did you start pushing yourself?

P6 Just the need to be able to do things on my own and not rely on people.

While the passing of time was seen to contribute to improving knee symptoms and function, participants also felt that they needed to be proactive and actively participate in their own recovery. In the early injury phase, this mainly involved testing their knee by gradually increasing their physical activity levels. The importance placed on physical activity was influenced by participants' own beliefs, previous personal injury experience or the injury experience of others, and initial injury management advice from healthcare professionals. Improving physical performance re-enforced the belief that physical activity was helpful.

P5 (16 year-old male with a first-time dislocation) I mean, at first it was like start walking without the crutches just to the next room along and then it was like a bit further, then a bit further and then a bit further. Then one day I was like, it was just about a few weeks after, I was like going to see if I need crutches at school one day. Because it was a Wednesday so I finish early anyway, but I was going to see if I needed the crutches today and so I didn't take them and I was pretty much fine all day without the crutches. So I was like right, I don't need them anymore.

For some, early recovery was aided by flexible knee splints which allowed greater knee movement or provided a sense of security, enabling an earlier return to functional activities. Reassurance from physiotherapists that resuming certain activities or removing splints was safe also helped recovery. Performing specific rehabilitation exercises, particularly those that strengthened muscle surrounding the knee also built confidence. As such, recovery was aided by both intrinsic and extrinsic factors.

P7 (36 year-old female with a recurrent dislocation) Yes I think initially at the hospital when I was told not, I was told to elevate it but not to immobilise it where I'm not doing anything. And I think

here at physio because I was wearing my splint for the first two three weeks all the time and he was encouraging me not to rely on it too much and to have periods of the day without it on, that helped build my confidence up a bit because I think I would have kept thinking, if I don't have it on its going to 'go' (dislocate), so that was helpful.

Category: looking to the future

There was a wide variation in recovery with some participants feeling they had recovered fully, regaining pre-injury knee symptoms and function, which included returning to high-energy hobbies like dance and sport.

P3 (16 year-old male with a first-time dislocation) Because I can do everything that – I don't know how to word this. I can do everything now that I could do before I dislocated my knee.

For others confidence had improved from the initial knee injury but there remained a wariness that the patella could dislocate again. This was driven by the sudden and unexpected nature of the original injury during activities perceived as normally safe and routine, resulting in a lack of trust in the knee. Wariness manifested itself in being careful by modifying or avoiding activities to reduce reinjury risk. Activities avoided or modified ranged from multidirectional sports to more routine daily activities. In contrast, physical symptoms, like knee stiffness or pain, were not a predominant feature during later recovery and were rarely a driver of activity modification.

P7 (36 year-old female with a recurrent dislocation) It's hard because you want to be able to do things normal like twist about and everything but I'm trying to think. I'm always careful when I get out of the bath, like out of the shower because I always get out and stand on this knee and so I'm always making sure my balance is okay. I'm trying to think of different activities, I know it's random, but just not even getting drunk and dancing, stuff like that.

Wariness was also influenced by a desire to avoid reliving the injury and recovery experience which was seen as unpleasant and inconvenient.

P1 (19 year-old female with a first-time dislocation) I had such a bad experience with my knee, I'm just so worried it's going to happen again and I never want it to happen again. It was just absolutely painful, and I never want it to happen, so it's just like, and also all the stress and worry I put my family through, I don't want to do that again.

Wariness was addressed by adopting a biomedical view of the knee. Being vigilant by keeping physically fit, maintaining a healthy weight, and strengthening the muscles surrounding the knee

were viewed as important to reduce re-injury risk. Participants drew on increased physical fitness, in particular leg muscle strength, as a source of confidence that they were ready to perform more challenging activities.

P1 (19 year-old female with a first-time dislocation) I think I will be a bit sceptical about going straight back into the gym and doing all I used to do. But I've got to think like, it's all about strengthening those muscles and think about it biologically, like this is helping me really even though I'm worried and a bit scared. It's actually helping me and so I've just got to push myself.

Participants who had experienced multiple patellar dislocations felt their injury would likely recur in future. Despite this, some felt their rehabilitation experience had provided them with the tools to reduce their reinjury risk and manage any recurrent dislocations, if they occurred. For others, uncertainty over whether a recurrent dislocation would occur made significant life choices, such as whether to start education courses, challenging. There was additional uncertainty over whether surgery, a potential future option for some, would be required. Participants weighed up the potential of surgery to reduce instability episodes with doubts about whether it would work and the inconvenience of prolonged rehabilitation.

P6 (36 year-old female with a recurrent dislocation) So, I kind of feel if I do go down the surgery route, will it actually work, will it stop it from slipping, will it be worth it. Because obviously they explained I will be in a lot of pain after the surgery and a lot of rehabilitation afterwards and kind of like, is that going to be worth it?

Of note, two participants, who had dislocated their patellar for the first time, had regained their pre-injury symptoms and function and had no concerns about their knee going forward.

Theme 3: acceptability of the interventions to participants

Category: supervised and self-managed rehabilitation

Participants took part in the pilot RCT for altruistic reasons and out of curiosity about what participating in a research study would be like. The decision to participate was aided by the perception that the study was low risk because both interventions involved the standard of care treatment i.e., physiotherapy, indicating the interventions were prospectively acceptable. Any treatment preference before randomisation was usually for self-managed rehabilitation because this

did not require attendance at follow-up sessions which were initially perceived as burdensome due to difficulties driving in the acute injury period, the need to arrange childcare, and the need to schedule appointments around school commitments.

P6 (36 year-old female with a recurrent dislocation) It was more just for the travel because you see I was struggling to drive. I have anxiety anyway so getting the bus through to the hospital on my own would have been a no go anyway, emm, and it was around the time of them dates, getting the bus with two little ones in tow just didn't appeal at all.

Participants valued physiotherapists' guidance on what activities they could resume and when they could remove knee splints, feeling this accelerated their recovery and increased confidence in the physical resilience of their knee.

Those allocated to supervised rehabilitation valued physiotherapists' expertise in prescribing exercises that were sufficiently challenging and tailored to their functional goals. Follow-up sessions also motivated participants to adhere to prescribed exercises. The physiotherapist's prescription of new more challenging exercises at review sessions re-enforced a sense of progression and that exercise adherence was helping their recovery. Knowing physical performance would be re-assessed and the perception that this would reveal whether participants had been performing prescribed exercises also aided exercise adherence.

P7 (36 year-old female with a recurrent dislocation) He puts this thing on my leg and you push against it to check the strength and so he's done that each time, so that helps monitor how I'm building the strength up. Then he gets me to do the exercises that were set to see how I'm getting on with them and so I think if I hadn't been doing many of them it would be obvious.

Participants allocated to self-management found this intervention was acceptable. Despite this, they expressed concerns that it may not be appropriate for everyone and that some people may require more support.

Category: intervention workbooks

In the pilot RCT, participants were given their intervention workbook upon randomisation and encouraged to implement the advice and initial exercises before their first physiotherapy session. An online version with exercise videos was also available for participants who wanted to use it.

Though some participants initially perceived their paper intervention workbook to be quite large, later they felt this was appropriate as the workbook contained all the necessary information to guide their recovery. Although recall of the workbook content was often poor, participants remembered valuing the easy-to-follow layout and the clear and structured guidance on what to do and when.

P5 (16 year-old male with a first-time dislocation) I thought it was quite big at first but then after you read it, I thought right, it's probably big because that's all the information that you need. Whereas like when you have first dislocated your knee do these, and then further along do these, and then further along do these. So, it was like instead of having one booklet for them, another booklet for the second part and another booklet like that, you put it all in one booklet and it's probably better.

Though there was variation, participants mainly used the paper workbooks because accessing the online version when a paper workbook was already provided was seen as unnecessary or inconvenient. The exception was exercise videos, which were valued by those that used them as a resource for either initially learning or refreshing their exercise technique. However, once participants felt they could perform exercises correctly, the paper exercise sheets were then used for time efficiency.

While most participants read the workbook before this physiotherapy session, initial exercises were rarely performed. This was driven by feelings that this was unsafe, the knee was not ready, or that the physiotherapist's expertise was necessary to decide what exercises were appropriate. Instead, participants' physical activity in this early stage focussed on improving their mobility which was seen as a natural progression during recovery and influenced by a desire to regain functional independence as previously discussed.

P1(19 year-old female with a first-time dislocation) I had a look through the exercises and to be honest I thought I could never do those, never. But yes, I did have a look through and [physio's name] elaborated on it all and he was like no you can do it and it made more sense of it.

CF Did you start any of the exercises before you saw [physiotherapist's name]?

P1 I think I was too scared to. I think the main thing at the beginning was walking and so that kind of just happened over time. He was quite surprised that I was up and walking somewhat, maybe not in the proper way.

Theme 4: acceptability of the follow-up methods

Completing follow-up questionnaires was seen as straightforward and offered a chance for reflection on progress made and aspects of recovery that still required attention. The outcomes, which focussed on the ability to return to normal activities, were generally seen to measure aspects of recovery important to patients.

Category: a straightforward process

Completing follow-up questionnaires was seen as a relatively simple and straightforward process. that was facilitated by receiving the questionnaires electronically which made accessing and completing them convenient. Automated email or text message reminders were helpful as it was easy to forget to complete questionnaires. Study questionnaires were also deemed comprehensible and required little time to complete.

P2 (17 year-old female with a recurrent dislocation) Yes it was pretty easy because you emailed it over and then I went on it and then I was answering all the questions and then by the time I thought, what time was it? I was like nearly finished.

There was one exception. One participant found completing the questionnaires a frustrating experience, citing a lack of introductory information about what the process involved, how many questionnaire sections there were, and the inconsistent formatting between sections. Although the participant completed the questionnaires out of a sense of obligation, they felt these issues could explain why retention can be poor. However, they also noted these issues are easily solvable, offering opportunities for refinement for a full-scale RCT.

P9 (50 year-old male with a recurrent dislocation) Well to be honest I can see how people would just give up, I can see that, but if they know from the outset here's what we're going to ask, here are the things you're going to go through, this is how long it will approximately take for an average person, rather than, thank you you've completed this section, by the way we've got a new section, and by the way we've got a new section. I think I had to go through three different sections to complete it.

Category: outcome assessed

Generally, participants felt that the questionnaires assessed outcomes that were important to them. In particular, participants valued that the questionnaires measured their ability to perform routine day-to-day and pre-injury activities which were seen as the most important outcomes to assess.

CF Did they ask the questions that you think are important for people with your injury?

P7 (36 year-old female with a recurrent dislocation) Yes, because I think people just want to get back to doing their normal day to day life and activities and so it was focused on that really, about what you feel you're able to do and what you're not able to do still.

However, there was variation. One participant felt that the study questionnaires were formulaic and the measurement of routine day-to-day activities inadequately captured the intervention's effect on them as an individual. There was a desire for a more individualised measurement method while acknowledging the challenges of implementing this in the context of research.

P8 (33 year-old female with a recurrent dislocation) It measures, I guess it measures very blanket day to day functional stuff, so the walking, the bending, the squatting, the this, that and the other. I guess what it doesn't ask is for me as an individual how it's helped. I don't think there was any free text boxes, and I can appreciate that that's difficult to measure from a research perspective. I guess if there was a way of capturing those important things on the initial questionnaire and then the last one being able to refer back to them, and go well you said this at the beginning, has that improved? I guess that would just help me as a patient to feel that it's remaining patient centred, if that makes sense, as opposed to it being a blanket questionnaire.

Category: an opportunity for reflection on recovery

For some participants, completing the pilot RCT follow-questionnaires was seen as a valuable experience, allowing them to reflect on their recovery. It reminded them of the progress they had made while also drawing their attention to aspects of their recovery that were still incomplete and required attention.

P1 (19 year-old female with a first-time dislocation) I thought, oh, alright I don't mind doing that, it won't take long. I've done questionnaires all my life, so it didn't phase me at all. I thought I might as well see what's changed because you don't realise until you have something in front of you to see how far you've come. So, I think that was really good in that sense because some people may not realise how far they've actually come. Then that kind of like reminds you, or it reminds you of the stuff that you need to work on and stuff like that.

For one participant, completing the questionnaires helped situate the impact of their injury on their broader life. It enabled them to see that the injury's impact had been minimal and reminded them that they had made a good recovery.

P8 (33 year-old female with a recurrent dislocation) I can't remember what I said previously and so that would be hard for me to say. I think what the questionnaire did allow me to see is that actually my knee dislocating hasn't really impacted on me. So, from that questionnaire, it wasn't like there loads of bits that jumped out and I was thinking, oh my god, I'm not able to do that or I find that really difficult. So, it did allow me that kind of reflection space I think to think about that.

6.4 Discussion

The experience of recovering from an acute patellar dislocation involved 'coming to terms with the initial injury' which involved initial pain and distress when the patella dislocated and shock that the injury happened so easily and without warning. Impaired mobility disrupted everyday life by affecting the ability to perform basic daily activities and impacting, to varying degrees, education, work, and family life. The desire to 'regain my former self' provided the impetus for recovery. Participants progressively tested their knee by increasing physical activity levels, resuming normal activities, and performing rehabilitation exercises which were vital to build confidence. Participants looked to the future with varying degrees of caution and optimism. For most being vigilant by keeping physically fit and maintaining strength of the muscles surrounding the knee was viewed as important to reduce re-injury risk. The potential relevance to future work of findings about the impact of impaired mobility on everyday life, fear of re-injury, and acceptability of the follow-up questionnaire and methods are discussed below.

Advice received in fracture clinic to move the knee and gradually increase physical activity levels provided reassurance and enabled a quicker functional restoration. Early recovery was also aided by flexible soft knee splints which provided security while allowing a functional range of knee movement. As seen in the previous chapter, restrictive knee bracing is commonly used, despite calls to use minimal or no immobilisation after an acute dislocation.[23] Internationally, recent work could not establish consensus over the type or duration of immobilisation[28] and survey data shows international practice varies but is typically restrictive e.g., 39% (172/438) of surveyed surgeons

recommended against knee movement for the first 15 days after a first-time dislocation.[214] This is a potential area of future investigation as there are limited high-quality trials.[116] Whether braces should be given for soft-tissue knee injuries is also a top 10 priority in the James Lind Alliance Priority Setting Partnership for first-time soft-tissue knee injuries.[49] In the absence of evidence supporting their effectiveness, using restrictive immobilisation after an acute patellar dislocation is questionable given its negative impact on patients' function.

The importance of early functional restoration to patients could help optimise intervention materials. Participants rarely started the basic initial exercises in intervention workbooks before the first physiotherapy session. Reasons included not feeling ready, being uncertain if this was safe, and wanting to wait to hear the physiotherapist's advice. Potentially it would be more helpful to provide advice and exercises upon randomisation that focussed more on restoring normal walking, functional knee movement, and basic daily activities. The remaining intervention materials would then be provided at the initial physiotherapy session, which could also incentivise participants to attend this session.

In the longer-term, there was a wide variety in recovery amongst participants. However, amongst those who had not returned to their normal activities this was driven mainly by a fear of re-injury rather than physical symptoms. This fear is not unreasonable. As discussed in chapter 1 (section 1.1.3), the 10-year risk of recurrence after a first-time patellar dislocation is 23%,[21] but risk factors such as younger age,[21] previous patellar dislocation,[17] and specific anatomical factors can increase this risk substantially.[18] While some increased psychological support may be needed to address excessive fears, it seems reasonable to also counsel patients honestly about their risk of recurrent dislocation and how they could mitigate this risk e.g., through long-term rehabilitation and potentially avoiding high-risk activities like multidirectional sports. This could better equip patients to manage their knee in the longer-term. Some of this information was included in intervention materials, but more comprehensive guidance may be beneficial.

Broadly, completing follow-up questionnaires was seen as straight forward and the outcomes measured were deemed important. The early impact of impaired mobility and the longer-term

challenges in returning to pre-injury activities, suggest that the KOOS is an appropriate primary outcome for a future full-scale RCT. The KOOS measures higher and lower level physical function as well as knee-related quality of life which includes questions about knee confidence and lifestyle modifications due to fear of reinjury.[164] Potentially, a specific PROM to assess fear of re-injury could also be used, given this was the primary reason participants did not return to all activities. However, this would require the availability of a suitable PROM with established measurement properties which is not evident in the literature. The potential negative impact of additional questionnaires on retention would also need to be considered.

The finding that follow-up methods were acceptable (notwithstanding suggestions on how to improve the user experience) suggests that strategies to improve retention in future should not prioritise altering the number and type of questionnaires used in the pilot RCT or their administration method. However, no participant who was lost to follow-up was interviewed, so the views of these participants is not represented. Consequently, this finding should be interpreted cautiously. Potential strategies to improve retention are discussed in the next chapter.

6.4.1 Limitations

Interviews were undertaken with nine participants with a range of characteristics. The findings highlight the physical and emotional impact of a patellar dislocation and how participants make sense of how they get better and look to the future. Further interviews could have provided an increased degree of confidence that the themes were saturated. Longitudinal interviews at a range of timepoints during recovery may add additional insights into the experience of their adaptation over time. There were additional limitations related to the sample composition and mode of interviews which are discussed below.

Only 25% of people invited agreed to be interviewed, which is lower than similar qualitative studies embedded within feasibility RCTs.[215,216] This may simply reflect that younger patients are more challenging to engage. Nevertheless, there are lessons from this study that could improve recruitment of these patients in future qualitative studies. For example, simply following up initial

email interview invites with a phone call instead of another email appeared to improve recruitment. Asking physiotherapists to broach the topic of interviews with participants was also helpful, supporting the view that an established rapport aids qualitative research recruitment.[217] In future, approaching participants sooner after injury when they are more likely to be engaged could also help, though the relevance of the data collection timing to the research question would have to be considered. There is also experimental evidence that a monetary incentive increases people's willingness to participate in interviews.[218] This could raise ethical concerns about coercion, and financial inducements in research involving children is not recommended.[153] Potentially, a minor financial reimbursement is a reasonable compromise, but future PPIE input on this would be valuable.

An additional limitation was the sample composition. I planned to interview patients aged <16 years and those who were lost to follow up or declined to participate in the pilot RCT, but no interviews with these patients were conducted. Only six participants <16 years were recruited to the pilot RCT, so in hindsight, purposive sampling on this characteristic may have been ambitious. Sampling participants lost to follow-up and those who declined to participate in the RCT is also challenging[219] because these participants are less engaged with the research. Yet, amongst participants there was variation in treatment allocation as intended, as well as potentially other important characteristics such as gender, first-time and recurrent dislocation, and participating site. This helped provide a breadth of experience which is recommended when assessing the feasibility of a full-scale RCT.[186]

Remote interviews, in particular those by phone, can be seen as inferior to face-to-face interviews because they cannot capture some potentially important contextual information, such as non-verbal reactions.[220] While the richness of the data generated did seem to be affected by phone interviews in this study, this was relatively minor, and no difference in the quality of data generated between video and face-to-face interviews was apparent. Remote interviews also enabled interviews with participants from across the country and without this option it is likely several interviews would not have happened. An unexpected benefit was that remote interviews were conducted in a

‘neutral’ location which appeared to encourage participants to talk more freely about their experience of physiotherapy than participants interviewed face-to-face at the physiotherapy department of a study site.

6.4.2 Conclusion

This embedded qualitative study contributes to our understanding of patients’ experience of recovery on their everyday lives, though further qualitative work is needed to explore this fully. The generally high intervention and follow-up method acceptability confirm that the full-scale RCT evaluating rehabilitation is feasible. The findings also helped explained some of the pilot RCT findings and will guide refinements for the full-scale evaluation.

Chapter 7 Final discussion

7.1 Introduction

The aim of this thesis was to determine the feasibility of a full-scale RCT evaluating rehabilitation for people after acute patellar dislocation by conducting a series of work packages. In this chapter, I summarise the main findings of each work package. This is followed by a discussion of the scientific contribution of this thesis, its strengths and limitations, and a brief reflection on the value of feasibility studies more broadly. I conclude this chapter by outlining my plans for future work which includes the potential design of the full-scale RCT.

7.2 Summary of findings

Chapter 2: Following current NIHR and MRC guidance on developing and evaluating complex interventions,[58] this chapter described how the interventions for the PRePPeD pilot trial were developed and how they were delivered. The intervention development process was rigorous and drew on several established intervention development approaches and frameworks. Development phases included reviewing the existing evidence, clinical guidelines, NHS practice, and relevant scientific theory. Initial intervention iterations were then created and discussed with relevant stakeholders. The interventions were then finalised considering their feedback, my preliminary study's findings, and what would be acceptable to patients and clinicians and deliverable in the NHS.

Chapter 3: To inform outcome selection for the full-scale RCT and the development of a COS, a systematic review of outcomes reported in patellar dislocation trials was conducted. Sixty-nine RCTs were included. These reported using 141 unique outcomes, 42 different PROMs, and variable outcome measurement timepoints. Primary outcome measures and timepoints were also inconsistent or not reported. Furthermore, although the most commonly reported outcome was a new ipsilateral patellar dislocation, how this was defined and measured was variable or unreported.

Chapter 4: This chapter described the design of an external pilot RCT and embedded qualitative study to assess the feasibility of conducting a full-scale RCT evaluating rehabilitation for people with an acute patellar dislocation. This chapter demonstrated my understanding of the methodological and logistical issues with designing and conducting an external pilot RCT and embedded qualitative study in the NHS.

Chapter 5: This described the results of the pilot RCT which was conducted in five English NHS hospitals. Fifty participants were recruited and randomly allocated 1: 1 to supervised or self-managed rehabilitation. The proportion of eligible patients approached who were willing to be randomised and the number of patients recruited per site per month met pre-specified criteria for progression to the full-scale trial. Results for the other quantitative feasibility outcomes, retention and intervention adherence, indicated refinements are needed to improve the proportion of participants that complete the primary outcome and that attend the intended number of intervention sessions. Overall, there was high physiotherapist-reported fidelity to the interventions indicating these can be delivered in the NHS.

Chapter 6: The embedded qualitative study explored patients' experience of recovery after an acute patellar dislocation, and the acceptability of the pilot RCT interventions and follow-up methods to participants. Semi-structured interviews were conducted with nine pilot RCT participants. The experience of recovery was conveyed through the themes 1) 'coming to terms with the initial injury' which involved a physical and emotional response to the initial injury, and 2) 'regaining my former self' which involved a desire to get better, and considering the impact of the injury on life going forward. Findings also indicated that the pilot RCT interventions and follow-up methods were seen as acceptable, though there was some variation.

Overall, the main finding of this thesis is that a full-scale RCT is feasible with modifications. These modifications should prioritise improving retention and participant attendance at the intended number of physiotherapy sessions. Possible modifications for the full-scale RCT are discussed later.

7.3 What this thesis adds

Intervention development and description

To my knowledge, Chapter 2 is the first description of the development and delivery of rehabilitation interventions for people with an acute patellar dislocation that have been tested in a research study. This transparent reporting will enable readers to clearly understand what was done and why, enhancing critical appraisal and interpretation of the pilot RCT results. This clear reporting could also help researchers designing other rehabilitation interventions, and facilitate future work to identify which intervention development approaches lead to effective interventions which is currently unknown.[58]

Systematic review

As far as I am aware, the systematic review is the first to synthesise what outcomes, outcome measurement instruments, and outcome measurement timepoints have been used in trials evaluating treatments for people with a patellar dislocation. The findings illustrate how current practices in outcome selection and reporting limit the comparison and synthesis of results from different trials in this area. The high variability in what is measured, when, and how underlines the need for a COS to reduce outcome heterogeneity. This systematic review represents the first step in the COS development process which is underway and I am a member of the project steering group.

The extent of outcome variability found means that the findings are unlikely to influence outcome selection for the full-scale trial (see next section) as intended. However, by synthesising what outcomes have been reported and highlighting important deficiencies in this area, this systematic review may be a useful resource for other researchers to consult when designing future trials until a COS is developed. However, the outcomes used were variable and likely represent those considered most important by researchers which may differ from other stakeholders.[53] So, outcome selection should be informed by relevant stakeholders' opinions and other considerations, such as guidance on outcome measurement instrument selection.[141]

Pilot RCT and embedded qualitative study

To date, the pilot is the joint second largest RCT of exercise-based rehabilitation for people with a patellar dislocation. It showed that a full-scale RCT evaluating rehabilitation is feasible, but similar to the only UK study of exercise-based rehabilitation,[41] found that retaining this patient population is challenging.[41] This highlights the need to identify strategies to improve retention for the full-scale trial and other future trials in this area.

The embedded qualitative study is the first conducted in people with an acute patellar dislocation, so contributes to our understanding of the experience of recovery after this injury. The impact of impaired mobility on everyday life highlights that initial management strategies that impair mobility, such as knee splints that restrict movement, are not without consequence for patients so should be supported by high-quality evidence. The finding that longer-term return to physical activity is largely hindered by fear of re-injury rather than physical symptoms is also new. This highlights how patellar dislocations, which can recur unexpectedly during daily activities, differ from other injuries like fractures. This suggests that future interventions need to strike a balance in addressing excessive fears which impede recovery while also counselling patients that returning to certain activities comes with a high-risk of re-injury.

7.4 Strengths and limitations

This strength and limitations of specific work packages have been discussed in their corresponding chapters, so this section relates to the overall strengths and limitations of this thesis.

Strengths

To try and ensure the research in this thesis was patient-centred, patients and members of the public were involved in all work packages with the exception of the systematic review. To ensure a clinically representative sample were invited to take part in the pilot RCT and qualitative study, patients aged <16 years were eligible, despite the additional work and logistical challenges this entailed. Following best practice, the systematic review and pilot RCT and embedded qualitative

study were prospectively registered and the protocols for these studies deposited on publicly accessible websites. Reporting of chapters also followed relevant reporting guidelines.

Limitations

The systematic review of outcomes was not completed before the pilot RCT, so the findings could not inform the selection of outcomes for that study. The review's central finding that a COS is required, yet this may not be developed in time for the full-scale RCT funding application, means that the systematic review may not inform outcome selection for the full-scale RCT as intended. In the pilot RCT, outcomes were selected based on PPIE consultations, the measurement properties of available instruments, and what was deemed feasible to collect. This and other planned work (see section 7.6.2) may have been sufficient to decide what outcomes to measure in the full-scale RCT. Nevertheless, the systematic review still makes an important scientific contribution to the patellar dislocation literature which has been discussed in the previous section.

Given that retention was the main uncertainty of a full-scale trial, greater efforts to optimise retention in the pilot RCT would have been valuable. This could have involved greater PPIE consultation, examining existing literature on participants' reasons for non-retention[219] to inform strategies to mitigate these, and using resources from the Trial Forge initiative from the outset.

While the embedded qualitative study has contributed to our understanding of patients experience of recovery from this injury, no young person agreed to be interviewed. Interviews with young people would have been valuable to inform judgements about whether patients aged <16 years should be included in a full-scale RCT.

Although PPIE was embedded throughout most of the thesis work packages, not all PPIE partners had experienced a patellar dislocation and some may not have been representative of people with this condition. In future, recording the characteristics of PPIE members and developing a broader PPIE group would be helpful. Inviting pilot RCT participants to become PPIE partners when sending them a summary of the study results is a potential strategy to develop a more representative PPIE group.

7.5 A reflection on feasibility studies

The pilot RCT and embedded qualitative study assessed the feasibility of the full-scale trial and these were the central work packages within this thesis. Designing and conducting a feasibility study can require significant time and resources.[221] If conducted unnecessarily, a feasibility study delays the full-scale RCT, which wastes resources and could adversely affect patient care.[221] All feasibility studies are also inherently limited, at least to some degree, by the uncertainty that remains around the parameters assessed due to the limitations of sample size and composition.

However, NIHR-funded feasibility studies have been shown to be cost saving by identifying studies that would have failed if taken straight to a full-scale trial.[221] They can also add value by refining the interventions and full-scale evaluation design.[57] Leading these studies is also a beneficial training experience for early career researchers, as was the case in this thesis, and the value of this should not be ignored. In this thesis, the feasibility work conducted proved justifiable. It identified important areas that need refinement ahead of the full-scale if this is to be conducted successfully.

7.6 Future work

Based on the findings of this thesis, a full-scale trial evaluating rehabilitation is feasible but future work to optimise the design and delivery of this full-scale RCT is required. Plans for that future work are in place and are discussed in section 7.6.2. The current potential design of the full-scale RCT is outlined below.

7.6.1 The full-scale RCT

Design

A pragmatic, multicentre, parallel, two-group, superiority RCT with 1: 1 allocation. An internal pilot to monitor participant completion of the primary outcome measure at early follow-up timepoints would probably be required based on the retention rates observed in the pilot RCT.

Population

The rationale for including people with a recurrent dislocation in the PRePPeD pilot RCT was provided in Chapter 1. In the pilot, these represented 42% of participants. This demonstrates that a significant proportion of patients with an acute patellar dislocation attending NHS secondary care hospitals have a recurrent dislocation. Qualitative findings also showed that some participants with a recurrent dislocation felt rehabilitation equipped them to self-manage their condition, though a small number of these participants were interviewed, limiting confidence in this finding. Nevertheless, taken together, these findings support the inclusion of people with a first-time and recurrent dislocation in a full-scale RCT. Outside the UK, surgical stabilisation is more routinely recommended for patients with a recurrent dislocation.[28,31] So, including these patients may affect uptake of the results internationally and should be considered when finalising the full-scale RCT's design.

A potential modification for the future trial would be to exclude patients aged <16 years. Only a third of eligible patients <16 years agreed to participate in the pilot RCT compared to roughly two thirds of eligible adults. Participants aged <16 years also represented just 10% of the pilot RCT study sample. Including a mixed sample of adults and young people within the same RCT creates significant logistical issues and extra work. As discussed in section 5.4, this may not be worthwhile. The full-scale trial's results might not be generalisable to young people if most do not take part and these patients represent only a small proportion of the total study sample.

While excluding specific subgroups of patients is justifiable if it is necessary to make the study deliverable, this must be carefully balanced against the need to recruit a study sample that is representative of the patient population. A representative study sample makes results more generalisable, increases uptake of results in clinical practice, and facilitates later meta-analyses investigating treatment effects in specific subgroups of patients.[222] As outlined in chapter 5 (section 5.4), I will collect ethnicity and index of multiple deprivation data of patients who decline participation in the full-scale trial to enable better judgements about whether the study sample is representative. In preparation for the full-scale trial funding application, I will also use the NIHR-

INCLUDE guidance during a stakeholder meeting (see section 7.6.2) to review if aspects of the pilot RCT design can be refined to improve the inclusion of under-served groups.[223]

Interventions

The key decision is whether self-managed rehabilitation should continue to involve one session with a physiotherapist or whether participants could be discharged with self-management materials from outpatient knee/fracture clinics. The justification for including a self-managed rehabilitation group was that referral to physiotherapy is routine for this injury, mainly based on clinical consultations as data is lacking. However, in the pilot RCT, roughly 40% of participants with a previous dislocation reported they did not receive physiotherapy for any of these previous injuries, indicating referral to physiotherapy may not be routine. Removing the physiotherapy session would also make interpretation of the full-scale RCT's result easier as there would be a clearer distinction between supervised and self-managed rehabilitation. Yet, 23/26 participants allocated to self-managed rehabilitation attended their physiotherapy session indicating participants thought it would be worthwhile. Qualitative findings also revealed participants valued physiotherapists' advice on when to remove their knee splint, and what activities and exercises they could begin. Therefore, unless future work indicates otherwise, retaining the supervised and self-managed interventions in the full-scale RCT appears prudent.

An area for refinement is increasing the proportion of participants that attend the minimum number of intervention sessions. This will ensure there is a clear difference in the number of physiotherapy sessions provided to treatment groups. Initial physiotherapy sessions normally occurred within two weeks of randomisation, so the relatively high proportion of participants who did not attend any physiotherapy session suggests that some participants may not have understood what study participation involved. In future, making this information more prominent in the PIS and ensuring researchers' establish patient understanding during the initial consent discussion could be helpful. In addition, providing more basic interventions materials upon randomisation with the remaining intervention materials provided by physiotherapists at the initial physiotherapy session could incentivise participants to attend this initial session. The basic intervention materials could focus

on functional restoration as this was seen as a priority at this stage of recovery by participants in the qualitative study. Input from PPIE members is likely to be helpful and funding has been secured to conduct this work in future (see section 7.6.2).

Based on qualitative findings, continuing with an online intervention workbook appears unnecessary. Instead, using paper intervention materials with a QR code or URL to access exercise videos appear sufficient.

Finally, the name of the interventions may need to be reconsidered. Ideally, intervention names should reflect the intervention's key distinguishing feature and be easily understandable by lay people. Inaccurate intervention names could lead to misinterpretation of the full-scale trial results. Arguably, 'self-managed rehabilitation' does not convey that participants allocated to this intervention receive a single physiotherapy session with additional support if required. Therefore, renaming this intervention 'supported self-management' may be necessary to clarify that participants allocated to this treatment do not manage their injury completely independently.

Outcomes

A COS may not be developed before the funding application for the full-scale RCT is submitted. In that scenario, the qualitative findings that the pilot RCT outcomes measured domains generally seen as important by participants supports the use of these outcomes in the full-scale trial. PROMs would include the KOOS4 as the primary outcome, individual KOOS subscales, and the EQ-5D-5L. Collecting patient complications and health resource use questionnaires would also be necessary for the analysis of safety and cost-effectiveness, respectively. The return to main pre-injury sport/physical activity questionnaire from the pilot should not be used due to the ceiling effects that were observed. Consultation with PPIE partners to determine if a separate questionnaire to assess physical activity restoration is required, or whether the KOOS subscale 'function in sports and recreational activities' is sufficient, would be valuable. PPIE input on the definition of a new patellar dislocation would also help ensure all important recurrence events are captured. In the qualitative study, some participants felt their intervention increased their

confidence to self-manage a recurrent dislocation should it occur. This is a potentially important finding. Stakeholder feedback on whether this should also be measured in future would be helpful. Plans for this stakeholder consultation work are in place and are discussed in the next section.

A pre-specified subgroup analysis of the primary outcome in participants with a first-time and recurrent dislocation should also be considered if both these patient groups are included. Although controversial, pre-specified sub-group analyses are justifiable in specific instances.[224] For example, if there is anticipated heterogeneity in the treatment effect between subgroups or in the application of the investigated treatments to these subgroups.[224] Both of these scenarios are plausible for the proposed interventions in people with a first-time and recurrent dislocation. This analysis would be underpowered, but would facilitate future meta-analyses investigating the effectiveness of rehabilitation treatments for these specific patient populations. The UK FASHIoN trial, which investigated treatment for femoroacetabular impingement, is an example of a NIHR-funded trial that used pre-specified subgroup analyses based on participant characteristics.[225] Longer-term collection of hard outcomes that typically occur later, such as subsequent surgery, via routinely collected data sources could also be considered.

The outcome measurement timepoints of three, six, and nine months after randomisation should be retained, with nine months remaining the primary outcome measurement timepoint for the reasons outlined in section 5.4.

Health economic evaluation

The health economic evaluation would likely be a cost-utility analysis. This is a type of health economic evaluation, recommended by NICE,[226] that compares the costs and generic health outcomes (normally quality-adjusted life years) between treatments.[227] Results are reported in standardised units allowing policy-makers to compare the cost-effectiveness of treatments for different healthcare conditions e.g., the cost-effectiveness of a patellar dislocation intervention to a low back pain intervention.[227] The analysis would involve calculating an incremental cost-effectiveness ratio i.e., the difference in costs between two treatments divided by the difference in

treatment effectiveness which would be measured in quality-adjusted life years calculated from the EQ-5D-5L.[228] Based on the health economic evaluation in a similarly designed trial from our group,[175] the analysis would use a within-trial time horizon (i.e., the time over which costs and quality-adjusted life years are collected would be the trial follow-up period), and be from a NHS and personal social services perspective as recommended by NICE.[226] However, for the full-scale trial, the design and conduct of the health economic evaluation would be performed by a health economist and be dependent on the research resources available.

Strategies to improve retention

Improving retention is the main area of refinement for the full-scale trial. Low retention introduces bias, reduces the usability of results, and wastes research resources.[211] Despite the negative consequences of retention and the considerable resources invested in clinical trials, the 2021 Cochrane review found no high-certainty evidence that any strategy improves trial retention.[211] Nevertheless, recent qualitative work on participants' reasons for dropping out[219] and the barriers and enablers to retention[210] offer potential solutions. Examples of strategies to improve retention that could be used in the full-scale trial include:

- Clarifying in the PIS what study participation involves and checking participants understand this during the initial consent discussion. While trial participants know some form of follow-up is part of participation, often they cannot recall the number or frequency of questionnaires they need to complete.[210] Questionnaires may then be seen as unexpected and repetitive, negatively affecting retention.[210]
- Emphasising throughout the trial that completing questionnaires contributes to the trial's success and knowledge about the most effective treatment for the investigated healthcare condition.[210] Clearly highlighting the value of retention for the duration of the trial could also prevent participants dropping out if they feel they have recovered or other life events take priority, which can be an issue.[219] To improve retention during the pilot RCT, this information was included in a newsletter sent to participants and in the revised wording of questionnaire invitations and reminders. These appeared to

improve questionnaire completion and should be used in future. Information about the importance of retention should also be made more prominent in the PIS e.g., in the form of an infographic at the start.

- Optimising questionnaire design and formatting to improve the user's experience can facilitate questionnaire completion.[210] Suggested refinements were obtained from one qualitative interview participant (see section 6.3.2) which should be implementable.
- Paying participants at the primary outcome measurement timepoint. The Cochrane review found some evidence that a monetary incentive (unconditional) may improve retention compared to no incentive. [211] A UK-based feasibility RCT of surgical versus non-surgical treatment for people with recurrent instability gave participants an unconditional £20 voucher at 12-month follow-up and had 95% retention.[34] This indicates a monetary incentive could improve follow-up in these patients, though the sample size was small (n = 19).

These strategies, in addition to the support of a full trial team, could improve retention in the full-scale trial.

Sample size

Developers of the KOOS suggest the minimal important difference is 8-10 points.[166] Although the minimal important difference for the KOOS4 has not been formally determined in a patellar dislocation population, a target difference of eight points was used to inform the sample size calculation in the NIHR Health Technology Assessment-funded REPPORT trial.[33] Given that trial is comparing surgical versus non-surgical treatment for people with a recurrent dislocation, a target difference of at least as small seems reasonable in a trial of rehabilitation interventions where the associated risks and costs are presumably smaller.

Using the aforementioned RCT design, a target difference of eight points on the KOOS4, and a two-sided 5% significance level, the sample size for the full-scale trial under various assumptions is presented in Table 7.1. These sample sizes have been increased to allow for 20% loss to follow-

up, the minimum likely to be accepted by a funder. A standard deviation of 21 was observed at nine months in the pilot RCT (see section 5.3.5), however this was based on data from 31 participants, so the standard deviation in a larger sample could be different. The effect of a standard deviation of 20 and 22 on the sample size is therefore shown. Conventionally, power is set at 80% or 90%.[173] A 90% power would be desirable to reduce the probability of a false-negative finding,[229] but this increases the sample size, and whether this number of participants could be recruited would need to be considered.

Table 7.1 Sample size of the full-scale RCT under various scenarios

SD	80% power		90% power	
	Per group	**Overall**	**Per group**	**Overall**
20	125	250	166	333
21	138	275	183	365
22	150	300	200	400

SD: standard deviation
Sample sizes have been rounded to whole numbers where relevant, and the sample sizes have been increased to allow for 20% loss to follow-up.

7.6.2 Other future work

Before conducting a full-scale RCT further work to optimise the design and delivery of this full-scale RCT is required. Refinements informed by consultations with the wider stakeholder community will increase the chances that the full-scale RCT is conducted successfully and the results taken up by the clinical community. Funding to conduct this additional work has been secured (see Appendix 17). This includes holding a consensus meeting with clinical and patient representatives, and working with a trial methodologist with expertise in trial retention. This will inform the application for the full-scale trial as part of a NIHR Advanced Clinical and Practitioner Academic Fellowship in 2025.

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Appendices

Appendix 1 Update of the systematic review of non-surgical treatment

Librarian reviewed search strategy from Moiz et al[35]

MEDLINE via EBSCOhost, searched on 19 April 2022	
S11	S8 NOT S9 **Limiters** - Date of Publication: 20170801-20221231
S10	S8 NOT S9
S9	MH “Animals” NOT MH “Humans"
S8	S4 AND S7
S7	S5 OR S6
S6	(MH “Orthotic Devices+” OR MH “Physical and Rehabilitation Medicine+” OR MH “Physical Therapy Modalities+” OR MH “Physical Therapy Specialty” OR MH “Immobilization+”) OR MW “Rehabilitation
S5	AB (“non-operative*” or nonoperative* or conservative* or physiotherap* or “physical therap*” or rehab* or exercis* or “manual therap*” or mobilis* or mobiliz* or massage or orthotic* or orthosis or orthoses or brace* or bracing or immobilis* or immobiliz* or “electronic stimulation” or “electrical stimulation” or “muscle stimulation” or tape* or taping or electrotherap* or “electro- therap*” or biofeedback or “bio-feedback” or cast or casts or casting or rest or resting or bandag* or “muscle strengthening” or “leg raise*” or cycling or bicycling or stretches or stretching or training or balance or sport or sports or jogging or running or crutch* or “weight bearing” or weightbearing or ice or elevat* or nonsurgical or “nonsurgical” or ultrasound)
S4	S1 OR S2 OR S3
S3	MH “Patellar Dislocation”
S2	MH “Patella” AND (MH “Joint Instability” OR MH “Joint Dislocations”)
S1	(patell* or kneecap* or “knee cap*”) N3 (dislocat* or instability or sublux* or unstable)

Embase via Ovid, searched on 12 April 2022	
1	("non-operative*" or nonoperative* or conservative* or physiotherap* or "physical therap*" or rehab* or exercis* or "manual therap*" or mobilis* or mobiliz* or massage or orthotic* or orthosis or orthoses or brace* or bracing or immobilis* or immobiliz* or "electronic stimulation" or "electrical stimulation" or "muscle stimulation" or tape* or taping or electrotherap* or "electro-therap*" or biofeedback or "bio-feedback" or cast or casts or casting or rest or resting or bandag* or "muscle strengthening" or "leg raise*" or cycling or bicycling or stretches or stretching or training or balance or sport or sports or jogging or running or crutch* or "weight bearing" or weight-bearing or ice or "nonsurgical non-surgical" or ultrasound).ti,ab.
2	exp physiotherapy/
3	exp rehabilitation/
4	rehabilitation medicine/
5	exp orthosis/
6	conservative treatment/
7	exp exercise/
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	patella/ and (dislocation/ or joint instability/ or subluxation/)
10	patella dislocation/
11	(patell* adj3 (dislocat* or instability or sublux* or unstable)).ti,ab.
12	(kneecap* adj3 (dislocat* or instability or sublux* or unstable)).ti,ab.
13	(knee cap* adj3 (dislocat* or instability or sublux* or unstable)).ti,ab.
14	9 or 10 or 11 or 12 or 13
15	8 and 14
16	limit 15 to yr="2017 -Current"

Screening and selection process

Types of study considered: Only RCTs and observational studies (except single-patient case reports) of non-surgical treatment, or studies that compared surgical versus non-surgical treatment if the non-surgical treatment contained sufficient data that could be extracted. Abstracts and studies that only evaluated immobilisation/bracing or included patients with genetic or connective tissue disorders were excluded as these were not the focus of the PRePPeD study. I also excluded my preliminary study.

Screening process: I uploaded retrieved records to Rayyan systematic review software. After deduplicating retrieved records, I first screened the titles and abstracts and then the full texts of potentially eligible studies.

Appendix 2 Search strategy for publicly available NHS patient information

Google was searched via Microsoft Edge using “!InPrivate” mode on 12 April 2022.

Search terms: (“Patella dislocation” OR “patellar dislocation” OR “patellofemoral dislocation” OR “kneecap dislocation” OR “knee cap dislocation” OR “dislocated patella” OR “dislocated kneecap” OR “dislocated knee cap” OR “dislocation of patella” OR “dislocation of kneecap” OR “dislocation of knee cap”) AND (NHS OR "national health service")

Appendix 3 Example exercise sheet

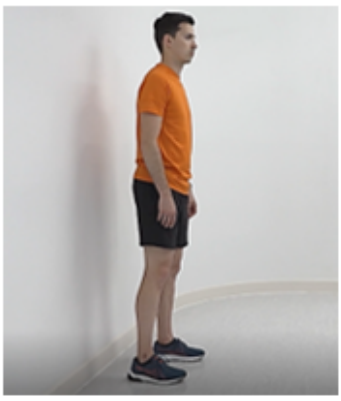
Balance exercises

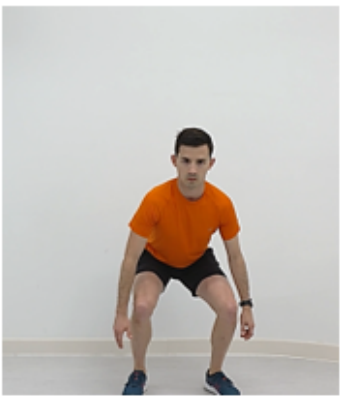
Hopping forwards and sideways on both legs: For video follow shorturl.at/jBP57 or

- Hop forwards aiming to land softly by bending at your hips and your knees and holding this position for 2-3 seconds
- Try and land on both feet at the same time and with equal weight through both legs
- When you land:

  From straight on: Your hips, knees and feet should all be in line. Your trunk should be straight and your arms down by your side

  From the side: Your knees should not come over your toes and your bum should go back as if sitting down to a chair. At the bottom of the movement, your shoulders should be positioned about halfway between your hips and knees
- Now repeat this movement hopping sideways in one direction then back again. Aim to land as described above





Repeat: .....

Do this (sets): .....

Number of times per day: .....

Number of days per week: .....

Make harder by: .....

Other tips/advice: .....

Appendix 4 PRePPeD intervention exercises

Supervised rehabilitation exercise options

Category	Exercise	
	Name	**Description**
Stretching		
Bending knee	Bending knee in sitting	Active ROM knee flexion in sitting
	Bending knee in lying	Active assisted ROM knee flexion in long sitting using hands
	Thigh muscle stretch	Quadriceps muscle stretch in standing
	Bending knee in kneeling	Lowering bum to heels in kneeling
Straightening knee	Straightening knee in lying	Static quadriceps muscle contractions
	Straightening knee in lying with foot elevated	Static quadriceps muscle contractions with foot elevated e.g., on rolled up towel
	Straightening knee in sitting	Passive ROM knee extension using hands in sitting
Balance	Putting weight through your injured leg	Weight shifting with upper limb support
	Standing on your injured leg with a hand on support	Single leg stand with contralateral upper limb support
	Standing on your injured leg without a hand on support	Single leg stand without upper limb support
	Squatting on your injured leg	Single leg squat
	Preparation for landing	Step from one leg to other landing in semi-squat position, repeat laterally and on both legs
	Hopping forwards and sideways on both legs	Double leg hop forward, repeat laterally
	Hopping forwards and sideways from one leg to the other	Single leg hop forward from one leg to other, repeat laterally and on both legs
	Hopping forwards and sideways on the same leg	Single leg hop forward onto same leg, repeat laterally and on both legs
	Hopping forwards and sideways on the same leg over cones	Single leg hop forward over a cone (or similar) onto the same leg, repeat laterally and on both legs

Category	Exercise	
	Name	**Description**
Strengthening		
Hip and knee flexion/extension pattern	Squat	Squat +/- weight
	Standing up and down working the injured leg	Squat to chair in split stance (unaffected leg in front)
	Squatting on the injured leg	Single leg squat to chair +/- weight
	Lunging backwards	Reverse lunge +/- weight
Quadriceps focussed	Straightening knee against resistance band	Resisted knee extension using resistance band
	Wall squat	Double leg wall squat
	Wall squat on one leg	Single leg wall squat
	Lunge working the back leg	Lunge biasing the quadriceps of the rear leg
Posterior chain focussed	Deadlift feet staggered	Single leg stiff leg deadlift with toes of rear leg on ground +/- weight
	Deadlift on one leg	Single leg stiff leg deadlift +/- weight
	Bridge on one leg	Single leg glute bridge
	Bridge on one leg with shoulders elevated	Single leg glute bridge with shoulders elevated (e.g., on bench/chair)
	Turning thighs out against resistance band	Resisted hip external rotation in semi-squat position using resistance band around thighs
Running	Preparing to slow down	Decelerating finishing in split stance, repeat alternating forward leg
	Slowing down	Decelerating finishing with both feet in line horizontally
	Changing direction	90º turn, repeat opposite direction

ROM: range of movement

Self-managed rehabilitation exercise options

Category	Exercise		Parameters	Progression
	Level	Description		
Stretching				
Knee bending	1:	Active ROM knee flexion in sitting	3 x 10 reps	Bend knee further using unaffected leg
	2:	Active assisted ROM knee flexion in long sitting using hands	3 x ≥30 s	Bend knee further
	3:	Quadriceps muscle stretch in standing	3 x ≥30 s	Bend knee further
	4:	Lowering bum to heels in kneeling	3 x ≥30 s	Lower bum further towards heels
Knee straightening	1:	Static quadriceps muscle contractions	3 x 10 reps	Push knee down harder
	2:	Static quadriceps muscle contractions with foot elevated e.g., on rolled up towel	3 x 10 reps	Push knee down harder
	3:	Passive ROM knee extension using hands in sitting	3 x ≥30 s	Push knee down harder and for longer
Balance	1:	Weight shifting with upper limb support	3 x 10 reps	Increase weight through affected leg, increase time up to 10 s
	2:	Single leg stand with contralateral upper limb support	3 x 10 reps	Lean on support less, increase time per rep up to 10 s
	3:	Single leg stand without upper limb support	3 x 10 reps	Increase time per rep up to 10 s
	4:	Single leg squat	3 x 10 reps	Squat lower
	5:	Single leg hop from unaffected to affected leg forward, repeat laterally	3 x 6-8 reps	Increase hop distance
Strengthening	1:	Squat to chair	3 x 10 reps, ≥1 min between sets	Increase weight through affected leg, use lower chair
	2:	Squat to chair in split stance (unaffected leg in front)	3 x 10 reps, ≥1 min between sets	Reduce weight on unaffected leg
	3:	Single leg squat to chair	3 x 10 reps, ≥1 min between sets	Use lower chair
	4:	Single leg squat to chair weighted	3 x 10 reps, ≥1 min between sets	Hold heavier weight, use lower chair

Min: minute; Reps: repetitions; ROM: range of movement

Appendix 5 PRISMA 2020 checklist for reporting systematic reviews

Reproduced from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n7, published CC BY 4.0

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	46
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	NA
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	12-13, 46
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	47
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	48-49
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	48
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	196-200
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	49-50
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	50-52
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	50-52

Section and Topic	Item #	Checklist item	Location where item is reported
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	50-52
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	52
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	53-54
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	53-54
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	53-54
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	53-54
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	53-54
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	NA
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	NA
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	NA
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	NA
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	54-55
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	211-214
Study characteristics	17	Cite each included study and present its characteristics.	56-58, 202-210
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	NA
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	NA

Section and Topic	Item #	Checklist item	Location where item is reported
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	NA
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	59-64
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	NA
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	NA
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	NA
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	NA
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	64-67
	23b	Discuss any limitations of the evidence included in the review.	66-67
	23c	Discuss any limitations of the review processes used.	66-67
	23d	Discuss implications of the results for practice, policy, and future research.	64-67, 150
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	47
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	47
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	201
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	NA
Competing interests	26	Declare any competing interests of review authors.	NA
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	NA

Appendix 6 Systematic review database and trial registry searches

Database searches

MEDLINE via OVID (1946 to present), initially searched on 13 January 2023 and updated on 31 January 2024[a]		
1	exp Patellar Dislocation/	1480
2	exp Patella/	10802
3	exp Patellofemoral Joint/	1880
4	(patell* or Kneecap* or "knee cap*" or PFJ).mp.	29901
5	2 or 3 or 4	29901
6	exp Joint Instability/ or exp Joint Dislocations/	61188
7	(Dislocat* or Instability or Unstable or Sublux*).mp.	312023
8	6 or 7	313728
9	5 and 8	6616
10	1 or 9	6616
11	randomized controlled trial.pt.	584391
12	controlled clinical trial.pt.	95157
13	randomized.ab.	589284
14	placebo.ab.	234875
15	drug therapy.fs.	2562379
16	randomly.ab.	399842
17	trial.ab.	631596
18	groups.ab.	2462258
19	11 or 12 or 13 or 14 or 15 or 16 or 17 or 18	5559910
20	exp animals/ not humans.sh.	5082250
21	19 not 20	4848020
22	10 and 21	997

[a]133 records retrieved in the updated search.

Embase via Ovid (1974 to present), initially searched on 13 January 2023 and updated on 31 January 2024[a]		
1	exp patella dislocation/	3309
2	exp patella/	10272
3	exp patellofemoral joint/	5206
4	(patell* or Kneecap* or "knee cap*" or PFJ).mp.	38911
5	2 or 3 or 4	38911
6	exp dislocation/	62677
7	exp joint instability/	18384
8	(Dislocat* or Instability or Unstable or Sublux*).mp.	400746
9	6 or 7 or 8	401064
10	5 and 9	8628
11	1 or 10	8628
12	Randomized controlled trial/	745839
13	Controlled clinical study/	467978
14	random$.ti,ab.	1878926
15	randomization/	95990
16	intermethod comparison/	291331
17	placebo.ti,ab.	352517
18	(compare or compared or comparison).ti.	584077
19	((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.	2635300
20	(open adj label).ti,ab.	103068
21	((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.	264999
22	double blind procedure/	202654
23	parallel group$1.ti,ab.	30718
24	(crossover or cross over).ti,ab.	120145
25	((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab.	397025
26	(assigned or allocated).ti,ab.	468362
27	(controlled adj7 (study or design or trial)).ti,ab.	428826
28	(volunteer or volunteers).ti,ab.	274883
29	human experiment/	610357
30	trial.ti.	379841
31	or/12-30	6040670
32	(random$ adj sampl$ adj7 ("cross section$" or questionnaire$1 or survey$ or database$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.)	9280
33	Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or control group$1.ti,ab.)	333687
34	(((case adj control$) and random$) not randomi?ed controlled).ti,ab.	20639
35	(Systematic review not (trial or study)).ti.	234525
36	(nonrandom$ not random$).ti,ab.	18352
37	Random field$.ti,ab.	2838
38	(review.ab. and review.pt.) not trial.ti.	1057733
39	we searched.ab. and (review.ti. or review.pt.)	45576

Embase via Ovid (1974 to present), initially searched on 13 January 2023 and updated on 31 January 2024[a]		
40	(databases adj4 searched).ab.	56525
41	(rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset$1).ti. and animal experiment/	1182518
42	Animal experiment/ not (human experiment/ or human/)	2482591
43	or/32-42	4139200
44	31 not 43	5341476
45	11 and 44	1709

[a]217 records retrieved in the updated search.

CENTRAL via Cochrane Library (inception to present), initially searched on 17 January 2023 and updated on 31 January 2024[a]		
#1	MeSH descriptor: [Patellar Dislocation] explode all trees	52
#2	MeSH descriptor: [Patella] explode all trees	319
#3	MeSH descriptor: [Joint Dislocations] explode all trees	790
#4	MeSH descriptor: [Joint Instability] explode all trees	838
#5	#3 OR #4	1553
#6	#2 AND #5	39
#7	#1 OR #6	81
#8	Patell* OR Kneecap* OR “knee cap*” or PFJ	3458
#9	Dislocat* OR Instability OR Unstable OR Sublux*	18710
#10	#8 AND #9	501
#11	#7 OR #10	501[b]

[a]28 records retrieved in the updated search.
[b]Only the 458 “trials” were exported, not the systematic reviews which were retrieved and included in the number of retrieved records.

CINAHL via EBSCOHost (1981 to present), initially searched on 13 January 2023 and updated on 31 January 2024[a]		
S34	S10 AND S33	496
S33	S32 NOT S31	945,862
S32	S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25	992,670
S31	S29 NOT S30	211,546
S30	MH (human)	2,632,689
S29	S26 OR S27 OR S28	245,177
S28	TI (animal model*)	3,633
S27	MH (animal studies)	150,292
S26	MH animals+	103,781
S25	AB (cluster W3 RCT)	482
S24	MH (crossover design) OR MH (comparative studies)	468,179
S23	AB (control W5 group)	141,277
S22	PT (randomized controlled trial)	148,733
S21	MH (placebos)	13,563
S20	MH (sample size) AND AB (assigned OR allocated OR control)	4,436
S19	TI (trial)	174,369
S18	AB (random*)	391,321
S17	TI (randomised OR randomized)	135,554
S16	MH cluster sample	5,181
S15	MH pretest-posttest design	51,603
S14	MH random assignment	77,324
S13	MH single-blind studies	15,871
S12	MH double-blind studies	53,814
S11	MH randomized controlled trials	135,487
S10	S1 OR S9	2,630
S9	S4 AND S8	2,630
S8	S5 OR S6 OR S7	62,452
S7	(TI dislocat* OR TI instability OR TI unstable OR TI sublux*) OR (AB dislocat* OR AB instability OR AB unstable OR AB sublux*) OR (SU dislocat* OR SU instability OR SU unstable OR SU sublux*)	62,247
S6	MH "Joint Instability+"	11,514
S5	MH "Dislocations+"	9,371
S4	S2 OR S3	11,879
S3	(TI patell* OR TI Kneecap* OR TI "Knee cap*" OR TI PFJ) OR (AB patell* OR AB Kneecap* OR AB "Knee cap*" OR AB PFJ) OR (SU patell* OR SU Kneecap* OR SU "Knee cap*" OR SU PFJ)	11,879
S2	MH "Patella+"	2,943
S1	MH “Patella Dislocation+"	325

[a]26 records retrieved in the updated search

Trial registry searches

ClinicalTrials.gov (https://clinicaltrials.gov/), initially searched on 13 January 2023 and updated on 31 January 2024[a]	
(Patella OR kneecap OR patellofemoral) AND (dislocate OR dislocated OR Dislocation OR instability OR sublux OR unstable OR subluxation OR subluxate OR subluxated)	117
[a]For the updated search, applied the filter first posted from: 01 January 2023, 15 records retrieved.	

ISRCTN registry (https://www.isrctn.com/), initially searched on 13 January 2023 and updated on 31 January 2024[a]	
patella	55
[a]For the updated search, applied the filter date from: 14 January 2023, 2 records retrieved.	

World Health Organisation International Clinical Trials Registry Platform (https://trialsearch.who.int/Default.aspx), initially searched on 13 January 2023 and updated on 31 January 2024[a]	
(Patell* or kneecap* or patellofemoral) and (dislocat* or instability or sublux* or unstable)	106
[a]For the updated search, applied the filter date of registration is between 14 January 2023 to 31 December 2024, 9 records retrieved.	

Appendix 7 Systematic review protocol changes

Number	Change	Rationale
1	I did not map unique outcomes onto the WHO International Classification of Functioning, Disability and Health framework to identify what outcome domains were measured in existing trials.	This mapping process will be completed later as part of the COS development process.
2	I did not synthesise all outcome measurement instruments in included studies as originally intended, instead only the PROMs that met the criteria described in section 3.2.6 were synthesised.	See chapter 3, section 3.2.6.
3	Originally, only protocols and trial registry data of ongoing/future RCTs were to be included. Subsequently, a study's status was not considered an eligibility criteria.	For completed studies where the main report was a trial registry record or a protocol, relevant outcome data normally could be extracted. So, it was decided to be inclusive and include these studies if they met the other eligibility criteria.
4	I did not contact study authors for missing outcome data.	See chapter 3, sections 3.2.4 and 3.4.
5	Records retrieved from searches of WHO ICTRP were deduplicated on Microsoft Excel instead of Rayyan systematic review software.	It was not possible to import WHO ICTRP records onto Rayyan, so Microsoft Excel was used instead.

COS: core outcome set; ICTRP: International Clinical Trials Registry Platform; PROM: patient-reported outcome; RCT: randomised controlled trial; WHO: World Health Organisation

Appendix 8 Systematic review included and excluded studies

Included studies and linked reports

Authors; publication year	Data source	Citation
Completed studies with results available		
Armstrong et al 2012	Journal article - results	Armstrong BM, Hall M, Crawfurd E, Smith TO. A feasibility study for a pragmatic randomised controlled trial comparing cast immobilisation versus no immobilisation for patients following first-time patellar dislocation. *Knee*. 2012;19:696-702.
Askenberger et al 2018	Journal article - results	Askenberger M, Bengtsson Moström E, Ekström W, et al. Operative repair of medial patellofemoral ligament injury versus knee brace in children with an acute first-time traumatic patellar dislocation: a randomized controlled trial. *American Journal of Sports Medicine*. 2018;46(10):2328-2340. doi:10.1177/0363546518770616
ISRCTN39959729	Trial registry record	ISRCTN39959729. Conservative versus arthroscopic refixation of the medial patellofemoral ligament (MPFL) after traumatic first time dislocation of the patella in children. https://doi.org/10.1186/ISRCTN39959729 (last edited 31 May 2018 at the time of data extraction)
Bitar et al 2012	Journal article - results	Bitar AC, Demange MK, D'Elia CO, Camanho GL. Traumatic patellar dislocation: Nonoperative treatment compared with MPFL reconstruction using patellar tendon. *American Journal of Sports Medicine*. 2012;40(1):114-122. doi:10.1177/0363546511423742
Bitar et al 2011	Journal article - results	Bitar AC, D'Elia CO, Demange MK, Viegas AC, Camanho GL. Randomized prospective study on traumatic patellar dislocation: conservative treatment versus reconstruction of the medial patellofemoral ligament using the patellar tendon, with a minimum of two years of follow-up. *Revista Brasileira de Ortopedia (English Edition)*. 2011;46(6):675-683. doi:10.1016/s2255-4971(15)30324-4
Bitar et al 2011	Abstract	Bitar AC, Camanho GL, D'Elia CO, Demange MK, Viegas ADC. Prospective randomized study about the traumatic patellar dislocation: the conservative treatment and the MPFL reconstruction with patellar tendon – a minimum 2-year follow-up. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*. 2011;27(10):e140-e141.
Bitar and Camanho 2010	Abstract	Bitar AC, Camanho GL. Prospective randomized study about the traumatic patellar dislocation: the conservative treatment and the MPFL reconstruction with patellar tendon - a minimum 2-year follow-up. *The Journal of Orthopaedic and Sports Physical Therapy*. 2010;40(3):A47. doi:10.2519/jospt.2010.0302
Camanho et al 2009	Journal article - results	Camanho GL, Viegas ADC, Bitar AC, Demange MK, Hernandez AJ. Conservative versus surgical treatment for repair of the medial patellofemoral ligament in acute dislocations of the patella. *Arthroscopy - Journal of Arthroscopic and Related Surgery*. 2009;25(6):620-625. doi:10.1016/j.arthro.2008.12.005
Chen et al 2023	Journal article - results	Chen H, Zhang Y, Xing C, et al. Clinical application and effectiveness of patellar tunnel locator in medial patellofemoral ligament reconstruction surgery. *Chinese Journal of Reparative and Reconstructive Surgery*. 2023;37(10):1230-1237.

Authors; publication year	Data source	Citation
Chrisman et al 1979	Journal article - results	Chrisman D, Snook GA, Wilson TC. A long-term prospective study of the Hauser and Roux-Goldthwait procedures for recurrent patellar dislocation. *Clinical Orthopaedics and Related Research*. 1979;(144):27-30.
Christiansen et al 2008	Journal article - results	Christiansen SE, Jakobsen BW, Lund B, Lind M. Isolated repair of the medial patellofemoral ligament in primary dislocation of the patella: a prospective randomized study. *Arthroscopy - Journal of Arthroscopic and Related Surgery*. 2008;24(8):881-887. doi:10.1016/j.arthro.2008.03.012
Damasena et al 2016	Journal article - results	Damasena I, Blythe M, Wysocki D, Kelly D, Annear P. Medial patellofemoral ligament reconstruction combined with distal realignment for recurrent dislocations of the patella. *American Journal of Sports Medicine*. 2017;45(2):369-376. doi:10.1177/0363546516666352
Annear et al 2016	Abstract	Annear P, Damasena I, Blythe M, Wysocki D. MPFL reconstruction with TTT versus TTT alone for recurrent patella instability: five year results of a randomized control trial. *Orthopaedic Journal of Sports Medicine*. 2016;4(2_suppl 1). https://doi.org/10.1177/2325967116S00019
Du et al 2017	Journal article - results	Du H, Tian XX, Guo FQ, et al. Evaluation of different surgical methods in treating recurrent patella dislocation after three-dimensional reconstruction. *International Orthopaedics*. 2017;41(12):2517-2524. doi:10.1007/s00264-017-3552-9
Ercan et al 2021	Journal article - results	Ercan N, Akmese R, Ulusoy B. Single-tunnel and double-tunnel medial patellofemoral ligament reconstructions have similar clinical, radiological and functional results. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2021;29(6):1904-1912. https://doi.org/10.1007/s00167-020-06260-6
Heyde 2001	Abstract	Heyde B. Die arthroskopische mediale raffnaht als minimalinvasive therapiealternative bei patellaluxation. In: *Unfallchirurgische Einzelfalldarstellungen*. 2001;490-491.
Honkonen et al 2022	Journal article - results	Honkonen EE, Sillanpää PJ, Reito A, Mäenpää H, Mattila VM. A randomized controlled trial comparing a patella-stabilizing, motion-restricting knee brace versus a neoprene nonhinged knee brace after a first-time traumatic patellar dislocation. *American Journal of Sports Medicine*. 2022;50(7):1867-1875. doi:10.1177/03635465221090644
NCT01344915	Trial registry record	NCT01344915. Restricted vs. free knee range of motion for primary traumatic patellar dislocation. https://clinicaltrials.gov/study/NCT01344915?term=%20NCT01344915&rank=1&tab=table (last updated 02 May 2011 at the time of data extraction)
Salonen et al 2021	Abstract	Salonen E, Sillanpää PJ, Reito A, Mäenpää HM, Mattila VM. A randomized controlled trial comparing patellar stabilizing, motion restricting knee brace vs. sham brace in non-operative treatment for first-time patellar dislocation. *Journal of ISAKOS*. 2021;6(6):505-506.
Ji et al 2017	Journal article - results	Ji G, Wang S, Wang X, Liu J, Niu J, Wang F. Surgical versus nonsurgical treatments of acute primary patellar dislocation with special emphasis on the MPFL injury Patterns. *Journal of Knee Surgery*. 2017;30(4):378-384. doi:10.1055/s-0036-1592151
Kang et al 2013	Journal article - results	Kang H, Cao J, Yu D, Zheng Z, Wang F. Comparison of 2 different techniques for anatomic reconstruction of the medial patellofemoral ligament: A prospective randomized study. *American Journal of Sports Medicine*. 2013;41(5):1013-1021. doi:10.1177/0363546513480468
Kang et al 2016	Journal article - results	Kang H, Wang F, Cao J, Liu X, Ji G. A prospective randomized trial evaluating two different tensioning techniques for medial patellofemoral ligament reconstruction. *Knee*. 2016;23(5):826-829.

Authors; publication year	Data source	Citation
Li et al 2019	Journal article - results	Li J, Li Z, Wang K, Liu C, Wang Y, Wang H. Medial patellofemoral ligament reconstruction: a comparison of single-bundle transpatellar tunnel and double-anchor anatomic techniques for the treatment of recurrent lateral patellar dislocation in adults. *Arthroscopy - Journal of Arthroscopic and Related Surgery*. 2019;35(3):845-854.e1. https://doi.org/10.1016/j.arthro.2018.08.050
Lind et al 2019	Journal article - results	Lind M, Nielsen T, Miller L, Sørensen OG, Mygind-Klavsen B, Faunø P. No difference in outcome between femoral soft-tissue and screw graft fixation for reconstruction of the medial patellofemoral ligament: a randomized controlled trial. *Arthroscopy - Journal of Arthroscopic and Related Surgery*. 2019;35(4):1130-1137. https://doi.org/10.1016/j.arthro.2018.11.051
Lind et al 2017	Abstract	Lind M, Faunoe P, Sørensen OG, Mygind-Klavsen B, Miller L, Nielsen TG. Comparison of soft tissue and bone graft fixation for reconstruction of the medial patellofemoral ligament. a randomized controlled trial. *Arthroscopy*. 2017;33(10):supplement e172.
NCT02180685	Trial registry record	NCT02180685. Reconstruction of the medial patellofemoral ligament - a randomised controlled trial comparing two surgery technics. https://clinicaltrials.gov/study/NCT02180685?term=NCT02180685&rank=1 (last updated 11 November 2019 at the time of data extraction)
Liu et al 2018	Journal article - results	Liu C, Duan G, Niu Y, et al. Lateral retinaculum plasty instead of lateral retinacular release with concomitant medial patellofemoral ligament reconstruction can achieve better results for patellar dislocation. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2018;26(10):2899-2905. doi:10.1007/s00167-017-4798-x
Ma et al 2012	Journal article - results	Ma LF, Wang CH, Chen BC, et al. Medial patellar retinaculum plasty versus medial capsule reefing for patellar dislocation in children and adolescents. *Archives of Orthopaedic and Trauma Surgery*. 2012;132(12):1773-1780. doi:10.1007/s00402-012-1598-0
Ma et al 2013	Journal article - results	Ma LF, Wang F, Chen BC, Wang CH, Zhou JW, Wang HY. Medial retinaculum plasty versus medial patellofemoral ligament reconstruction for recurrent patellar instability in adults: A randomized controlled trial. *Arthroscopy - Journal of Arthroscopic and Related Surgery*. 2013;29(5):891-897.
Matuszewski et al 2018	Journal article - results	Matuszewski Ł, Tram M, Ciszewski A, et al. Medial patellofemoral ligament reconstruction in children: A comparative randomized short-term study of fascia lata allograft and gracilis tendon autograft reconstruction. *Medicine*. 2018;97(50). doi:10.1097/MD.0000000000013605
Nikku et al 1997	Journal article - results	Nikku R, Nietosvaara Y, Kallio PE, Aalto K, Michelsson JE. Operative versus closed treatment of primary dislocation of the patella. Similar 2-year results in 125 randomized patients. *Acta Orthopaedica Scandinavica*. 1997;68(5):419-423. doi:10.3109/17453679708996254
Nikku et al 2005	Journal article - results	Nikku R, Nietosvaara Y, Aalto K, Kallio PE. Operative treatment of primary patellar dislocation does not improve medium-term outcome: A 7-year follow-up report and risk analysis of 127 randomized patients. *Acta Orthopaedica*. 2005;76(5):699-704. doi:10.1080/17453670510041790
Palmu et al 2008	Journal article - results	Palmu S, Kallio PE, Donell ST, Helenius I, Nietosvaara Y. Acute patellar dislocation in children and adolescents: A randomized clinical trial. *Journal of Bone and Joint Surgery*. 2008;90(3):463-470. doi:10.2106/JBJS.G.00072

Authors; publication year	Data source	Citation
Nietosvaara et al 2009	Journal article - surgical technique	Nietosvaara Y, Paukku R, Palmu S, Donell ST. Acute patellar dislocation in children and adolescents: Surgical technique. *Journal of Bone and Joint Surgery*. 2009;91(Suppl_2):139-145. doi:10.2106/JBJS.H.01289
Niu et al 2016	Journal article - results	Niu C, Fu K, Lu J, et al. A medium-term follow-up outcome of medial retinaculum plasty versus double-bundle anatomical medial patellofemoral ligament reconstruction for recurrent patellar dislocation in adults. *Int J Clin Exp Med*. 2016;9(6):9064-9072.
Niu et al 2021	Journal article - results	Niu J, Lin W, Qi Q, Lu J, Dai Y, Wang F. Anatomical medial patellofemoral ligament reconstruction for recurrent patella dislocation: two-strand grafts versus four-strand grafts. *Journal of Knee Surgery*. 2021;34(2):147-154.
Petri 2013	Journal article - results	Petri M, Liodakis E, Hofmeister M, et al. Operative vs conservative treatment of traumatic patellar dislocation: Results of a prospective randomized controlled clinical trial. *Archives of Orthopaedic and Trauma Surgery*. 2013;133(2):209-213. doi:10.1007/s00402-012-1639-8
Qiao et al 2022	Journal article - results	Qiao Y, Xu J, Ye Z, et al. Double-tunnel technique was similar to single-tunnel technique in clinical, imaging and functional outcomes for medial patellofemoral ligament reconstruction: A randomized clinical trial. *Arthroscopy - Journal of Arthroscopic and Related Surgery*. 2022;38(11):3058-3067. https://doi.org/10.1016/j.arthro.2022.04.019
ChiCTR-IOR-17010738	Trial registry record	ChiCTR-IOR-17010738. Medial patellofemoral ligament reconstruction for recurrent patella dislocation: Single tunnel vs double tunnel. http://www.chictr.org.cn/showproj.aspx?proj=18263 (last updated 12 October 2021 at the time of data extraction)
Rahman et al 2020	Journal article - results	Rahman U, Gemperle-Mannion E, Qureshi A, et al. The feasibility of a randomised control trial to assess physiotherapy against surgery for recurrent patellar instability. *Pilot and Feasibility Studies*. 2020;6(94). https://doi.org/10.1186/s40814-020-00635-9
ISRCTN14950321	Trial registry record	ISRCTN14950321. Patellar instability: physiotherapy or surgery? (PIPS feasibility trial). https://doi.org/10.1186/ISRCTN14950321 (last edited 10 July 2020 at the time of data extraction)
Rashwan et al 2019	Abstract	Rashwan AS, Misbah H. Divergent patellar bony tunnels versus patellar anchor fixation for reconstruction in isolated medial patellofemoral ligament (MPFL) rupture. *Journal of ISAKOS*. 4(4):204.
Regalado et al 2016	Journal article - results	Regalado G, Lintula H, Kokki H, Kröger H, Väätäinen U, Eskelinen M. Six-year outcome after non-surgical versus surgical treatment of acute primary patellar dislocation in adolescents: a prospective randomized trial. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2016;24(1):6-11. doi:10.1007/s00167-014-3271-3
Rood et al 2012	Journal article - results	Rood A, Boons H, Ploegmakers J, van der Stappen W, Koëter S. Tape versus cast for non-operative treatment of primary patellar dislocation: A randomized controlled trial. *Archives of Orthopaedic and Trauma Surgery*. 2012;132(8):1199-1203. doi:10.1007/s00402-012-1521-8
Sillanpää et al 2009	Journal article - results	Sillanpää PJ, Mattila VM, Mäenpää H, Kiuru M, Visuri T, Pihlajamäki H. Treatment with and without initial stabilizing surgery for primary traumatic patellar dislocation: A prospective randomized study. *Journal of Bone and Joint Surgery*. 2009;91(2):263-273. doi:10.2106/JBJS.G.01449
NCT00551668	Trial registry record	NCT00551668. A prospective, randomized study of operative and nonoperative treatment for primary traumatic patellar dislocation.

Authors; publication year	Data source	Citation
		https://clinicaltrials.gov/study/NCT00551668?term=NCT00551668&rank=1 (last updated 31 October 2007 at the time of data extraction)
Sillanpää et al 2011	Abstract	Sillanpää PJ, Mäenpää HM, Paakkala A. A prospective randomized study comparing non-operative treatment with and without knee immobilization for primary traumatic patellar dislocation. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*. 2011;27(10):e183-e184.
Smith et al 2015	Journal article - results	Smith TO, Chester R, Cross J, Hunt N, Clark A, Donell ST. Rehabilitation following first-time patellar dislocation: A randomised controlled trial of purported vastus medialis obliquus muscle versus general quadriceps strengthening exercises. *Knee*. 2015;22(4):313-320. doi:10.1016/j.knee.2015.03.013
Straume-Næsheim et al 2022	Journal article - results	Straume-Næsheim TM, Randsborg PH, Mikaelsen JR, Årøen A. Medial patellofemoral ligament reconstruction is superior to active rehabilitation in protecting against further patella dislocations. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2022;30(10):3428-3437. doi:10.1007/s00167-022-06934-3
Nilsgård et al 2023	Journal article - results	Nilsgård TL, Øiestad BE, Randsborg PH, Årøen A, Straume-Næsheim TM. Association between single leg hop tests and patient reported outcome measures and patellar instability in patients with recurrent patellar dislocations. *BMJ Open Sport and Exercise Medicine*. 2023;9(4). doi:10.1136/bmjsem-2023-001760
NCT02263807	Trial registry record	NCT02263807. Knee function in patients with two or more episodes of patella dislocations (MPFL). https://clinicaltrials.gov/study/NCT02263807?term=NCT02263807&rank=1 (last updated 27 October 2022 at the time of data extraction)
Tucker et al 2018	Journal article - protocol	Tucker A, McMahon S, McArdle B, Rutherford B, Acton D. Synthetic versus autologous reconstruction (Syn-VAR) of the medial patellofemoral ligament: A study protocol for a randomised controlled trial. *Trials*. 2018;19(1). doi:10.1186/s13063-018-2622-7
ISRCTN16657952	Trial registry record	ISRCTN16657952. Synthetic versus autologous reconstruction of the medial patellofemoral ligament. https://doi.org/10.1186/ISRCTN16657952 (last edited 14 March 2023 at the time of data extraction)
Wang et al 2021	Journal article - results	Wang XL, Peng C, Tu YW, et al. Effects of lateral patellar retinaculum release for recurrent patella dislocation: A prospective study. *International Journal of General Medicine*. 2021;14:5527-5535. doi:10.2147/IJGM.S329026
Xie et al 2012	Journal article - results	Xie G, Zhao J, Huangfu X, He Y. Medial patellofemoral ligament reconstruction using semitendinosus tendons: Polyester suture augmentation versus nonaugmentation. *American Journal of Sports Medicine*. 2012;40(6):1365-1374. doi:10.1177/0363546512441324
Xinmin et al 2024	Journal article - results	Xinmin W, Wenkai Y, Yahui S, Fei L. Leukocyte- and platelet-rich fibrin with autologous hamstring tendon for traumatic patella dislocation. *Chinese Journal of Tissue Engineering Research*. 2024;28(3):404-410. doi:10.12307/2023.888
Xiong et al 2023	Journal article - results	Xiong Y, Wang D, Li S, et al. Adductor canal block combined with general analgesia for patients with recurrent patellar dislocation undergoing "3-in-1" procedure surgery: A prospective randomized controlled trial. *Orthopaedic Surgery*. 2023;15(6):1636-1644. doi:10.1111/os.13706
ChiCTR2000032482	Trial registry record	ChiCTR2000032482. Adductor canal block for postoperative pain and knee function in patients with patellar dislocation undergoing simultaneous "'3-in-1'" surgery. http://www.chictr.org.cn/showproj.aspx?proj=52876 (last updated 29 April 2020 at the time of data extraction)

Authors; publication year	Data source	Citation
ChiCTR2000032484	Trial registry record	ChiCTR2000032484. Adductor canal block for postoperative pain and knee function in patients with patellar dislocation undergoing MPFL reconstruction, lateral support band loosening, and tibial tubercle displacement. https://www.chictr.org.cn/showproj.html?proj=52851 (last updated 05 May 2020 at the time of data extraction)
ChiCTR2000032395	Trial registry record	ChiCTR2000032395. Adductor canal block combined with local infiltration analgesia in patients with patellar dislocation undergoing MPFL reconstruction, lateral support band loosening, and tibial tubercle displacement. http://www.chictr.org.cn/showproj.aspx?proj=52877 (last updated 27 April 2020 at the time of data extraction)
Zhao et al 2012	Journal article - results	Zhao J, Huangfu X, He Y, Liu W. Recurrent patellar dislocation in adolescents: Medial retinaculum plication versus vastus medialis plasty. *American Journal of Sports Medicine*. 2012;40(1):123-132. doi:10.1177/0363546511420551
Zhao and Xie 2011	Abstract	Zhao J, Xie X. Recurrent patella dislocation in adolescence: medial retinaculum plication versus vastus medialis plasty. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*. 2011;27(10):e136-e137.
Zhao et al 2012	Journal article - results	Zhao J, Huangfu X, He Y. The role of medial retinaculum plication versus medial patellofemoral ligament reconstruction in combined procedures for recurrent patellar instability in adults. *American Journal of Sports Medicine*. 2012;40(6):1355-1364. doi:10.1177/0363546512439193
Zhao 2011	Abstract	Zhao J. Treatment of recurrent patella dislocation in adult: medial retinaculum reefing versus medial patella femoral ligament reconstruction. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*. 2011;27(10):e140.
Completed > 12 months studies results unavailable		
ACTRN12612000366853	Trial registry record	ACTRN12612000366853. Does the type of knee brace used after kneecap dislocation affect pain and function? https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=362316 (last updated 23 July 2018 at the time of data extraction)
ChiCTR1800014648	Trial registry record	ChiCTR1800014648. The effects of rapid recovery to the function, gait and patellar height of patients who had tibial tuberosity transposition for patellar dislocation. http://www.chictr.org.cn/showproj.aspx?proj=24486 (last updated 26 January 2018 at the time of data extraction)
ChiCTR2100042365	Trial registry record	ChiCTR2100042365. The efficacy of intra-articular injection of tranexamic acid in medial patellofemoral ligament reconstruction: a randomized controlled trial. http://www.chictr.org.cn/showproj.aspx?proj=120529 (last updated 19 April 2021 at the time of data extraction)
ChiCTR2100042235	Trial registry record	ChiCTR2100042235. The efficacy of periarticular multimodal drug infiltration in medial patellofemoral ligament reconstruction: a randomized controlled trial. http://www.chictr.org.cn/showproj.aspx?proj=120224 (last updated 16 April 2021 at the time of data extraction)
ChiCTR-INR-17013928	Trial registry record	ChiCTR-INR-17013928. Trochleoplasty for refractory patellar dislocations. http://www.chictr.org.cn/showproj.aspx?proj=23825 (last updated 14 December 2017 at the time of data extraction)
ChiCTR-IOR-17010528	Trial registry record	ChiCTR-IOR-17010528. Fixation versus unfixation of osteochondral fractures after patellar dislocations in adolescent patients: a randomized contolled trial. http://www.chictr.org.cn/showproj.aspx?proj=17416 (last updated 26 January 2017 at the time of data extraction)

Authors; publication year	Data source	Citation
NCT00743873	Trial registry record	NCT00743873. Platelet-rich plasma (PRP) treatment for medial retinaculum tear post medial patellar dislocation. https://clinicaltrials.gov/study/NCT00743873?term=NCT00743873&rank=1 (last updated 12 July 2011 at the time of data extraction)
NCT00816647	Trial registry record	NCT00816647. A prospective randomized study of medial patellofemoral ligament (MPFL) reconstruction. https://clinicaltrials.gov/study/NCT00816647?term=NCT00816647&rank=1 (last updated 14 June 2011 at the time of data extraction)
NCT02185001	Trial registry record	NCT02185001. Repair of medial patellofemoral ligament compared to conservative treatment for first time patella dislocation. https://clinicaltrials.gov/study/NCT02185001?term=NCT02185001&rank=1 (last updated 09 March 2017 at the time of data extraction)
RBR-8kf6ks	Trial registry record	RBR-8kf6ks. Influence of hip and thigh muscle strength in the treatment of patellar dislocation. http://ensaiosclinicos.gov.br/rg/RBR-8kf6ks (last updated date not available)
RBR-87dkhg	Trial registry record	RBR-87dkhg. Thigh muscle strengthening associated with a therapeutic electrical stimulation compared to an isolated thigh muscle strengthening in subjects with atraumatic patellar dislocation. http://ensaiosclinicos.gov.br/rg/RBR-87dkhg (last updated date not available)
Completed <12 months ago, results unavailable		
ChiCTR2300073062	Trial registry record	ChiCTR2300073062. Efficacy of three-dimensional printing guide plate for femoral tunnel position assist medial patellofemoral ligament reconstruction. https://www.chictr.org.cn/showproj.html?proj=193305 (last updated 25 August 2023 at the time of data extraction)
NCT02333825	Trial registry record	NCT02333825. Pediatric and adolescent patellar instability (PAPI). https://clinicaltrials.gov/study/NCT02333825?term=NCT02333825&rank=1 (last updated 19 January 2023 at the time of data extraction)
NCT04556799	Trial registry record	NCT04556799. The clinical results of derotational osteotomy based on 3D osteotomy template for treatment of recurrent patellar dislocation combined with patellofemoral maltracking. https://clinicaltrials.gov/study/NCT04556799?term=NCT04556799&rank=1 (last updated 21 September 2020 at the time of data extraction)
Ongoing studies with published report of preliminary results		
Malatray et al 2019	Journal article - results	Malatray M, Magnussen R, Lustig S, Servien E. Lateral retinacular release is not recommended in association to MPFL reconstruction in recurrent patellar dislocation. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2019;27(8):2659-2664. doi:10.1007/s00167-018-5294-7
NCT01719666	Trial registry record	NCT01719666. Medial patellofemoral ligament reconstruction with or without lateral retinaculum release. https://clinicaltrials.gov/study/NCT01719666?term=NCT01719666&rank=1 (last updated 03 March 2023 at the time of data extraction)
Purcell et al 2022	Abstract	Purcell N, McKay S, Saloom A, Mitchell K. The effects of early range of motion versus immobilization following acute first-time lateral patellar instability episode: randomized control trial. *Orthopaedic Journal of Sports Medicine*. 2022;10(5_suppl2). doi:10.1177/2325967121s00439
NCT04294199	Trial registry record	NCT04294199. Effect of early range of motion following first time patellar dislocation. https://clinicaltrials.gov/study/NCT04294199?term=NCT04294199&rank=1 (last updated 31 May 2023 at the time of data extraction)
Ongoing studies completed <12 months ago, results unavailable		

Authors; publication year	Data source	Citation
ACTRN12619000778189	Trial registry record	ACTRN12619000778189. A trial to compare two different surgical techniques used to prevent the unstable knee cap from further episodes of dislocation in patients at significant risk or recurrence. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377532 (last updated 11 January 2023 at the time of data extraction)
Bartsch et al 2022	Journal article - protocol	Bartsch A, Nüesch C, Rieger B, Mündermann A, Egloff C. Dynamic versus static medial patellofemoral ligament reconstruction technique in the treatment of recurrent patellar dislocation: a randomized clinical trial protocol. *Journal of Orthopaedic Surgery and Research*. 2022;17(1). doi:10.1186/s13018-022-03158-6
NCT04849130	Trial registry record	NCT04849130. Comparison of dynamic and static medial patellofemoral ligament operation technique for recurrent patellar dislocation (DynMPFL). https://clinicaltrials.gov/study/NCT04849130?term=NCT04849130&rank=1 (last updated 13 September 2022 at the time of data extraction)
Brightwell et al 2022	Journal article - protocol	Brightwell BD, Stone A, Li X, et al. Blood flow Restriction training After patellar INStability (BRAINS Trial). *Trials*. 2022;23(1):1-8. doi:10.1186/s13063-022-06017-1
NCT04554212	Trial registry record	NCT04554212. Blood Flow Restriction Training After Patellar INStability (BRAINS). https://clinicaltrials.gov/study/NCT04554212?term=NCT04554212&rank=1 (last updated 10 April 2023 at the time of data extraction)
ChiCTR2200057574	Trial registry record	ChiCTR2200057574. The application value of non-absorbent surgical suture FiberWire or autologous tendon in the reconstruction of medial patellofemoral ligament (MPFL). https://www.chictr.org.cn/showproj.html?proj=151152 (last updated 13 November 2022 at the time of data extraction)
ISRCTN17972668	Trial registry record	ISRCTN17972668. Physiotherapy or surgery for repeat kneecap dislocation: a randomised controlled trial. https://doi.org/10.1186/ISRCTN17972668 (last edited 09 June 2023 at the time of data extraction)
Liebensteiner et al 2021	Journal article - protocol	Liebensteiner M, Keiler A, El Attal R, et al. Conservative versus tailored surgical treatment in patients with first time lateral patella dislocation: a randomized-controlled trial. *Journal of Orthopaedic Surgery and Research*. 2021;16:1-8. doi:10.1186/s13018-021-02513-3
NCT02267564	Trial registry record	NCT02267564. MPFL reconstruction with or without tibial tubercle transfer. https://clinicaltrials.gov/study/NCT02267564?term=NCT02267564&rank=1 (last updated 08 June 2023 at the time of data extraction)
NCT05488275	Trial registry record	NCT05488275. MPFL vs Campbell in Recurrent Patella Dislocation. https://clinicaltrials.gov/study/NCT05488275 (last updated 15 August 2022 at the time of data extraction)
NCT05533671	Trial registry record	NCT05533671. Conservative versus operative - first time patella dislocations. https://clinicaltrials.gov/study/NCT05533671?term=NCT05533671&rank=1 (last updated 10 March 2023 at the time of data extraction)
NCT05706363	Trial registry record	NCT05706363. Comparison of two graft choices in mediale patellofemoral ligament reconstruction (MPFL). https://clinicaltrials.gov/study/NCT05706363?term=NCT05706363&rank=1 (last updated 31 January 2024 at the time of data extraction)
NCT05759039	Trial registry record	NCT05759039**.** SHould You transFer the Tubercle? (SHYFT). https://clinicaltrials.gov/ct2/show/NCT05759039 (last updated 14 December 2023 at the time of data extraction)

Authors; publication year	Data source	Citation
NCT06086080	Trial registry record	NCT06086080. Non-operative treatment in first-time patellar dislocation. https://clinicaltrials.gov/study/NCT06086080?term=NCT06086080&rank=1 (last updated 23 October 2023 at the time of data extraction)

Studies excluded at full-text screening with exclusion reasons

Authors; publication year	Data source	Citation	Exclusion reason
Bert et al 1991	Journal article - results	Bert J, Stark J, Maschka P, Chock C. The effect of cold therapy on morbidity subsequent to arthroscopic lateral retinacular release. *Orthopaedic Review*. 1991;(9):755-758.	Wrong population
Bitar et al 2011	Journal article - results	Bitar A, D'Elia C, Demange M, Viegas A, Camanho G. Randomized prospective study on traumatic patellar dislocation: conservative treatment versus reconstruction of the medial patellofemoral ligament using the patellar tendon, with a minimum of two years of follow-up. *Revista brasileira de ortopedia*. 2011;46(6):675-683.	Non-English language version of included English-language record
ChiCTR-ONQ-16007824	Trial registry record	ChiCTR-ONQ-16007824. Open reduction and internal fixation versus removing the osteochonfral fragments in treatment of patela dislacation associated with osteochondral fracture. https://www.chictr.org.cn/showproj.html?proj=13239	Not an RCT
Chrisman et al 1972	Journal article - results	Chrisman O, Snook G, Wilson T. The protective effect of aspirin against degeneration of human articular cartilage. *Clinical Orthopaedics and Related Research*. 1972;(84):193-196.	Not an RCT
ChiCTR2200062742	Trial registry record	ChiCTR2200062742. Risk factors related to anterior cruciate ligament injury combined with patellar instability and evaluation of the effect of combined rconstruction or not: a randomized controlled study. http://www.chictr.org.cn/showproj.aspx?proj=152826	Wrong population
ChiCTR2200058011	Trial registry record	ChiCTR2200058011. Optimization of therapeutic strategies for muscle atrophy and functional rehabilitation of knee joint in different stages after arthroscopy for knee sports injury. https://www.chictr.org.cn/showproj.html?proj=159762	Wrong population
Del Castillo et al 2021	Abstract	Del Castillo JM, Sierra M, Dupont J, von Heideken J, Enrique J, Pujada K. Evaluation of medial patellofemoral ligament reconstruction in inmature skeleton. A comparative study between two techniques. *Journal of ISAKOS*. 2021;6(6):458.	Not a RCT
DRKS00027261	Trial registry record	DRKS00027261. Effects of an app based individual physiotherapy program for anterior knee pain - a prospective multicenter randomized control trial. https://drks.de/search/en/trial/DRKS00027261	Wrong population
Ferrer et al 2016	Journal article - results	Ferrer GA, Miller RM, Murawski CD, et al. Quantitative analysis of the patella following the harvest of a quadriceps tendon autograft with a bone block. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2016;24(9):2899-2905. doi:10.1007/s00167-015-3550-7	Wrong population
Franciozi et al 2017	Abstract	Franciozi CE da, Ambra F, Albertoni LJB, et al. MPFL reconstruction combined with anteromedialization tibial tubercle osteotomy versus isolated MPFL reconstruction in patients with recurrent patellar instability: a quasi-randomized controlled trial. *Arthroscopy - Journal of Arthroscopic and Related Surgery*. 2017;33(10):e73-e74.	Wrong population
Franciozi et al 2019	Journal article - results	Franciozi CE, Ambra LF, Albertoni LJB, et al. Anteromedial tibial tubercle osteotomy improves results of medial patellofemoral ligament reconstruction for recurrent patellar	Not a RCT

Authors; publication year	Data source	Citation	Exclusion reason
		instability in patients with tibial tuberosity–trochlear groove distance of 17 to 20 mm. *Arthroscopy - Journal of Arthroscopic and Related Surgery*. 2019;35(2):566-574. doi: https://doi.org/10.1016/j.arthro.2018.10.109	
Geng et al 2023	Journal article - results	Geng T, Xiaoqian J, Guo Y. Retracted: Lower Limb Joint Nursing and Rehabilitation System Based on Intelligent Medical Treatment. *Journal of Healthcare Engineering*. Published online 2023. https://doi.org/10.1155/2021/6646977	Retracted
Giesler 2021	Abstract	Giesler P. MR Imaging after Patellar MACI and MPFL reconstruction: Comparing isolated with combined procedures. *Seminars in Musculoskeletal Radiology*. 2021;25(S 01):S1-S23.	Not a RCT
Hafez et al 2012	Journal article - results	Hafez AR, Zakaria A, Buragadda S. Eccentric versus concentric contraction of quadriceps muscles in treatment of chondromalacia patellae. *World Journal of Medical Sciences*. 2012;7(3):197-203. doi:10.5829/idosi.wjms.2012.7.3.6427	Wrong population
ISRCTN17 972668	Trial registry record	ISRCTN17972668. Physiotherapy or surgery for repeat kneecap dislocation: a randomised controlled trial. https://doi.org/10.1186/ISRCTN17972668	Duplicate of included record
ISRCTN16 657952	Trial registry record	ISRCTN16657952. Synthetic versus autologous reconstruction of the medial patellofemoral ligament. https://doi.org/10.1186/ISRCTN16657952	Duplicate of included record
ISRCTN14 950321	Trial registry record	ISRCTN14950321. Patellar Instability: Physiotherapy or Surgery? (PIPS feasibility trial). https://doi.org/10.1186/ISRCTN14950321	Duplicate of included record
ISRCTN39 959729	Trial registry record	ISRCTN39959729. Conservative versus arthroscopic refixation of the Medial PatelloFemoral Ligament (MPFL) after traumatic first time dislocation of the patella in children. https://doi.org/10.1186/ISRCTN39959729	Duplicate of included record
Koskinen et al 1998	Journal article - results	Koskinen SK, Rantanen JP, Nelimarkka OI, Kujala UM. Effect of Elmslie-Trillat and Roux-Goldthwait procedures on patellofemoral relationships and symptoms in patients with patellar dislocations. *American Journal of Knee Surgery*. 1998;11(3):167-173.	Not a RCT
Malecki et al 2016	Journal article - results	Malecki K, Fabis J, Flont P, Lipczyk Z, Niedzielski K. Preliminary results of two surgical techniques in the treatment of recurrent patellar dislocation. *International Orthopaedics*. 2016;40(9):1869-1874. doi:10.1007/s00264-016-3119-1	Not a RCT
Malecki et al 2023	Journal article - results	Małecki K, Niedzielski K, Korczyc-Stępnicka A, et al. A clinical, radiological and isokinetic evaluation in patients with recurrent patellar dislocation undergoing MPFL reconstruction according to Avikainen: a prospective study evaluating early degenerative changes after a minimum 10-year follow-up period. *BMC Musculoskeletal Disorders*. 2023;24(1). doi:10.1186/s12891-023-06249-5	Not a RCT
Marullo et al 2014	Abstract	Marullo M, Zanon G, Perticarini L, Rocca L, Benazzo F. Single or double-bundle medial patello-femoral ligament reconstruction. *Journal of Orthopaedics and Traumatology*. 2014;15(suppl 1):s49.	Not a RCT
Mikashima et al 2004	Journal article - results	Mikashima Y, Kimura M, Kobayashi Y, Asaguma H, Tomatsu T. Medial patellofemoral ligament reconstruction for recurrent	Not a RCT

Authors; publication year	Data source	Citation	Exclusion reason
		patellar instability. *Acta Orthopaedoca Belgica*. 2004;70(6):545-550.	
Mikashima et al 2006	Journal article - results	Mikashima Y, Kimura M, Kobayashi Y, Miyawaki M, Tomatsu T. Clinical results of isolated reconstruction of the medial patellofemoral ligament for recurrent dislocation and subluxation of the patella. *Acta Orthopaedica Belgica*. 2006;72(1):65-71.	Not a RCT
Milinkovic et al 2023	Journal article - results	Milinkovic DD, Zimmermann F, Balcarek P. Medial patellofemoral ligament reconstruction using nonresorbable sutures yields comparable outcomes to reconstruction with a pedicled quadriceps tendon autograft when performed in addition to bony risk factor correction. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2023;31(1):264-271. doi:10.1007/s00167-022-07104-1	Not a RCT
Mohammed et al 2017	Journal article - results	Mohammed R, Hunt N, Gibbon A. Patellar complications in single versus double tunnel medial patellofemoral ligament reconstruction. *Journal of Orthopaedic Surgery*. 2017;25(1):1-4. doi:10.1177/2309499017691007	Not a RCT
Møller and Krebs 1996	Journal article - results	Møller a BN, Krebs B. Dynamic knee brace in the treatment of patellofemoral disorders. *Arch Orthop Trauma Surg*. 1986;104:377-379.	Wrong population
NCT02263807	Trial registry record	NCT02263807. Knee function in patients with two or more episodes of patella dislocations (MPFL). https://clinicaltrials.gov/study/NCT02263807?term=NCT02263807&rank=1	Duplicate of included record
NCT04554212	Trial registry record	NCT04554212. Blood Flow Restriction Training After Patellar INStability (BRAINS). https://clinicaltrials.gov/study/NCT04554212?term=NCT04554212&rank=1	Duplicate of included record
NCT05375071	Trial registry record	NCT05375071. BFR After Biceps Tendon Repair and MPFLR. https://clinicaltrials.gov/study/NCT05375071	Wrong population
NCT05426954	Trial registry record	NCT05426954. BFRT MPFL and ACL reconstruction rehab. https://ClinicalTrials.gov/show/NCT05426954	Wrong population
NCT05533671	Trial registry record	NCT05533671. Conservative versus operative - first time patella dislocations. https://clinicaltrials.gov/study/NCT05533671?term=NCT05533671&rank=1	Duplicate of included record
NCT05759039	Trial registry record	NCT05759039**.** SHould You transFer the Tubercle? (SHYFT). https://clinicaltrials.gov/ct2/show/NCT05759039	Duplicate of included record
NCT05854056	Trial registry record	NCT05854056. Tibial tubercle distalisation and accelerated rehabilitation. https://clinicaltrials.gov/study/NCT05854056?term=NCT05854056&rank=1	Wrong population
Pieler-Bruha 2008	Commentary	Pieler-Bruha E. Acute patellar dislocation in children and adolescents: a randomized clinical trial: Commentary. *Journal für Mineralstoffwechsel*. 2008;15(2):96-97.	Not a RCT

Authors; publication year	Data source	Citation	Exclusion reason
Pieler-Bruha 2008	Commentary	Pieler-Bruha E. Acute patellar dislocation in children and adolescents: a randomized clinical trial: Commentary. *Journal für Mineralstoffwechsel*. 2008;15(2):96-97.	Duplicate of excluded record
Sillanpää et al 2008	Journal article - results	Sillanpää P, Mattila VM, Visuri T, Mäenpää H, Pihlajamäki H. Ligament reconstruction versus distal realignment for patellar dislocation. *Clinical Orthopaedics and Related Research*. 2008;466(6):1475-1484.	Not a RCT
Straume-Næsheim et al 2022	Journal article - results	Straume-Næsheim TM, Randsborg PH, Mikaelsen JR, et al. Recurrent lateral patella dislocation affects knee function as much as ACL deficiency - However patients wait five times longer for treatment. *BMC Musculoskeletal Disorders*. 2019;20(1). doi:10.1186/s12891-019-2689-7	Not a RCT
Vögele et al 2023	Journal article - results	Vögele C, Koch DA, Kircher P. Comparison of the reoperation rates of three techniques for tibial tuberosity transposition in medial patellar dislocation. *Schweizer Archiv fur Tierheilkunde*. 2023;165(9):585-593.	Not a RCT
Wilbur et al 2022	Abstract	Wilbur R, Song B, Wasserburger J, et al. MPFL repair has a higher failure rate at long-term follow-up compared to MPFL reconstruction for recurrent patellar instability. *Orthopaedic Journal of Sports Medicine*. 2022;10(7):suppl5.	Not a RCT
Wilbur et al 2022	Abstract	Wilbur R, Song B, Wasserburger J, et al. MPFL repair has a higher failure rate at long-term follow-up compared to MPFL reconstruction for recurrent patellar instability. *Orthopaedic Journal of Sports Medicine*. 2022;10(7):suppl5.	Duplicate of excluded record

Appendix 9 Creation of unique from extracted verbatim outcomes

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
Adverse event related outcomes		
37	Adverse event(s)	Adverse events and complications related to the surgical procedure
		Adverse events attributable to undergoing surgical reconstruction of the MPFL
		Adverse events including surgical complications
		Adverse or serious adverse event
		Complications
		Complications and sequelae of treatment
		Discomfort with trial brace
		Important harms or unintended effects
		Infection
		Knee stiffness
		Occurrence of nausea
		Occurrence of…vomiting
		Palpatory pain in relation to graft fixation in femur
		Patella fracture
		Post-operative complications
		Prepatellar sensibility
		Other occurring complications
		Serious complications
		Surgical complications
		Surgical scar…sensibility
		Tenderness along the…medial femoral condyle
		Tenderness along the…medial patella edge
		Tenderness over the…hamstring donor sites
		Tenderness over the osteotomy
18	Later surgery	Additional surgeries
		All-reason revision surgery
		Functional failures requiring operations
		Further knee surgery
		Later operations on the knee
		Patellar reoperation rate
		Rate of subsequent patellar-stabilizing surgery
		Recurrent…surgery
		Reoperations
		Reoperation for recurrence

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
		Revision surgery
		Subsequently required surgery
		Surgically stabilized (or reoperation)
54	Patellar dislocation (ipsilateral leg)	Episode of…dislocation
		Further dislocation
		Graft rupture/failure (MPFL)
		How often the patella has dislocated
		Incidences of recurrent dislocation
		Medial dislocation
		Participants who redislocate their knee
		Patellar dislocations
		Patellar dislocation rates
		Patellar redislocation
		Recurrence of patellar dislocation
		Recurrent dislocation
		Recurrent patella dislocation
		Recurrent patellar instability
		Recurring patellar dislocation
		Redaction in recurrent dislocation of the patella
		Redislocations
		Re-dislocation rates
		Reluxation
7	Patellar dislocation (contralateral leg)	Contralateral dislocations
		Episode of patellar dislocation in the contralateral leg
		LPD (lateral patellar dislocation) on the contralateral knee
		Patellofemoral instability of the contralateral knee (i.e., patellar dislocation)
		Patellar dislocation…on the contralateral leg
25	Patellar subluxation (ipsilateral leg)	Episodes of instability (separate outcome to ipsilateral dislocation)
		Incomplete lateral patellar redislocation and instability without a true dislocation
		Medial…subluxation
		Multiple episodes of patellar instability (separate outcome to ipsilateral dislocation)
		Partially…kneecap dislocations
		Patellar subluxation
		Patient-reported episode of subluxation
		Persistent instability (separate outcome to ipsilateral dislocation)

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
		Recurrence of patellar…instability (separate outcome to ipsilateral dislocation)
		Recurrent subluxation
		Signs of subluxation
		Signs of subluxation without recurrence
		Subjective sensation of subluxation
		Subluxation
		Subluxation rate
		Subluxation sensation
5	Patellar subluxation (contralateral leg)	At least 2 episodes of patellar instability on the contralateral leg (separate outcome to contralateral dislocation)
		Patellar instability on the contralateral leg (separate outcome to contralateral dislocation)
		Patellofemoral instability of the contralateral knee (i.e., history of subluxations)
1	Time to adverse event(s)	Time interval from MPFL surgery to occurring complication
2	Time to later surgery	Time interval from the MPFL surgery to revision surgery
		Time to MPFL reconstruction
5	Time to patellar dislocation (ipsilateral leg)	Time of dislocations
		Time from the first LPD to recurrence
		Time from the primary traumatic patellar dislocation to a redislocation
		Time to first re-dislocation
Biomarkers of cartilage degradation outcomes		
1	MRI T1 rho relaxation time	MRI T1ρ…relaxation time
1	MRI T2 relaxation time	MRI…T2 relaxation time
1	C-terminal cross-linked telopeptides of type II collagen	Urinary C-terminal cross-linked telopeptide type II collagen
1	Neoepitope of collagen cleavage	Neoepitope of type I…collagen cleavage
		Neoepitope of…type II collagen cleavage
Blood biochemistry outcomes		
1	Fibrin concentration	Fibrin
1	Fibrinogen concentration	Fibrinogen
General health-related quality of life outcomes		
10	General health-related quality of life	EQ-5D-5L
		EQ-5D-Y
		EuroQol-5D-5L
		12-Item Short Form Survey score
		SF-12 score

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
		Short-Form 12
		Short Form-36
		WHOQOL-bref
Healthcare resource use outcomes		
1	Duration of physiotherapy treatment	Duration…of out-patient physiotherapy treatment
2	Healthcare resource use	Resource use
		Resources used by interventions
1	Hospital length of stay	Hospitalization time
2	Number of physiotherapy sessions	Number of physiotherapy sessions
		Physio appointments
3	Operation time	Duration of operating procedure
		Operation time
1	Pain medication use	Total rescue analgesic consumption
Knee symptoms and/or physical function outcomes		
1	Anterior cruciate ligament quality of life (ACL-QOL) score	Anterior cruciate ligament (ACL) Quality of Life Score
7	Banff Patella Instability Instrument	Banff-II-score
		Banff Patellar Instability Instrument (BPII)
		Banff Patellar Instability Index (BPII)
		Banff Patellofemoral Instability-Instrument (BPII) 2.0
		Banff Patellofemoral Instability Instrument (BPII 2.0)
1	Crosby-Insall grading system	Crosby–Insall grading system
1	Donor site morbidity questionnaire	Donor site morbidity score
1	Fulkerson scale	Fulkerson score
16	IKDC Subjective Knee Form	IKDC-2000
		IKDC score
		International Knee Documentation Committee form
		International Knee Documentation Committee (IKDC) score
		International Knee Documentation Committee: subjective score
		IKDC subjective score
		International Knee Documentation Committee (IKDC) Subjective Knee Evaluation
		Pedi-IKDC
1	KOOS4	Knee Osteoarthritis Outcome Score (KOOS4)
8	KOOS pain subscale	Knee injury and Osteoarthritis Outcome Score (KOOS)[b]
		KOOS-Child pain

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
		KOOS **p**ain
8	KOOS symptoms subscale	Knee injury and Osteoarthritis Outcome Score (KOOS) [b]
		KOOS-Child symptoms
		KOOS symptoms
8	KOOS activities of daily living subscale	Knee injury and Osteoarthritis Outcome Score (KOOS)[b]
		KOOS activities of daily living
		KOOS ADL
		KOOS-Child ADL
		KOOS function in daily living activities
9	KOOS sport and recreation subscale	Knee injury and Osteoarthritis Outcome Score (KOOS) [b]
		KOOS-Child sport/play
		KOOS function in sports and recreation
		KOOS sports
		KOOS sports and recreation
		KOOS sport/rec
9	KOOS quality of life subscale	Knee injury and Osteoarthritis Outcome Score (KOOS)**[b]**
		KOOS-Child QOL
		KOOS knee-related quality of life
		KOOS QoL
		KOOS quality of life
1	KOOS patellofemoral pain and osteoarthritis subscale	Knee Injury and Osteoarthritis Outcome Score Patellofemoral questionnaire (KOOS-PF)
50	Kujala Patellofemoral Score	Anterior knee pain scale kujala
		Kujala
		Kujala anterior knee pain scale
		Kujala (anterior knee pain scale)
		Kujala knee pain questionnaire
		Kujala knee score
		Kujala patellofemoral disorder score
		Kujala patellofemoral functional score
		Kujala patellofemoral joint score
		Kujala patellofemoral score
		Kujala questionnaire
		Kujala scale
		Kujala score
		Kujal score
		Kujala score of the knee
		Kujala scoring questionnaire

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
1	Larsen and Lauridsen Criteria	Knee function (score according to Larsen and Lauridsen)
2	Lower Extremity Functional Scale	LEFS
		LEFS questionnaire (Lower Extremity Functional Scale)
33	Lysholm Knee Scoring Scale	Lysholm
		Lysholm II score
		Lysholm knee functional score
		Lysholm knee score
		Lysholm knee scoring scale
		Lysholm score
		Lysholm score of the knee
		Modified Tegner-Lysholm score
1	Modified Cincinnati Knee Rating System	Modified Cincinnati knee rating system
1	Modified Functional Index Questionnaire	Modified functional index questionnaire
1	Modified Hughston Clinic Questionnaire	Hughston VAS (visual analog scale) knee score
8	Norwich Patellar Instability Score	Nich patellar instability (NPI)
		Norwich Patellar Instability questionnaire
		Norwich Patellar Instability Scale
		Norwich Patellar Instability (NPI) score
		Norwich Patellar Instability Score
1	Oxford Knee Score – Activity and Participation Questionnaire	Oxford Knee Score – Activity and Participation Questionnaire (OKS-APQ)
19	Pain intensity	Knee joint pain
		Pain
		Pain at rest
		Pain intensity
		Pain level
		Post-operative knee pain
		Numerical Pain Rating Scale (NPRS) at rest
		Numerical Rating Scale (NRS-pain score)
1	Pain intensity after activity	Post exercise pain
3	Pain intensity during activity	Numerical Pain Rating Scale (NPRS) at…effort
		Pain (on movement)
		Pain (on flexion)
		Subjective pain...during activity

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
1	Patient-reported knee pain and function	Subjective assessments of pain and functional knee limitations in daily living and sports activities (study-specific questionnaire)
2	Patient-rated overall change	Patient global impression of change
		Self-reported global assessment of change
2	Patient-rated overall outcome	Subjective result
		Patient's own overall opinion
4	Patient-rated knee function	Functional assessment (study-specific questionnaire)
		Functional outcome (VAS score)
		Knee function (study-specific questionnaire)
1	Patient-rated lower limb muscle weakness	Subjective symptoms of…weakness in the affected lower limb
1	Patient-rated knee joint stiffness	Subjective symptoms of knee stiffness…in the affected lower limb
2	Patient-reported patellar insecurity	Insecurity visual analog scale
		Lack of trust in the knee
3	Physical activity level and frequency	Noyes sports activity rating scale
		Modified version of the Marx Score
		Hospital for Special Surgery Pediatric Functional Activity Brief Scale
1	PROMIS Pain Interference	Patient-Reported Outcome Measurement Information System (PROMIS) pain interference
1	PROMIS Physical Function	Patient-Reported Outcome Measurement Information System (PROMIS) Physical Function
25	Tegner Activity Score	Activity score according to Tegner and Lysholm
		Lysholm-Tegner (activity score)
		Tegner activity level
		Tegner activity level scale
		Tegner activity scale
		Tegner activity score
		Tegner level of activity score
		Tegner score
		Tegner score of the knee
5	Return to pre-injury physical activity	Returned to full activity
		Returned to…preinjury level of sport
		Returning to sports
		Return to sports
		Return to their previous level of physical activity
3	Time to return to pre-injury physical activity	Time to return to full activity or sports
		Time to returning to…sporting activities
		Time to...return to sports

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
1	Victorian Institute of Sport Assessment-Patella	Victorian Institute of Sport Assessment-Patella (VISA-P)
Patient satisfaction outcomes		
10	Patient-reported satisfaction with treatment	General satisfaction with treatment
		Inpatient **s**atisfaction **q**uestionnaire
		Overall satisfaction with the procedure
		Patient satisfaction
		Patients' satisfaction with the brace
		Patient subjective satisfaction
		Satisfaction
		Subjective patient satisfaction
		Satisfaction with treatment
Physical examination related outcomes		
21	Apprehension to lateral patellar translation	Apprehension
		Apprehension sign
		Apprehension sign +
		Apprehension test
		Apprehension to lateralization of the patella
		Patella stability (assessed by apprehension test)
		Patellar apprehension
		Positive apprehension sign
		Patellar apprehension test
		Positive apprehension
		Positive apprehension test
		Rate of positive patellar apprehension
2	Knee joint swelling	Edema assessment
		Knee swelling
5	Lateral patellar translation end feel	Soft versus firm end point to lateral patellar translation
		Soft versus firm end point to patellar lateral shift
8	Lateral patellar translation distance	Lateral patellar translation grade
		Objective patella lateralization at full extension
		Patellar lateral shift
1	Medial patellar translation distance	Medial patellar glide test
1	Patellar tilt	Patellar tilt at rest
1	Patellar tracking	Percentage of participants with patellar J sign
1	Presence of patellofemoral crepitus	Patellofemoral crepitus
6	Thigh muscle mass	Girth of the quadriceps femoris muscle
		Thigh hypotrophy

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
		Quadriceps muscle atrophy
		Quadriceps muscle volume
		Reduction in thigh muscle circumference
Physical performance outcomes		
1	Ability to straight leg raise	Straight leg raising
1	Gait analysis -unspecified	Index of gait analysis
1	Hip abductor muscle strength	Hip muscle strength (hip abduction)
1	Hip external rotator muscle strength	Hip muscle strength (hip external rotation)
1	Knee adduction excursion during dynamic task (limb symmetry)	Knee adduction excursion...during walking (limb symmetry)
		Knee adduction excursion…during…running (limb symmetry)
		Knee adduction excursion...during…anterior step downs (limb symmetry)
1	Knee adduction moment during dynamic task (limb symmetry)	Knee adduction moment…during walking (limb symmetry)
		Knee adduction moment…during…running (limb symmetry)
		Knee adduction moment…during…anterior step downs (limb symmetry)
3	Knee extension range of movement	Active...extension range of the affected knee
		Passive knee extension
		Passive range of motion (extension)
1	Knee extensor moment during dynamic task (limb symmetry)	Knee extensor moment…during walking (limb symmetry)
		Knee extensor moment…during…running (limb symmetry)
		Knee extensor moment…during…anterior step downs (limb symmetry)
1	Knee flexion excursion during dynamic task (limb symmetry)	Knee flexion excursion…during walking (limb symmetry)
		Knee flexion excursion…during…running (limb symmetry)
		Knee flexion excursion…during…anterior step downs (limb symmetry)
5	Knee flexion range of movement	Active flexion... range of the affected knee
		Active knee flexion
		Passive range of motion (flexion)
		Range of motion of the knee (knee flexion)
		Regain of knee flexion
7	Knee range of movement - movement unspecified	Knee joint range of motion
		Knee range of motion
		Knee ROM
		Range of knee motion
		Range of motion of the knee

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
		ROM of the affected knee
1	Lower limb kinematics during dynamic task (limb symmetry)	Kinematics (during) walking trials on the walkway with embedded force plates (asymmetry index)
		Kinematics (during) walking on the treadmill at 0% slope (asymmetry index)
		Kinematics (during) downhill treadmill walking (asymmetry index)
		Kinematics (during) uphill…treadmill walking (asymmetry index)
		Kinematics (during) preferred running speed (asymmetry index)
		Kinematics (during) a single-leg vertical drop landing (asymmetry index)
1	Lower limb kinetics during dynamic task (limb symmetry)	Pressure data (during) walking trials on the walkway with embedded force plates (asymmetry index)
		Pressure data (during) walking on the treadmill at 0% slope (asymmetry index)
		Pressure data (during) downhill treadmill walking (asymmetry index)
		Pressure data (during) uphill…treadmill walking (asymmetry index)
		Pressure data (during) preferred running speed (asymmetry index)
		Pressure data (during) a single-leg vertical drop landing (asymmetry index)
1	Manually tested knee extensor muscle strength (ipsilateral leg)	Quadriceps strength (level 0–5) of the injured limb
1	Objective hip muscle strength - movement unspecified	hip...muscle strength (isometric dynamometer)
5	Objective knee extensor muscle strength (ipsilateral leg)	Isokinetic concentric peak torque quadriceps…injured knee
		Quadriceps strength (biodex)
		Isokinetic strength (affected side knee extension)
		Quadriceps muscle strength (isometric dynamometer)
		Isometric knee extensor muscle strength
1	Objective knee extensor muscle strength (contralateral leg)	Isokinetic concentric peak torque quadriceps…uninjured knee
4	Objective knee extensor muscle strength (limb symmetry)	Isokinetic concentric peak torque quadriceps (limb symmetry index)
		Isokinetic extension (asymmetry index)
		Quadriceps strength symmetry (isometric)
		Quadriceps strength symmetry (isokinetic)

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
		Quadriceps activation…results of the operated side were compared with those of the non-operated side and the percentage deficit was recorded (IsoMed2000 dynamometer)
2	Objective knee flexor muscle strength (ipsilateral leg)	Isokinetic concentric peak torque hamstring…injured knee
		Isokinetic strength…affected side knee flexion
1	Objective knee flexor muscle strength (contralateral leg)	Isokinetic concentric peak torque hamstring… uninjured knee
3	Objective knee flexor muscle strength (limb symmetry)	Isokinetic concentric peak torque hamstring… (limb symmetry index)
		Isokinetic flexion (asymmetry index)
		hamstring activation…results of the operated side were compared with those of the non-operated side and the percentage deficit was recorded (IsoMed2000 dynamometer)
1	Objective muscle strength - unspecified	Strength (isometric dynamometry)
1	Single leg 6-metre timed hop (limb symmetry)	6-metre timed hop (limb symmetry index)
1	Single leg cross-over hop for distance (limb symmetry)	Crossover hop for distance (limb symmetry index)
1	Single leg hop test battery - unspecified (limb symmetry)	Limb Symmetry Index on 4 single-leg hop test battery
2	Single leg maximum hop for distance (ipsilateral leg)	1-legged hop for distance (injured knee)
		Hop-for-distance
1	Single leg maximum hop for distance (contralateral leg)	1-legged hop for distance (uninjured knee)
3	Single leg maximum hop for distance (limb symmetry)	1-legged hop for distance limb (symmetry index)
		One-leg hop (quotient between the best distance for the injured and the uninjured side)
		Single leg hop for distance (limb symmetry index)
1	Single leg side hop test (ipsilateral leg)	Side hop test (injured knee)
1	Single leg side hop test (contralateral leg)	Side hop test (uninjured knee)
1	Single leg side hop test (limb symmetry)	Side hop test (limb symmetry index)
1	Single leg triple hop for distance (limb symmetry)	Triple hop for distance (limb symmetry index)
1	Single-limb mini squat test (ipsilateral leg)	Single-limb 30-second mini-squat (injured knee)
1	Single-limb mini squat test (contralateral leg)	Single-limb 30-second mini-squat (uninjured knee)

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
1	Single-limb mini squat test (limb symmetry)	Single-limb 30-second mini-squat (limb symmetry index)
1	Timed double leg squats	Maximum number of squat-downs within one minute
1	Timed figure of eight run	Figure-of-8 run
1	Timing of lower limb muscle activity during dynamic task (limb symmetry)	EMG data (during) walking trials on the walkway with embedded force plates (asymmetry index)
		EMG data (during) walking on the treadmill at 0% slope (asymmetry index)
		EMG data (during) downhill treadmill walking (asymmetry index)
		EMG data (during) uphill…treadmill walking (asymmetry index)
		EMG data (during) preferred running speed (asymmetry index)
		EMG data (during) a single-leg vertical drop landing (asymmetry index)
1	Walking distance	Walking distance
1	Walking time	Ambulation time
1	Y balance test	Y balance scores
Radiological outcomes (all assessed by imaging modalities e.g., MRI, X-ray etc.)		
4	Knee joint structural changes	Femoral chondral lesion
		Joint degeneration
		Outerbridge grade of any cartilage lesions
		Patellar chondral lesion
		Patellofemoral osteoarthrosis progression
		Severity of osteoarthrosis in patellofemoral joint
13	Lateral patellar position	Lateral displacement
		Lateral patellar displacement
		Lateral patellar translation
		Lateral shift ratio
		Patellar lateral shift
11	Lateral patellofemoral angle	Lateral patellofemoral angle
		Lateral patellar angle
2	MPFL graft integrity	Graft integration and maturation
		Laxity or insufficiency of the graft
6	Patellar height	Caton-deschamps index
		Insall-Salvati index
		Insall-Salvati ratio
		Patellar height (tendon length/patellar length)
		Patellar height (Blackburn and Peel)
		Patella-trochlea distance

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
23	Patellar tilt	Patellar tilt
		Patellar tilt angle
		Patellar tilt angle (quadriceps contracted)
		Patellar tilt angle (quadriceps relaxed)
		Patellar tilt with the quadriceps contracted
		Patellar tilt with the quadriceps relaxed
17	Patellofemoral joint congruence	Congruence angle
		Congruence angle (quadriceps contracted)
		Congruence angle (quadriceps relaxed)
		Congruence of the lateral patellofemoral articular surface
		Patellar congruence angle
1	Quadriceps angle	Q angle
1	Sulcus angle	Sulcus angle
1	Surgical patellar tunnel length	The ideal (patellar bone) canal length minus the actual canal length
1	Surgical patellar tunnel location	Distance between the ideal (patellar tunnel) entrance and the actual entrance
1	Surgical prepatellar tunnel cortical thickness	The ideal prepatellar cortical thickness minus the actual prepatellar cortical thickness
1	Surgical femoral tunnel location	Distance between the center of femoral tunnel and Schottle point
8	Tibial tuberosity to trochlear groove distance	Tibial tubercle-trochlear groove
		Tibial tuberosity-trochlear groove distance
		TT-TG distance
		TT-TG (line between tibial tuberosity and trochlear groove)
		Tuberositas-tibiae-trochlea-groove distance
Return to work and education outcomes		
1	Cincinnati Occupational Rating Scale	Cincinnati Occupational Rating Scale
1	Return to education	Education status
2	Return to work	Absent from work
		Work…status
1	Time to return to education	Time to return to…school
2	Time to return to work	Time to return to work
		Time to returning to work
Other outcomes		
1	Bespoke multi-domain questionnaire	Subjective feeling questionnaire (study-specific questionnaire)
1	Exercise adherence	Exercise compliance
1	Intraoperative blood loss	Intraoperative blood loss

Frequency outcome measured (n = studies)	Unique outcome name	Extracted verbatim outcome[a]
1	Length of surgical incision	Incision length
1	Medial retinaculum healing time	Redaction in healing time (MPFL)
1	Modified Grana and O'Donoghue rating system	Rating system of Grana and O'Donoghue grading…with the exception that crepitus was not graded
1	PROMIS Depression	Patient-Reported Outcome Measurement Information System (PROMIS) depression
1	PROMIS Short Form - Satisfaction with Social Roles and Activities 4a	PROMIS Satisfaction with Social Roles and Activities 4a Short Form
1	Sleep quality	Sleep quality
1	Time to first pain medication request	Time for first analgesic request

IKDC: International Knee Documentation Committee; KOOS: Knee injury and Osteoarthritis Outcome Score; MPFL: medial patellofemoral ligament; MRI: magnetic resonance imaging; PROMIS: Patient-Reported Outcomes Measurement Information System

[a]For clarity, additional relevant information has been provided in brackets after verbatim outcomes.

[b]Two trial registry records reported measuring the KOOS but did not specify which subscales, so it was inferred all KOOS subscales were being measured.

Appendix 10 How new patellar dislocations were defined and measured as an outcome

Authors (publication year)	Definition	Measurement method
		Clinical examination
ACTRN12619000778189	NR	Participants reviewed by a surgeon at follow-up timepoints and results recorded in the surgeon's notes
Askenberger et al (2018)	Participants advised to contact the study team if they have any problems with their knee or a redislocation. Patellar dislocation confirmed by a physical and radiological examination	See adjacent cell
Damasena et al (2016)	NR	Clinical evaluation at each follow-up timepoint
Ercan et al (2021)	NR	Evaluation by a surgeon
Ji et al (2017)	Defined as a complete loss of congruence between the patella and trochlea during the patellar apprehension test	See adjacent cell
Kang et al (2013)	Patella moves 3 quadrants with a soft end point or translates greater than 3 quadrants during the patellar apprehension test at 30º knee flexion	See adjacent cell
Kang et al (2016)	Complete loss of congruence between the patella and trochlea during the patellar apprehension test	See adjacent cell
Liu et al[a] (2018)	Patella moves 4 quadrants medially during the medial patellar glide test at 30º knee flexion	See adjacent cell
Qiao et al (2022)	NR	Physical examination
		Participant and/or clinician reported
ACTRN12612000366853	Documented by a health professional or convincing participant account of a full dislocation	See adjacent cell
Honkonen et al (2022)	Participant-reported complete lateral dislocation of the patella	Assessed at follow-up visits and participants encouraged to contact the study surgeons if a redislocation occurred
Bartsch et al (2022)	NR	Participant's recall at post operative follow-ups
Li et al (2019)	NR	Subjectively assessed at follow-up timepoints
Lind et al (2019)	NR	At follow-up visits information was obtained on incidences of recurrent dislocation

Authors (publication year)	Definition	Measurement method
NCT05706363	NR	Question about how often the patella has dislocated after surgery (no dislocation, 1-2 dislocations, more dislocations)
NCT02333825	Participant-reported feeling of dissociation of the patellar from the trochlear groove and the patella needs a change in position or force (i.e. extending the knee or applying a medial force on the patella) to reduce it	NR
Petri (2013)	NR	Participant-reported follow-up questionnaire
Rahman et al (2020)	NR	Participant-reported follow-up questionnaire
Smith et al (2015)	Required accident and emergency attendance or healthcare management	Data collected by a physiotherapist, blinded to allocation, in each centre at follow-up timepoints
Straume-Næsheim et al (2022)	Participants asked at the outpatient orthopaedic clinic 'have you experienced any events of partially or complete kneecap dislocations'? Answer options were Yes or No	See adjacent cell
Xie et al (2012)	NR	Participants informed to report to the senior surgeon any recurrence (dislocation or instability) and any dislocations were subjectively assessed at each follow-up timepoint
Zhao et al (2012)	NR	By correspondence, e-mail, or telephone review for participants who had surgery ≥3 years ago
Zhao et al[b] (2012)	NR	Subjectively assessed at each follow-up timepoint
		Other
Bitar et al (2012)	Required a further visit to a physician or hospital	NR
Camanho et al (2009)	Complete loss of congruence between the patella and trochlea	Participants allocated to surgery examined at least every 6 months and questioned about occurrence of dislocations but it was unclear if this also applied to non-surgical participants
Liebensteiner et al (2021)	NR	Participants are interviewed by telephone each month in addition to visits at 6 and 12 months post operatively and then yearly
NCT02185001	Complete loss of congruence between the patella and trochlea	NR
Nikku et al (1997)	NR	Examination at two years then telephone interview at later follow-up timepoints
Regalado et al (2016)	NR	Unspecified clinical and functional assessment at 3 years and functional assessment by telephone interview at 6 years

Authors (publication year)	Definition	Measurement method
RBR-8kf6ks	Requires emergency care	NR

NR: Not reported; UC: unclear
[a]This definition is also used for a medial subluxation elsewhere in the study report.
[b]Both medial and lateral dislocations measured.

Appendix 11 Interview topic guide

PRePPeD: Physiotherapy Rehabilitation Post Patellar Dislocation

Interview Topic Guide

This is a topic guide, which is flexible to allow questions to derive from the participant's responses. Topics arising in the interviews will be added to the topic guide for the following interviews.

The key questions will be: 1) what has it been like since your knee injury? 2) what did you think about the treatment/advice/exercises you received for your knee injury? 3) what was it like being part of the PRePPeD study (or being asked to take part in the PRePPeD study)? 4.) What was filling in the study questionnaires online/on paper like?

If required, prompts might be:

Recovery

Can you tell me about your knee injury?

What was it like in the early stages after your injury?

How do you feel about your recovery?

Have you returned to everything you used to do before your injury?

Do you have full confidence in your injured knee?

Do you think about what your knee will be like in the future?

Study

How did you find out about the study?

What did you think when you were asked about taking part?

When you were told about the study, was there anything you thought was good or bad about that?

What helped you decide to take part/not take part?

*Would you change anything about the study to improve it for other participants?

What do you think about the study now?

Treatment

Can you tell me about the treatment/advice/physiotherapy you had for your knee injury?

Did you get any advice about how you could help yourself get better?

What do you think about the advice you got?

What did you think about the exercises you were given?

How do/did you fit the exercises into your day or life?

Have you done the exercises as often as you were advised/your physiotherapist recommended?

Do you do any of the exercises you were given now?

What did you think about your treatment/advice/physiotherapy?

Was there anything you thought was particularly good or bad?

Is there anything about the treatment/advice/physiotherapy you would like to change?

Follow-up

*How did you find the study questionnaires/paperwork?

Conclusion

Is there anything else you would like to tell me?

*Does not apply to people who declined to participate in the PRePPeD pilot RCT

Appendix 12 CONSORT checklist for reporting pilot and feasibility trials

Reproduced from: Eldridge SM et al. CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. BMJ 2016;355:i5239.

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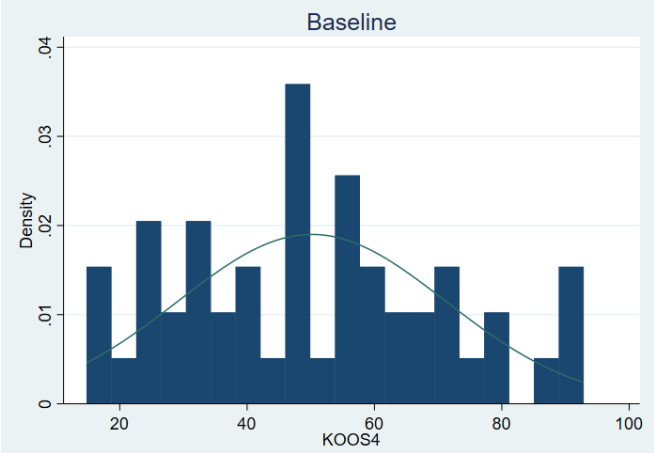
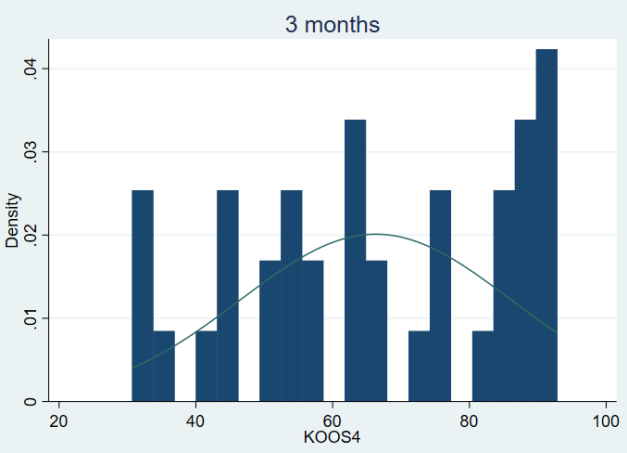
Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	NA
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	NA
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	7-12
	2b	Specific objectives or research questions for pilot trial	72
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	72
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	74-76
	4b	Settings and locations where the data were collected	99-100
	4c	How participants were identified and consented	75-77
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	28-40
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	78
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	59

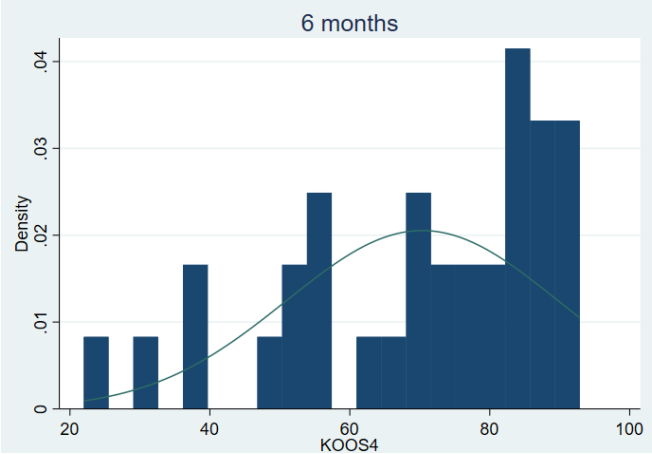
Section/Topic	Item No	Checklist item	Reported on page No
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	79-80
Sample size	7a	Rationale for numbers in the pilot trial	86
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence Generation	8a	Method used to generate the random allocation sequence	77
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	77
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	77
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	77
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	78
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	78-83
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	1002
	13b	For each group, losses and exclusions after randomisation, together with reasons	102
Recruitment	14a	Dates defining the periods of recruitment and follow-up	100-101
	14b	Why the pilot trial ended or was stopped	100-101
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	105-107
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	107-111

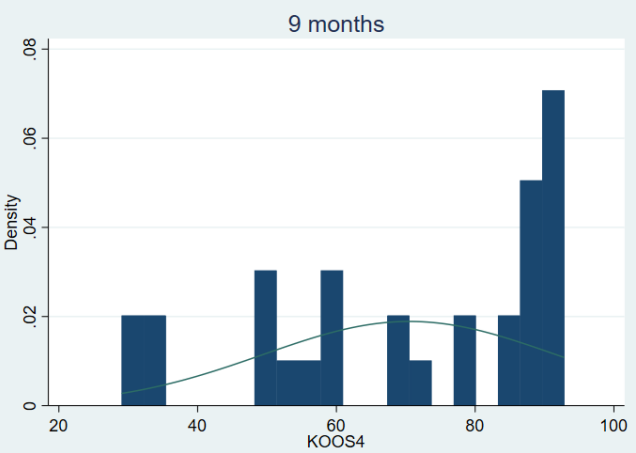
Section/Topic	Item No	Checklist item	Reported on page No
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	107-111
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	112-122
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	116-117
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	126-127
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	13-127, 153-158
--Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	123-127
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	153-158
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	72
Protocol	24	Where the pilot trial protocol can be accessed, if available	72
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	NA
	26	Ethical approval or approval by research review committee, confirmed with reference number	95

Appendix 13 Histograms of the KOOS4 at follow-up timepoints









Appendix 14 Qualitative study themes, categories and examples of supporting participant quotations

Theme	Category	Quotation (assigned code)
Coming to terms with the initial injury	Physical response to the initial injury	*P6 (36 year-old female with a recurrent dislocation) I was trying to correct my breathing* *CF Yeah* *P6 Because I had actually – I think I was, at the beginning having a panic attack and I couldn't breathe very well and my head was pounding and I felt sick, so I was trying to correct all that (panic)* *P2 (17 year-old female with a recurrent dislocation) I felt really sick and then I managed to get it in but it took longer and I couldn't walk much after that. (being or feeling sick)* *P4 (22 year-old male with a recurrent dislocation) I was kind of like, I wasn't very mobile, I could kind of, so I was working from home and I kind of sat on the sofa or like, sat in bed, I didn't walk around too much. Or I would… so initially for the first couple of days we have a shop complex, it's like only 200 metres away maybe so I'd walk to there and back and stuff but yes I certainly wasn't doing much exercise. (impact of impaired mobility)*
	Emotional response to the initial injury	*P3 (16 year-old male with a first-time dislocation) I was just like standing, I wasn't doing anything I was standing still and then my knee just like well dislocated I guess. (mechanism of injury)* *P7 (36 year-old female with a recurrent dislocation) So I think this time round I think I was literally just going to sit on the bed to lean across to get my phone and half my body went one way and then my leg went the other way…So it took me by surprise because it hadn't given me any issues for so long, so yeah it did shock me that it did come out. (shock)* *P8 (33 year-old female with a recurrent dislocation) Frustrating because I couldn't do anything and my leg was stuck in full extension. I couldn't drive, I could just about walk. They gave me crutches because they said, if you can, don't weight bear through that leg and I was thinking oh my god I don't know how I'm going to do this. My husband works long hours, he's a [name of husband's job] and so he's out early in the morning, and he gets back late and so it suddenly impacted on my husband, my in-laws and my parents. And I'm very independent and very self-sufficient and so it was more frustrating than anything. (concern for the practical implications of the injury)*
Regaining my former self	Getting better	*P1 (19 year-old female with a first-time dislocation) I think to begin with it was very daunting because I've never been to physio before, but I was quite excited to actually do something about my knee instead of just waiting for it to sort itself out, like actively do something, so that was really good. (being proactive)* *CF What kind of helped you to kind of get up and go?*

		P7 (36 year-old female with a recurrent dislocation) Probably my little girl really and the puppy and I didn't want to be just lying around not doing anything or have people waiting on me. Yes, I think I just wanted to get the strength back and confidence as well because I was worried it was going to happen again. (return to normal life)
	Looking to the future	*P4 (22 year-old male with a recurrent dislocation) Well I feel a bit wary as I've said, just because it happened out of nowhere last time, it could happen again. I do feel, like, stronger that the muscles around it now are stronger now than when I did the injury, so yes, I do feel in an alright position. (wary)* *P7 (36 year-old female with a recurrent dislocation) Yes, I think it's something that I can't change apart from just keeping trying to build the strength up because it was only something so slight that made it dislocate last time. I think it's also realising that loads of stuff I was doing before was helping. I didn't even think about the gym, and just different exercise and weight loss or anything like that. (acceptance that knee will not fully recover)* *CF So then going forward looking to the future, how do you feel about the future and your knee?* *P8 (33 year-old female with a recurrent dislocation) Really like positive about it and hopeful. I think I've been given tools and strategies now to self-manage. I wish in a way I'd done this process sort of fifteen/sixteen years ago when it first happened because having that education earlier probably would have helped and I guess that's just something for me to take away. (empowered)*
Acceptability of the interventions to participants	Supervised and self-managed rehabilitation	*P1 (19 year-old female with a first-time dislocation) When he said I could get back to the gym, this is like a couple of months ago and I was like, nah, that's not going to happen. Obviously because of my financial situation I was unable to but I would have if I was in the right position, so that was really good advice because that gave me more confidence. I think most of the advice he has given me has given me a lot of confidence, I don't think there was any bad advice he's given me. (physio provides reassurance)* *P6 (36 year-old female with a recurrent dislocation) It's kind of like having somebody there to, like, that you've got to answer to type of thing. So, you've got to say whether you've been doing them and they don't actually know. So, you're less likely to not do the exercises if that makes sense? (being monitored was motivating)*
	Intervention workbooks	*P5 (16 year-old male with a first-time dislocation) I watched one video, I can't remember what the video was and I did the exercises and I was like right, this was taking longer than using the paper so I just used the paper. (thoughts about the online materials)* *P7 (36 year-old female with a recurrent dislocation) I thought it was handy because it had different exercises and setting some goals as well for what I wanted to achieve. Yeah, I think it gave it a bit more structure as well. Yeah, I didn't find it daunting. (workbook formatting)* *P8 (33 year-old female with a recurrent dislocation) Well I quite like folders and bits of paper, so I was quite excited by it personally which I know sounds very sad but it didn't overwhelm me, it didn't daunt me. I guess I was*

		really grateful to have really clear pictures and instructions and guidance on how to do it and what to do. So I was grateful for it more than anything. (workbook formatting)
Acceptability of the follow-up methods to participants	A straightforward process	*P1 (19 year-old female with a first-time dislocation) I thought oh alright I don't mind doing that, it won't take long. I've done questionnaires all my life so it didn't faze me at all. I thought I might as well see what's changed because you don't realise until you have something in front of you to see how far you've come. (process of completing questionnaires)* *P4 (22 year-old male with a recurrent dislocation) It was fine really. I remember they only took me like five to ten minute to go through. I found some of the questions to be just a little repetitive, not that they were exact repeats but were very similar questions, but I found it quite interesting to fill in. (process of completing questionnaires)* *P8 (33 year-old female with a recurrent dislocation) But it was really quick to do and easy and it was good, it gave me time to kind of reflect on what things were like. (process of completing questionnaires)*
	Outcomes assessed	*CF Just in terms of your recovery what are the most important things for you?* *P3 (16 year-old male with a first-time dislocation) Just to be able to get back to what I was doing before.* *CF So is that in terms of activities or ….?* *P3 Just general day to day things I guess (outcomes measured were appropriate)*
	An opportunity for reflection	*P6 (36 year-old female with a recurrent dislocation) Obviously the fact that there's like questionnaires quite often to see how things have changed and stuff it allows me to look back on how my recovery's been as well. (questionnaires helped monitor recovery)*

Appendix 15 Publications during this DPhil

Publications related to this DPhil

Chapter 4

Forde C, Costa ML, Cook JA, Tutton E, Appelbe D, Franssen M, Barker R, Keene DJ. Physiotherapy Rehabilitation Post Patellar Dislocation (PRePPeD)—protocol for an external pilot randomised controlled trial and qualitative study comparing supervised versus self-managed rehabilitation for people after acute patellar dislocation. *Pilot and Feasibility Studies*. 2023 Jul 10;9(1):119.

Other publications

Keene, D. J., Achten, J., **Forde, C.,** Png, M. E., Grant, R., Draper, K., Appelbe, D., Tutton, E., Peckham, N., Dutton, S. J., Lamb, S. E., & Costa, M. L. (2024). Effectiveness of supervised versus self-directed rehabilitation for adults aged 50 years and over with ankle fractures: protocol for the AFTER trial. *Bone & Joint Open*, *5*(6), 499–513. https://doi.org/10.1302/2633-1462

Forde C, Nicolson PJ, Vye C, Pun JC, Sheehan W, Costa ML, Lamb SE, Keene DJ. Lower limb muscle strength and balance in older adults with a distal radius fracture: a systematic review. *BMC Musculoskeletal Disorders.* 2023 Sep 18;24(1):741.

Manuscripts related to this DPhil submitted for publication

Chapter 2

Forde C, Costa ML, Tutton E, Cook JA, Keene DJ. Development of the rehabilitation interventions for people with an acute patellar dislocation in the PRePPeD (Physiotherapy Rehabilitation Post Patellar Dislocation) pilot randomised controlled trial. Under review.

Other manuscripts submitted during this DPhil

Forde C, Costa ML, Achten J, Grant R, Lamb SE, Keene DJ. Development and delivery of the rehabilitation interventions for older adults with an ankle fracture in the AFTER (Ankle Fracture Treatment Enhancing Rehabilitation) trial. Under review.

Appendix 16 Presentations during this DPhil

Presentations related to this thesis

Chapter 3

Forde C, Mortimer C, Costa ML, Cook JA, Tutton E, Smith TO, Minty P, Lucas G, Keene DJ. A systematic review of outcomes used in trials evaluating treatments for people with a patellar dislocation. *International Clinical Trials Methodology Conference.* 2024. Poster presentation.

Chapters 4-6

Forde C, Costa ML, Cook JA, Tutton E, Franssen M, Appelbe D, Keene DJ. Physiotherapy Rehabilitation Post Patellar Dislocation (PRePPeD): a pilot randomised controlled trial and qualitative study. *British Orthopaedic Association Annual Congress.* 2024. Oral presentation.

Forde C, Costa ML, Cook JA, Tutton E, Franssen M, Appelbe D, Keene DJ. Physiotherapy Rehabilitation Post Patellar Dislocation (PRePPeD): a pilot randomised controlled trial and qualitative study. *Oxford University Hospitals NHS Foundation Trust NMAHPPS conference*. 2024. Oral presentation.

Forde C, Costa ML, Cook JA, Tutton E, Franssen M, Appelbe D, Keene DJ Physiotherapy Rehabilitation Post Patellar Dislocation (PRePPeD): an external pilot randomised controlled trial and qualitative study. *Oxfordshire Councial for Allied Health Professions Research.* 2023. Oral presentation.

Forde C, Costa ML, Cook JA, Tutton E, Appelbe D, Franssen M, Barker R, Keene DJ. Physiotherapy Rehabilitation Post Patellar Dislocation (PRePPeD): a pilot randomised controlled trial and qualitative study. *Physiotherapy Research Society.* 2023. Poster presentation.

Other presentations

Forde C, Achten J, Herbert K, Dutton SJ, Marian IR, Gould J, Grant R, Costa ML, Keene DJ. Grip strength measurements at home: are self-administered measurements feasible? *International Clinical Trials Methodology Conference 2022*. Poster presentation.

Appendix 17 Prizes and research funding awarded during this DPhil

Prizes

Botnar Institute Student Symposium, June 2024–runner up in 3rd year oral presentations

Grants awarded

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Appendix 18 Acknowledgements

Chapter	Task	Performed by
Chapter 2: intervention development and description	Intervention website build	DA
	Intervention feedback	AG, CM, CR, TOS, MM, GS
	Reviewed search strategies	NWR
Chapter 3: systematic review	Reviewed search strategy	KS
	Checked personal files for potentially eligible records	CF, TOS
	Independently screened titles and abstracts	CF all; CM, PM, and GL one third each
	Independently screened the full texts of potentially eligible record	CF all; CM, PM, and GL one third each
	Independent data extraction	CF and CM
	Independently identified and named unique outcomes	CF and CM
Chapter 5: pilot RCT results	REDCap database build	DA
	Trial management support	MF
Chapter 6: embedded qualitative study results	Transcribed qualitative interviews	CB

AG: Andy Green; CB: Chris Bouse; CM: Crispin Mortimer; CR: Claire Robertson; DA: Duncan Appelbe; GL: Georgina Lucas; GS: Genevieve Simpson; KS: Kat Steiner; MF: Marloes Franssen; MM: Michelle Moynihan; NWR: Nia Wyn Roberts; PM: Paul Minty; TOS: Toby O Smith
Does not include tasks performed by supervisors which are described in the thesis.