Oxford University Hospitals
NHS Foundation Trust

CITY
UNIVERSITY OF LONDON
EST 1894

Study protocol

Individualised exercise for adults with an acute lateral patellar dislocation: a feasibility study

Short title: INDEX-KD: INDividualised EXercise for Kneecap Dislocations

Date: 17/12/2018

IRAS ID: 251913

Abbreviations

AE	Adverse Event
CONSORT	Consolidated Standards of Reporting Trials
ED	Emergency Department
GCP	Good Clinical Practice
HCPC	Health and Care Professions Council
LPD	Lateral Patellar Dislocation
MRC	Medical Research Council
MRI	Magnetic Resonance Imagery
NHS	National Health Service
NIHR	National Institute for Health Research
NPC	New Patient Clinic
PROM	Patient Reported Outcome Measure
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAMPL	Statistical Analyses and Methods in Published Literature
SOP	Standard Operating Procedure
TBC	To be confirmed
TIDieR	Template for Intervention Description and Replication

Contents

SECTION 1. ADMINISTRATIVE INFORMATION

SECTION 1.1 Title

Individualised exercise for adults with an acute lateral patellar dislocation: a feasibility study

SECTION 1.2. World Health Organisation Registration Data Set

Data category	Information
Primary registry and trial identifying number	Clinicaltrials.gov Trial registration number: To be confirmed (TBC)
Date of registration in primary registry	TBC
Source(s) of monetary or material support	MRes Clinical Research National Institute of Health Research (NIHR) Studentship Award
Primary sponsor	City, University of London
Sponsor's reference	MRes/18-19/04
Contact for public queries	Colin Forde Physiotherapy Trauma Outpatients, Level 2, John Radcliffe Hospital, Oxford, United Kingdom, OX3 9DU Tel. 01865 221540 Email: Colin.Forde@ouh.nhs.uk
Contact for scientific queries	Colin Forde Physiotherapy Trauma Outpatients, Level 2, John Radcliffe Hospital, Oxford, United Kingdom, OX3 9DU Tel. 01865 221540 Email : Colin.Forde@ouh.nhs.uk
Public title	INDEX-KD: INDividualised EXercise for Kneecap Dislocations
Scientific title	Individualised exercise for adults with an acute lateral patellar dislocation: a feasibility study
Countries of recruitment	England
Health condition(s) or problem(s) studied	Primary and recurrent lateral patellar dislocation
Intervention:	Participants will be provided with up to 6 sessions of individualised physiotherapy over a maximum duration

	of 3 months. Initially participants will be required to select their activity related goals from treatment. They will then commence a progressive exercise programme focussed on resolving acute knee impairments (i.e. swelling and reduced range of movement), improving lower limb strength and motor control, and facilitating a return to their activity related goals. The exercises chosen will be based on the physiotherapist's assessment, adapted to the participant's physical ability and agreed with the participant. Participants will be required to complete the exercises independently at least 3 times a week. Strategies to increase adherence will also be employed.
Key eligibility criteria	Ages eligible for study: ≥ 16 years of age Sexes eligible for study: both
	Attending the John Radcliffe hospital trauma and orthopaedic service New Patient Clinic (NPC) or trauma outpatient physiotherapy department with an acute first time or recurrent traumatic or atraumatic lateral patellar dislocation (LPD)
Study type	Type of study: Interventional
	Study design: Prospective observational cohort
	Phase: Feasibility
Date of first enrolment	January 2019
Planned trial period	9 months
Target sample size	15
Recruitment status	Pending
Primary outcome(s)	• Eligibility (proportion of participants with a diagnosis of LPD screened for eligibility who satisfy the eligibility criteria)

	• Recruitment rate (proportion of eligible participants who consent to participate in the study) • Acceptability of the intervention (assessed by an internally designed participant satisfaction questionnaire and the proportion of participants lost to follow-up) • Adherence (proportion of scheduled physiotherapy sessions attended, and prescribed exercise sessions completed)
Key secondary outcomes	• Acceptability of outcome data collection (completion rates) of the following patient reported outcome measures (PROMs) at 3 months: ➢ Tegner Activity Score ➢ Lysholm Knee Scoring Scale ➢ EQ-5D-5L • Assess harms associated with participation in the study • Determine what assessment findings are consistent with a diagnosis of LPD • Assess delivery of the intervention

SECTION 1.3. Protocol version

Date:	10/12/2018
Version:	2.0
Authors	Colin Forde (*CF*), Mark Haddad (*MH*), Shashi Hirani (*SH*), David Keene (*DK*)
Revision chronology	Nil

SECTION 1.4. Funding

CF is funded by a NIHR Masters in Clinical Research studentship award. This protocol represents independent research funded by the NIHR. The views expressed are those of the authors and do not necessarily represent the views of the NIHR, National Health Service (NHS) or Department of Health.

MH is supported by the NIHR (NIHR Programme Grants for Applied Research RPPG-1210-12011). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

SH is a Senior Lecturer in Health Services Research and Health Psychology at City, University of London, who support his research. The views expressed in this publication are those of the author(s) and not necessarily those of City, University of London.

DK is supported by the NIHR (NIHR Post Doctoral Fellowship, Dr David Keene, PDF-2016-09-056). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

SECTION 1.5. Roles and responsibilities

1.5a Contributorship

Chief investigator:	Dr Mark Haddad, Visiting Lecturer in Health Service Research, Honorary Senior Lecturer in Mental Health, and Senior Tutor for Research, City, University of London, Northampton Square, London, EC1V 0HB, United Kingdom. Tel. 020 7040 3521 Email: mark.haddad.1@city.ac.uk
Student:	Colin Forde, Physiotherapy Trauma Outpatients, Level 2, John Radcliffe Hospital, Oxford, United Kingdom, OX3 9DU. Tel. 01865 221540 Email: Colin.Forde@ouh.nhs.uk
Co-investigators:	Dr Shashivadan Hirani, Senior Lecturer in Health Psychology / Health Services Research at the School of Health Sciences, City, University of London, Northampton Square, London, EC1V 0HB, United Kingdom. Tel. 020 7040 0880 Email: Shashi.hirani.1@city.ac.uk

	Dr David Keene, University of Oxford, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Kadoorie Research Centre, John Radcliffe Hospital, Oxford, UK, OX3 9DU Tel. 01865 223121 Email: david.keene@ndorms.ox.ac.uk

CF conceived the study idea. *MH*, *SH* and *DK* provided expertise on study design. All authors contributed to refinement of the study protocol and approved the final version of the protocol.

1.5b Sponsor and funder

The NIHR and City, University of London, had no role in study design and will have no role in implementation of the study, data collection and analysis, and decision to submit for publication.

SECTION 2. LAY SUMMARY

Background

Kneecap dislocations are relatively common, accounting for approximately 3% of all sports related knee injuries. It occurs most often in mid to late adolescence, during sports and activities that involve twisting and changing direction. Commonly encountered problems after this injury include reduced activity levels, an increased risk of osteoarthritis of the kneecap joint in later life, and feelings of kneecap instability during sport and dynamic activities such as hopping and changing direction. After this injury 20-50% of patients will suffer another dislocation.

There is a lack of evidence to support any one treatment for this condition but to help recovery most patients are referred for physiotherapy. The management of recurrent dislocation is more controversial as surgery is sometimes considered, but data we collected from our service shows that these patients are routinely referred for physiotherapy.

The best form of physiotherapy remains to be determined. In the NHS, the average duration of physiotherapy after a first-time dislocation is between 7 weeks and 3 months and

typically involves advice and exercises to restore movement of the knee, improve balance, and strengthen the muscles on the front of the thigh. The duration and content of physiotherapy for recurrent dislocation in the NHS is unknown. In the medical literature, published exercise programmes are poorly described, making it difficult to determine if they have been appropriately designed and of sufficient intensity. This variability in the duration and content of physiotherapy may explain the poor outcomes in this predominantly young, active population following this injury. Determining the optimal rehab programme therefore is a research priority

Aims of the research

The aim of this study is to assess areas of uncertainty relating to the implementation of an individualised exercise programme for patients with a recent kneecap dislocation. This will help determine if a future larger study is feasible and inform the design and conduct of future research that would aim to optimise outcomes for people after a kneecap dislocation.

Research plan

We aim to recruit 15 participants with a recent kneecap dislocation from the John Radcliffe Hospital. Participants will be enrolled in the exercise intervention which involves up to 6 physiotherapy sessions over a maximum of 3 months. Our exercise programme was designed using the best available evidence. The programme aims to increase leg muscle strength. There is also a focus on facilitating a return to the participant's usual activities, which may include dynamic activities such as hopping and changing of direction. The dynamic exercises differentiates it from other published exercise programmes. Participants will be required to perform the exercises at least 3 times a week independently. Strategies to increase adherence to the exercise programme will also be used.

The study objectives are to determine how many patients match our eligibility criteria, to determine the recruitment rate, and to assess the acceptability of the intervention to the participants. The feasibility of using eligibility criteria and collecting outcome measures that would be used in a future definitive study will also be assessed.

SECTION 3 INTRODUCTION

SECTION 3.1 Background and rationale

3.1a Background

Lateral patella Dislocations are a relatively common injury of the knee, accounting for approximately 3% of sports related knee injuries.[1] Incidence rates of primary LPDs range from 23.1 – 42 per 100,000 person years in the general population, are similar amongst males and females, and peak during mid to late adolescence.[2, 3]

50-60% of LPDs result from sporting activities, with the majority of these occurring during multi-directional and pivoting sports.[4, 5] The most common mechanism of injury is thought to involve a combination of knee flexion and femoral internal rotation on an externally rotated tibia,[6] and has been compared to the non-contact anterior cruciate ligament mechanism of injury.[7]

Recurrent LPD is a commonly encountered problem with 23-30% of patients suffering a recurrent LPD within 10 years.[2, 3] In younger patients this is significantly higher with recurrent ipsilateral LPD rates of 50% reported in patients under 18 years of age at 20 years follow-up.[8] Additional negative sequalae include reduced activity levels, [9, 10] an increased risk of patellofemoral osteoarthritis,[11] and persistent feelings of instability. [12]

Due to a paucity of high-quality evidence the optimal management of LPD is unknown.[13] There are currently no published clinical guidelines to guide the treatment of this condition in the United Kingdom (UK). Current expert opinion recommends conservative management in the form of physiotherapy for first time LPD, in the absence of an osteochondral lesion or fracture, with surgical intervention reserved for recurrent LPD.[14] These recommendations however are made by clinicians based in the United States and do not necessarily reflect current practice within the NHS. We collected data on all patients with a diagnosis of LPD attending the John Radcliffe trauma service in 2017. This revealed that 76/94 patients with a diagnosis of LPD were referred for physiotherapy. Of these, 32 were first-time LPDs, 41 were recurrent LPDs and 21 were unknown. This indicates that both first-time and recurrent LPDs are routinely referred for physiotherapy in an NHS setting.

In the NHS, after a first-time dislocation, physiotherapy lasts on average between 7 weeks and 3 months and is comprised of advice, range of movement, proprioception and

strengthening exercises, but sport specific rehabilitation is rare.[15] The duration and content of physiotherapy in the NHS for recurrent dislocations is unknown. Reviews of conservative interventions for LPDs has been unable to determine the most effective form of treatment, citing a lack of adequately reported interventions and well-designed trials comparing exercise interventions.[16, 17]

This absence of evidence to inform the design and conduct of rehabilitation programmes for this patient cohort may explain the poor outcomes in this predominantly young, athletic patient population. Determining the optimum rehab programme therefore remains a research priority

3.1b Rationale for this study

Prior to conducting a future definitive trial, current Medical Research Council (MRC) guidelines for the development of complex interventions recommend conducting preliminary research to address areas of uncertainty, thereby informing the design and conduct of future research.[18]

Our attempts to estimate the number of patients with an acute LPD matching our eligibility criteria attending the John Radcliffe trauma services has been limited by insufficient information available in the patient's medical records. This study aims to address this by determining how many patients with a LPD diagnosis satisfy our eligibility criteria.

Determining the recruitment rates will help estimate the duration of recruitment required for future studies. This is important given the difficulty in recruitment of participants to previous trials of conservative interventions for this condition in the UK.[19, 20]

As outlined previously, there is a paucity of evidence to inform the content of rehabilitation programmes after a LPD.[16, 17] There has been only one published Randomised controlled trial (RCT) comparing different exercise interventions[19] which showed no clinically significant difference between general quadriceps strengthening exercise compared to vastus medialis specific strengthening exercise in a cohort of first-time LPD patients. Of note, there was an attrition rate of 52%, significantly limiting the utility of the results. The reasons for this are unknown but suggest aspects of the study design were not acceptable to the participants. Therefore, determining the acceptability of our intervention and data collection methods before a future definitive trial is important.

The poor reporting of interventions has been highlighted in a review of non-operative treatment for LPD.[17] This makes it difficult to ascertain if the exercise interventions complied with current guidelines to optimise muscle strength.[21] There was also wide variability in the exercises used. Only one study incorporated a running exercise into their programme and none reported using hopping, change of direction or sports specific exercises, or were inadequately described to determine if they did. This is particularly concerning as these are activities this patient cohort perceive to make their patella unstable[12] and the majority of LPDs occur during sporting activities.[22, 5]

Although more progressive exercise programmes have been recommended,[23, 24] trials incorporating these programmes are absent.

SECTION 3.2 Objectives

The aim of this study is to address uncertainty relating to key parameters and methodological processes in implementing an individualised exercise programme for patients with an acute LPD. It will identify aspects of the research design that are suboptimal and if these can be refined.[18] This will provide preliminary evidence on the feasibility of future research, and if feasible, inform the conduct of this research.

Numerical targets for the primary objectives (e.g. 25% recruitment rate) to determine the feasibility of a future study have not been set. This is due to the small sample size and the difficulty in determining whether a larger scale study is feasible based on preliminary work, particularly as it is unknown a priori if the problems encountered can be resolved.

3.2a Primary objectives

- To determine the number of patients presenting with a diagnosis of LPD, screened for eligibility, who satisfy the eligibility criteria
- To determine the recruitment rates of eligible participants
- To determine the acceptability of the intervention to participants by using an internally designed patient satisfaction questionnaire and measuring the participant attrition rate (% of patients who fail to complete follow up data collection at 3 months)

- To determine participant adherence by measuring the proportion of scheduled physiotherapy sessions attended and prescribed exercise sessions completed by participant self-reporting

3.2b Secondary objectives

- To determine the acceptability of outcome data collection to participants by measuring the completion rates of PROMs
- Assess harms associated with participation in the study
- To determine what assessment findings are consistent with a diagnosis of LPD.
- Assess delivery of the intervention

SECTION 3.3 Study design

This study is a feasibility study as defined by the NIHR – a study conducted to provide further information about certain parameters to inform a future larger study, as opposed to a pilot study in which all aspects of a full study are conducted in a miniature form.[25]

SECTION 4 METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

SECTION 4.1 Study setting

Participants will be recruited from the John Radcliffe hospital only. Potential participants will be identified at the trauma service NPC or from referrals to the trauma outpatient physiotherapy department. Eligibility of potential participants identified at the NPC will be determined by a physiotherapist or orthopaedic surgeon working as part of the orthopaedic and trauma team. Eligibility of potential participants identified from referrals to the trauma outpatient physiotherapy department will be determined by *CF*.

SECTION 4.2 Eligibility criteria

To reflect current local practice where patients with a diagnosis of LPD are routinely referred to a conservative management pathway with physiotherapy, all participants ≥16 years of age diagnosed with LPD by a member of the trauma and orthopaedic team will be considered eligible for the study.

4.2a Inclusion and exclusion criteria

Inclusion criteria:

- Male or female ≥16 years of age
- Attending the John Radcliffe trauma and orthopaedic service NPC or referred to the trauma outpatient physiotherapy department
- First time or recurrent LPD (traumatic or atraumatic) meeting the diagnostic criteria of 1) requiring reduction by paramedics **or** 2) diagnosed by a member of the trauma and orthopaedic team.

Exclusion criteria:

- Concurrent anterior cruciate ligament or posterior cruciate ligament injury confirmed by negative Lachman's and posterior drawer test or confirmed by Magnetic Resonance Imagery (MRI); medial collateral and lateral collateral ligament injury requiring application of a hinged knee brace or surgical repair; concomitant injury that would prohibit participation in the exercise intervention
- > 4 weeks from injury to presentation to acute care (ED or trauma services)
- Unable to give written informed consent
- Previous surgery on the affected knee
- Presence of fracture on plain radiograph including osteochondral fractures
- Medial patellar dislocation
- Considered inappropriate for referral to physiotherapy (by member of trauma and orthopaedic team assessing the patient)
- History of severe neuromuscular or congenital disorders
- Patients referred for orthopaedic opinion who are subsequently listed for surgery prior to completion of the study intervention
- Unable to understand written or spoken English
- Unable to attend physiotherapy sessions at the John Radcliffe trauma outpatient physiotherapy department

4.2b Study personnel

The intervention will be administered by Health and Care Professions Council (HCPC) registered physiotherapists. Physiotherapists will be provided with information on study

rationale, objectives and intervention in the form of a clinician handbook and will be required to attend either one-to-one or group practical training on administering the exercise intervention.

SECTION 4.3 Intervention

All participants will receive the study intervention in addition to standard management of acute LPD by the trauma and orthopaedic service at the John Radcliffe hospital. Typically, this involves the provision of a lateral buttress splint and referral to physiotherapy with no limitations on weight-bearing or knee range of movement. Patients may receive advice on pain management, gait re-training and instruction of basic knee exercise from a member of the orthopaedic team or physiotherapist working in the NPC. No attempt will be made to modify this but what has been delivered in addition to the study intervention will be recorded in the study treatment logs to help characterise what acute care was delivered overall.

The intervention will be comprised of up to 6, one-to-one, physiotherapy sessions over a maximum duration of 3 months. 1 or 2 more sessions will be allowed only if deemed clinically essential. Additional sessions and the reasons for these will be recorded to understand if the intervention would need adapting for future studies. Less than 6 physiotherapy sessions can be agreed with the participant if they are self-managing effectively and their goals have been achieved, (these stopping rules will be recorded). A treatment duration of up to 3 months is representative of current care in the NHS for first-time LPD.[15] Initial physiotherapy sessions will be 45-60 minutes and subsequent physiotherapy sessions will be 30 minutes as per local practice.

The exercise intervention has been designed to address the biomechanics associated with the LPD mechanism of injury, improve common lower limb strength deficits in this patient population and facilitate a return to the participant's desired activities which may include activities such as running, hopping and twisting.

The LPD mechanism of injury is thought to result from a quadriceps contraction with the knee in a position of slight knee flexion, femoral internal rotation and tibial external rotation which forces the patella laterally.[6, 7] This is supported by studies demonstrating peak lateral displacement of the patella at angles of 0-30° knee flexion in patients with patellofemoral

instability[27] and increased contact pressures on the lateral aspect of the patella with femoral internal rotation and tibial external internal rotation.[28] Movement patterns at the trunk and lower limb known to increase knee abduction loading[29, 30] will also be targeted as increased knee abduction loading at reduced knee flexion angles during sport specific tasks is associated with other common knee injuries such as patellofemoral pain and anterior cruciate ligament injury.[31] Correction of these movement patterns will be achieved by advising participants on correct technique during the performance of their exercise programme and through strengthening of the lower limb muscles that control these movements.

Strengthening exercises will be a core component of the exercise intervention as reduced strength of the hip extensors, abductors and external rotators is associated with greater knee valgus during single leg drops landing,[32] and reduced quadriceps strength is common in patients with a history of LPD[4, 16] and a risk factor for the development of patellofemoral osteoarthritis.[33]

To ensure the intervention is standardised, exercises prescribed to participants will be from a pre-determined list of exercises categorised into range of movement, strength and neuromotor exercises of progressive difficulty. Physiotherapists will also have the option of choosing one exercise not on this list if they feel it is necessary for the participant's rehabilitation. This will be recorded in the study treatment logs. Exercises will be selected based on the physiotherapist's assessment, and the participant's preferences and activity related goals.

To ensure progressive improvements in muscle strength, the prescribed dose of strengthening exercises will be in line with current guidelines.[21] There is currently a lack of evidence to inform the most effective dose for exercises that incorporate sport specific and functional tasks such as agility, hopping and balance.[34] Therefore, the dose of these exercises prescribed will be at the discretion of the physiotherapist and noted in the study treatment log. Patients will be required to perform the exercise programme independently a minimum of three times per week on non-consecutive days as recommended.[21, 34] Initially when pain may limit participants attaining the prescribed exercise intensity for strengthening exercise, participants can perform their exercises more frequently if they find this beneficial.

The intervention will also incorporate simple behaviour change techniques known to increase participant adherence to exercise. These will include goal setting, provision of written instruction, and demonstration and participant practice of the selected exercises.[35, 36] Guidance and recommendations on how to implement these strategies into practice have been developed[37, 38] and have informed the design of our intervention.

At the initial assessment, participants will be required to select an activity related long-term goal. Short-term goals to be achieved by the next treatment session will be selected at all subsequent appointments except the last one. Participants will be facilitated in setting appropriate goals by their physiotherapist using recommended guidelines.[37]

Written information will be provided in the form of a participant information booklet. This will contain information about the nature of their injury, self-management and guidance on the exercises to be completed. Rationale for the intervention and proposed benefits associated with this will be re-emphasised throughout the intervention.

Physiotherapists will demonstrate the selected exercises followed by participants. Feedback will be provided, and participants will be asked if they would like to be recorded performing the exercises on their smartphone to increase technique compliance. The patient will be asked about their intention to adhere. If the intention is low, the barriers to adherence will be elicited and strategies to overcome them will be explored (following the principals of patient centred goal setting).

Participants will be provided with, and asked to complete, an exercise diary containing their exercises and guidance on achieving an effective dose. At the end of each session participants will be encouraged to ask questions, their understanding will be assessed and any clarifications needed will be provided. At each review session participant adherence and achievement of short-term goals will be reviewed and strategies to overcome any barriers will be explored

4.3a Intervention – modifications

In the event of increased pain or swelling while completing the exercise intervention participants will, where possible, be advised to complete less repetitions or sets while remaining within the prescribed set and repetition range of the exercise identified as provoking their symptoms, or to regress to the previous level of this exercise, until

symptoms are at a level the participant is happy to continue to exercise with. If a specific exercise cannot be identified as the cause of the symptoms, all exercises will be reduced to a level, or set and repetition range, the patient is happy to continue to exercise with. If it is not possible to continue exercising for that exercise session, advice about application of ice, analgesia and relative rest will be provided where necessary and the patient will be reviewed at the next exercise session.

4.3b Intervention – concomitant care

As the efficacy of the intervention is not in question, concomitant health care such as medication use will not be recorded, and other aspects of care will continue as usual.

SECTION 4.4 Outcomes

4.4a Primary outcomes

- Eligibility defined as the % of participants with a diagnosis of LPD, screened for eligibility, who satisfy the eligibility criteria
- Recruitment rates defined as the % of eligible participants who consent to participate in the study
- Acceptability defined as the % attrition rate (participants who fail to complete follow up data collection at 3 months) and participant response to a patient satisfaction questionnaire
- Adherence defined as the % of scheduled physiotherapy sessions attended and participant self-reported intervention adherence defined as the % of prescribed exercise sessions completed

4.4b Secondary outcomes

- Acceptability of outcome data collection by participants defined as the % completion of the PROMs outlined below.
- The Tegner Activity Scale[39] measures activity on a scale from 0-10, with higher scores indicating higher activity. It has shown good reliability and content validity in patients with acute patellar dislocation and prior dislocation/subluxation and shown to measure a distinct aspect of recovery demonstrated by its low correlation with knee specific and general health questionnaires in this cohort.[40] It has previously been used to assess the effect of conservative management in patients with first

time LPD patients. [19, 41] It will be completed after informed consent has been obtained prior to the first physiotherapy session based on **pre-injury** activity levels and at 3 months after the first physiotherapy session based on their activity levels at that time. It will be administered as a patient completed questionnaire. The change in Tegner Activity Scale scores will be used for analysis.

- The Lyhsolm Knee Scoring Scale was originally developed for patients with knee ligament injuries[42] and subsequently revised.[39] It is scored from 0-100 with lower scores indicating higher pain and disability. It has since demonstrated good test-retest reliability in patients with first time LPD and prior subluxation/dislocation and was able to discriminate between those who subsequently developed recurrent instability and those who did not.[40] It has been used to assess the effect of conservative management in patients with first time LPD[19] and recurrent LPD.[43] It will be completed after informed consent has been obtained prior to the first physiotherapy session and 3 months after the first physiotherapy session based on **current** knee symptoms at that time. It will be administered as a patient completed questionnaire. The change in Lysholm Knee scores will be used for analysis.
- The EQ-5D is a commonly used quality of life questionnaire.[44] It will be completed after informed consent has been obtained prior to the first physiotherapy session and 3 months after the first physiotherapy session based on **current** symptoms at that time. It will be administered as a patient completed questionnaire. The change in EQ-5D scores will be used for analysis.

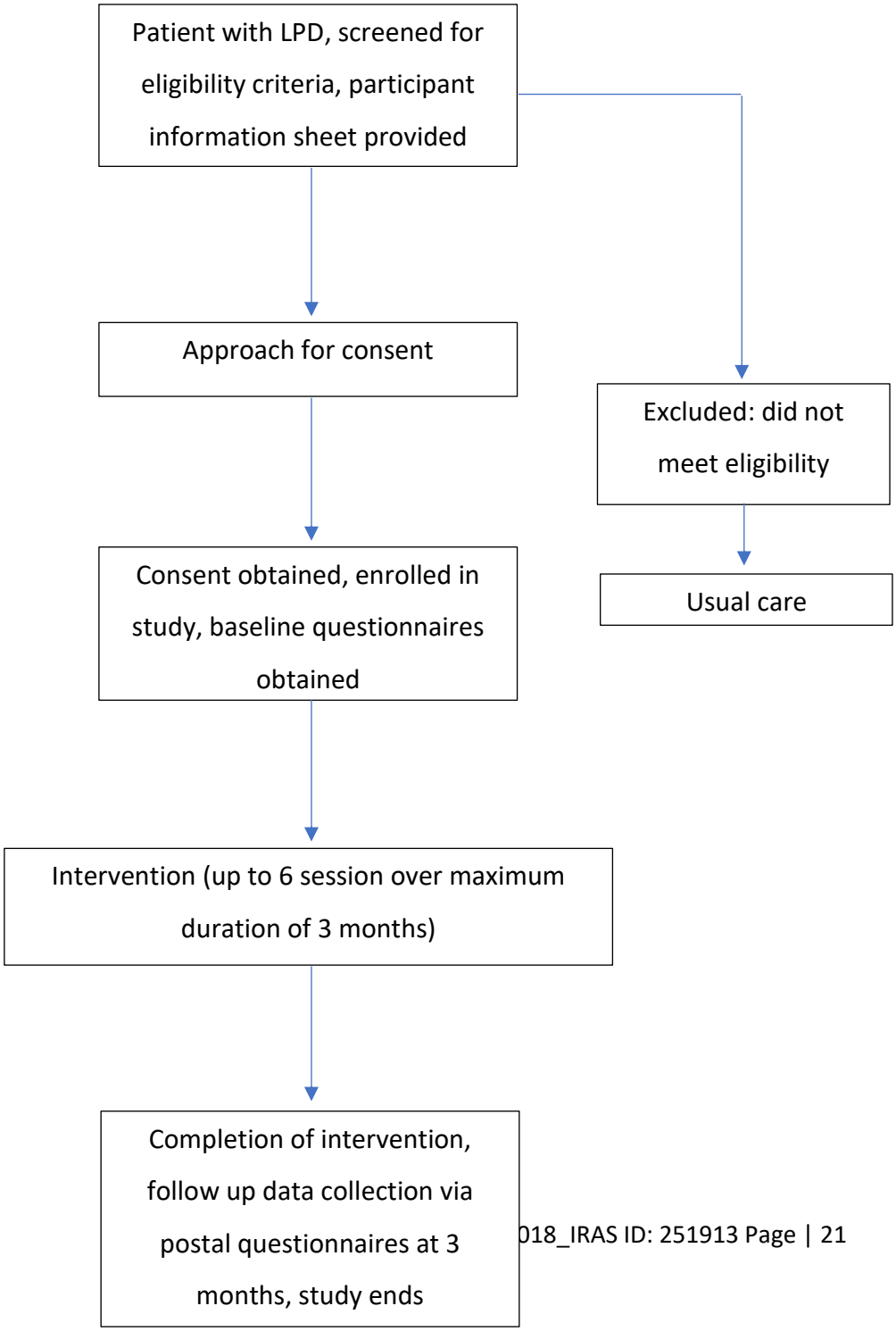
- Harms. For this study harms will be defined as any unfavourable sign or symptom related to completing the study intervention. The recording of harms has been recommended in feasibility studies to inform future research design and processes.[45] This will be measured from commencement of the intervention to 3 month follow-up as outlined is section 6.2a.
- Determine what assessment findings are consistent with a diagnosis of LPD. A member of the trauma and orthopaedic team will be required to assess the presence/absence of proposed assessment findings to include in the eligibility criteria for future studies as outlined in section 5.1. This will inform the feasibility of using these assessment findings in the eligibility criteria for future studies.

- Intervention delivery. Treatment logs will be analysed to record the duration from injury to commencing the intervention, the number of physiotherapy sessions received by participants, the duration of intervention and the exercises prescribed.

Additional demographic data will be collected as part of the study. Further information on this and the time points for data collection are outlined in section 5.1

SECTION 4.5 Participant timeline

Participant time line schematic diagram



SECTION 4.6 Sample size

4.6a Target sample size

Data we collected from the John Radcliffe trauma service for 2017 conservatively estimates 31 LPD patients match our eligibility criteria and 51 LPD patients are of unknown eligibility, due to the required information not being available in the patient's medical records. Of those of unknown eligibility, 23 are due to the direction of dislocation not being reported. As medial patellar dislocations are exceedingly rare[46] a conservative estimate would be 54 eligible participants per year and 27 for our planned recruitment period of 6 months.

We aim to recruit 15 participants over 6 months. Recruitment will cease at the end of the designated recruitment period of 6 months or earlier if the target of 15 participants is achieved.

Previous trials in the UK investigating conservative interventions for this condition have reported low recruitment rates but not explicitly stated what these rates were.[19,20] This makes it difficult to estimate recruitment rates for this study and why it forms one our primary objectives. We feel a recruitment target of 15 participants is feasible due to our conservative estimate of eligible participants and the broader inclusion criteria in our study compared to previous studies. [19,20]

As this is a feasibility study, no power calculation has been performed. A sample size of 15 is a pragmatic choice. This has been used for a study similar to ours, a single group prospective study investigating the acceptability and feasibility of exercise for patients with endometrial cancer. [47]

SECTION 4.7 Recruitment

4.7a Screening and eligibility assessment

Clinic lists for the trauma and orthopaedic NPC will be screened for patients with a knee injury. Patients will be assessed by a member of the trauma and orthopaedic team as per their usual practice. Patients subsequently diagnosed with a LPD will be assessed to see if they meet the study eligibility criteria (as described in section 4.2a). Eligible participants will be provided with the participation information sheet and asked if they wish to participate in the study.

Referrals to the trauma outpatient physiotherapy department at the John Radcliffe hospital will also be screened to identify additional potential participants (e.g. patients referred to physiotherapy directly from the Emergency Department (ED) and not seen in the trauma and orthopaedic NPC). Information packs, containing an invitation letter and participation information sheet, will be sent to potential participants with *CF*'s email address and phone number. The invitation letter and participant information sheet will advise that consent to participate in the study is strictly voluntary, ongoing and can be withdrawn at any time (as described in section 7.3). Patients interested in participating in the study will register their interest by telephone or email. An initial consultation to review eligibility criteria and obtain informed consent will be arranged at the time of their first physiotherapy appointment to limit participant inconvenience.

Eligible patients who decline to participate will have their age and gender recorded. They will also be asked their reasons for declining to participate, and if given, these will also be recorded. This will allow us to compare the characteristics of those recruited and those who chose not to participate. Those who do not meet the eligibility criteria or who decline to participate will be referred to their local physiotherapy provider (including the John Radcliffe trauma outpatient department where appropriate) as they normally would.

Informed consent for eligible participants who wish to participate in the study will be obtained as outlined in section 7.3.

SECTION 5 METHODS: DATA COLLECTION, MANAGEMENT, AND ANALYSIS

SECTION 5.1 Data collection methods

5.1a Outcomes and time points at which they will be assessed

Outcome	Measurement	Time point
Demographics	Age, sex, height, weight, affected knee, mechanism of injury (traumatic/atraumatic), previous history of ipsilateral patella dislocation, previous history of contralateral patella dislocation,	Baseline

	time from injury to presentation to acute care (ED or trauma services), family history of patella dislocation, employment status, level of education, ethnicity	
Assessment findings	Presence/absence of the following on: • A convincing patient history of a visible deformity on the lateral aspect of the knee or a sensation of the patella 'popping' out of joint followed by spontaneous reduction • Presence of a haemarthrosis or joint effusion on clinical examination • Tenderness along the medial patellofemoral complex (tenderness at the following bony landmarks or at any point extending between these two points: at or just proximal to the medial epicondyle of the femur and the midpoint of the medial aspect of the patella extending to the junction of the medial quadriceps tendon and the patella)[26] • Apprehension on laterally directed force of the patella	Baseline
Eligibility	% of participants with a diagnosis of LPD who meet the eligibility criteria	Completion of study
Recruitment	% of eligible participants who consent to participate in the study Reasons for not consenting will also attempt to be collected	Completion of study
Adherence	% of scheduled physiotherapy sessions attended	Completion of intervention 3 months post first

	Participant self-reported % of prescribed home exercise sessions completed	physiotherapy session
Acceptability	% attrition rate Patient satisfaction questionnaire	Completion of study 3 months post first physiotherapy session
Follow up	% of participants who consent to treatment who return 3 month questionnaires	Completion of study
Knee function, pain and instability	Lysholm Knee Scoring Scale	Baseline, 3 months post first physiotherapy session
Activity level	Tegner Activity Scale	Baseline, 3 months post first physiotherapy session
General health status	EQ-5D-5L	Baseline, 3 months post first physiotherapy session
Intervention delivery	Duration from LPD to first physio session, initial injury management, number of physiotherapy sessions attended, number of physiotherapy appointments participants unable to attend/did not attend, duration of the intervention from enrolment to discharge, exercises and dose of exercise	Completion of intervention

	prescribed from treatment logs completed by therapists	
Harms	Patient and staff reported adverse events including any recurrent patellar dislocation, subsequent listing for knee surgery for mechanical instability and any increases in pain or swelling resulting from the exercise intervention lasting > 1 week	From beginning of intervention to 3 months post first physiotherapy session

5.1b Baseline data collection

All baseline data will be collected after informed consent to participate in the study has been obtained prior to the first physiotherapy session. Participants will be asked to complete a questionnaire at baseline to capture the demographic information and PROMs outlined in section 5.1a. Telephone or email contact will be used to obtain a score, where relevant, if baseline data collection is subsequently identified as being incomplete.

5.1c Follow up data collection

Follow up data collection will take place 3 months after the first physiotherapy session. For participants whose final physiotherapy appointment is within 1 week of this time, questionnaires will be administered after this appointment. Follow-up data collection for all other participants will be via postal questionnaire.

At least one reminder, via telephone or email, will be sent to participants who do not return postal questionnaires. Telephone or email contact will be used to obtain a score if follow up data collection is subsequently identified as being incomplete.

5.1d Retention

Participants will be informed their participation is voluntary and they can withdraw at any time with no obligation to explain why and without affecting the quality of their care. *CF* will attempt to contact participants who wish to withdraw, or do not adhere to the exercise intervention, to determine if they are willing to participate in follow up data collection. Participants who withdraw from treatment but participate in data collection will not be

considered withdrawals. Participant data prior to withdrawal will be used unless the participant expressly refuses consent to use of this data. The reason to withdraw, if provided, will be recorded on the study withdrawal case report form. Participants may be withdrawn after enrolment by the authors if it is subsequently determined they do not meet the eligibility criteria.

SECTION 5.2 Data management

5.2a Data entry

Each participant will be assigned a unique subject code/number. All study documents, except the signed consent form and contact details for postal questionnaires, will refer to the patient by their unique subject code/number only.

Data from paper questionnaires, case reports forms and treatment logs will be entered by *CF* into an electronic database that will be password protected, and on computers at the John Radcliffe hospital, that are swipe card access for NHS employees only.

Study personnel collecting data will be provided with detailed written information outlining how to record and store outcome data. This will include how to complete case reports forms, advice to complete case report forms in ink, to avoid use of correction fluid, the normal range of values where appropriate and how to store case report forms on site.

Standard physiotherapy notes will be made in accordance with standard local practice and documented on the local electronic notes system (EPR). These will not include any data recorded for the study that is not routinely collected during standard practice.

5.2b Data storage during and after the study

All study documents will be stored securely in locked filing cabinets accessible by study staff and authorised personnel only. Any personal details (e.g. addresses for postal questionnaires) will be held separately to outcome data. Electronic data will be password protected and stored on computers with swipe card access for authorised personnel only.

Follow-up outcome data will be collected from participants via stamped pre-addressed envelope to *CF* at the physiotherapy trauma outpatient department at the John Radcliffe Hospital

Any study related data transferred from *CF* to his supervisors will refer to participants by their unique code/number only and be transferred using an encrypted memory stick device. This data will be deleted as soon as it is no longer needed.

Personal data will be stored for up to 12 months after the study and then destroyed. Anonymised research data will be stored securely at City, University of London for 10 years after the study has finished.

Oxford University Hospital NHS Foundation Trust will collect information participant information from their medical records for this research study in accordance with our instructions. Oxford University Hospital NHS Foundation Trust will use the participant's name, NHS number and contact details to contact participants about the research study, make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Individuals from City, University of London and regulatory organisations may look at the participant's medical and research records to check the accuracy of the research study. Oxford University Hospital Foundation Trust will pass these details to City, University of London along with the information collected from the participant and/or their medical records. The only people in City, University of London who will have access to information that identifies participants will be people who need to contact the participants to monitor the conduct of the study or audit the data collection process. The people who analyse the information will not be able to identify participants and will not be able to find out the participant's name, NHS number or contact details.

City, University of London is the data controller for the personal data collected for this research project. Participant personal data will be processed for the purposes outlined in this notice. The legal basis for processing participant personal data will be that this research is a task in the public interest.

SECTION 5.3 Statistical methods

5.3a Statistical Methods for analysing primary and secondary outcomes

Statistical methods and results will be reported, where possible, in accordance with SAMPL guidelines.[48] All analyses will be conducted using the latest version of SPSS (IBM Corp. Armonk, NY).

Eligibility, recruitment, acceptability and adherence will be described using descriptive statistics and expressed as integers and percentages where relevant.

Tegner Activity scores will represent ordinal data. Baseline and 3 months post 1st physiotherapy session scores will be described using descriptive statistics using median and inter-quartile range.

Lysholm scores will represent continuous data. Baseline and 3 months post 1st physiotherapy session scores will be described using descriptive statistics using mean and standard deviations if scores are normally distributed or median and inter-quartile range if data is skewed.

EQ-5D-5L scores will represent continuous data. Baseline and 3 months post 1st physiotherapy session scores will be described using descriptive statistics using mean and standard deviations if scores are normally distributed or median and inter-quartile range if data is skewed.

Patient satisfaction scores will be described using descriptive statistics. Ordinal data will be expressed using medians and inter-quartile ranges, and categorical data will be expressed as integers and percentages.

Baseline characteristics and additional outcome data on intervention delivery and harms will be expressed using descriptive statistics. Continuous variables will be described using means and standard deviations for normal distributions or medians and inter-quartiles range for non-normal distributions. Categorical data will be expressed as integers and percentages.

5.3b Missing data

Missing data for each questionnaire and item level missingness will be reported to help select future study outcome instruments**.**

SECTION 6 MONITORING

SECTION 6.1 Data monitoring committee

A data monitoring committee will not be formed. The intervention is of a relatively short duration and not substantially different from 'usual care' and therefore considered to be of minimal risk. Oversight of the conduct of the study will be provided by *MH, SH* and *DK.*

SECTION 6.2 Harms

6.2a Adverse events

For this study an adverse event (AE) will be described as any unfavourable sign or symptom related to completing the study intervention.

This study involves rehabilitation after a recent LPD. No additional risks are foreseen compared to usual rehabilitation at the John Radcliffe Trauma Outpatient Physiotherapy department.

Possible (expected) complications of rehabilitation are:

Newly acquired or temporary increases in knee pain and knee swelling; delayed onset muscle soreness, persistent patellar instability and recurrent patellar dislocation. Some of these may require the need for further surgery.

Symptoms such as delayed onset muscle soreness and increases in knee pain or swelling lasting less than 1 week that do not require medical attention will not be regarded as AEs, as these are common after commencing a new exercise regime post injury. These will be managed as outlined is section 4.3a and explained in the participation information booklet. In the unlikely event of a further patellar dislocation patients will be referred to the trauma and orthopaedic service for assessment and treatment. If physiotherapist become aware of any AEs while administering the intervention, whether the AE is related to the intervention will be determined by the physiotherapist and verified by *CF* in discussion with his supervisors. All AEs will be recorded on case report forms by the participant's physiotherapist.

AEs related to the intervention will also be recorded by participant reported questionnaire at 3 month follow-up.

6.2b Serious adverse events

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

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalisation or prolongation of existing hospitalisation,
- Results in persistent or significant disability/incapacity, or
- Consists of a congenital anomaly or birth defect.

Other "important medical events" may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

A SAE arising due to completion of the exercise intervention during this study is unlikely. If a SAE occurs during the period from commencing to finishing the exercise intervention, a SAE form must be completed by the participant's clinician and forwarded to *CF* or one of his academic supervisors within 24 hours. *CF* in discussion with his supervisors *SH, MH* and *DK* will determine if the SAE is attributable to the intervention.

Only SAEs that are:

- Related to the study (i.e. they resulted from administration of any of the research procedures) and
- Unexpected (i.e. not listed in section 6.2a as an expected occurrence)

will be reported to the Research Ethics Committee (REC) who granted the study a favourable opinion approval and the study sponsor within 15 days of *CF* or his supervisors becoming aware of the event. It will be followed up until conclusion. If it is not deemed related to the intervention it will be recorded in the case report form.

SECTION 7: ETHICS AND DISSEMINATION

SECTION 7.1 Ethical approval

UK NHS ethical approval for this protocol and associated documents will be sought from the local REC prior to enrolment of the first study participant. The study will be conducted in accordance with ethical standards which include Good Clinical Practice (GCP) and the Declaration of Helsinki.

SECTION 7.2 Protocol amendments

Any amendments to the protocol after ethical approval that affect the safety of study subjects, scientific value of the study, conduct or management of the study will be classed as substantive. Decisions to implement substantive amendments to the protocol will be taken by members of the study team in conjunction with the study sponsor and communicated to the local REC and the Health Research Authority (HRA) within 3 days by means of an amendment form generated through Integrated Research Application System (IRAS). All protocol amendments will be accompanied by an appropriate amendment to the protocol version and date. If substantive amendments are made after enrolment of the first participant, these will be outlined in the final study report.

SECTION 7.3 Consent

Written consent will be obtained in accordance with GCP guidelines and by a researcher identified in the delegation log as being able to take consent. Participants will be informed about the study design, aims of the study and what it will involve for them. Participants will be informed the purpose of the study is not to assess the efficacy of the intervention. Participants will also be provided with written information in the form of a participant information sheet and offered an opportunity to ask questions. Participants will be offered time to consider their participation in the study should they wish to do. Participants will be informed their participation is voluntary and ongoing, and they can withdraw consent at any time with no obligation to explain why and without affecting the quality of their care.

If participants are happy to proceed to enrolment in the study the consent form will be signed and dated by the participant and the researcher. A copy will be provided to the patient, a copy will be placed in the patient's medical notes, and the original kept by the study team.

SECTION 7.4 Confidentiality

The study staff will ensure participant's anonymity is maintained. Each participant will be assigned a unique subject code/number. All study documents, except the signed consent form and contact details for postal questionnaires, will refer to the patient by their unique subject code/number only. All study documents will be stored securely in locked filing cabinets accessible by study staff and authorised personnel only. Only staff involved in running the study and responsible members from Oxford University Hospital Foundation Trust, the sponsor City, University of London, and other authorities that audit and quality assure health research the NHS will have access to this information. The study will comply with the Date Protection Act and GDPR protocols, which state all data should be anonymised as soon as it is practical to do so and stored in accordance to their guidelines.

SECTION 7.5 Declarations of interests

CF is in receipt of a MRes Clinical Research NIHR Studentship Award and employed by Oxford University Hospital Foundation Trust as a band 6 trauma outpatient physiotherapist. Competing interests: none.

MH is supported by the NIHR (NIHR Programme Grants for Applied Research RPPG-1210-12011) Competing interests: none.

*S*H is supported by City, University of London and has funding for research from the Bart's Charity, NIHR RfPB scheme, and the EPSRC. Competing interests: none.

DK is supported by the NIHR (NIHR Post Doctoral Fellowship, Dr David Keene, PDF-2016-09-056). Competing interest: none.

SECTION 7.6 Access to data

CF, MH, SH and *DK* will have access to an anonymised version of the dataset. Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations. Upon completion of the study, and with participant consent, fully anonymised research data may be shared with other organisations and researchers.

SECTION 7.7 Ancillary care

Any AEs related to the study intervention will be managed as outlined in section 5.2a. Any serious adverse events will be managed by standard local NHS pathways.

SECTION 7.8 Dissemination policy

7.8a Study results

The study will be reported in line with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for pilot and feasibility trials.[45] The exercise intervention will be reported in line with the Template for Intervention Description and Replication (TIDieR) guidelines for reporting of interventions.[49]

CF will initially write up the results as a dissertation for a Masters in Clinical Research at City, University of London. Following submission all authors will review and agree upon the final version to be submitted for publication to a peer reviewed academic journal. Submission for publication will be made regardless of study results. Participants will be asked if they wished to be informed of study results as part of the consenting process.

7.8b Authorship

Authorship will be granted in accordance with the International Committee of Medical Journal Editors' guidelines.[50] Contributors who do not meet these criteria will be acknowledged.

7.8C Reproducible research

The study will be prospectively registered on ClinicalTrials.gov. prior to enrolment of the first participant.

REFERENCES

1. Majewski M, Susanne H, Klaus S. Epidemiology of athletic knee injuries: a 10-year study. Knee. 2006 Jun;13(3):184-8
2. Gravesen KS, Kallemose T, Blønd L, Troelsen A, Barfod KW. High incidence of acute and recurrent patellar dislocations: a retrospective nationwide epidemiological study involving 24.154 primary dislocations. Knee Surg Sports Traumatol Arthrosc. 2018 Apr;26(4):1204-1209. doi: 10.1007/s00167-017-4594-7.

3. Sanders TL, Pareek A, Hewett TE, Stuart MJ, Dahm DL, Krych AJ. Incidence of first-time lateral patellar dislocation: a 21-year population-based study. Sports Health. 2018 Mar/Apr;10(2):146-151. doi: 10.1177/1941738117725055.
4. Atkin DM, Fithian DC, Marangi KS, Stone ML, Dobson BE, Mendelsohn C. Characteristics of patients with primary acute lateral patellar dislocation and their recovery within the first 6 months of injury. Am J Sports Med. 2000 Jul-Aug;28(4):472-9.
5. Waterman BR, Belmont PJ, Owens BD. Patellar dislocation in the United States: role of sex, age, race, and athletic participation. J Knee Surg. 2012 Mar;25(1):51-7.
6. Greiwe RM, Saifi C, Ahmad CS, Gardner TR. Anatomy and biomechanics of patellar instability. Operative Techniques in Sports Medicine. 2010 Jun 1;18(2):62-7.
7. Lion A, Hoffmann A, Mouton C, Theisen D, Seil R. Risk factors for patellar dislocations: A narrative review. Sports Orthopaedics and Traumatology Sport-Orthopädie-Sport-Traumatologie. 2016 Jun 1;32(2):139-47.
8. Christensen TC, Sanders TL, Pareek A, Mohan R, Dahm DL, Krych AJ. Risk factors and time to recurrent ipsilateral and contralateral patellar dislocation. Am J Sports Med. 2017 Jul;45(9):2105-2110. doi: 10.1177/0363546517704178
9. Atkin DM, Fithian DC, Marangi KS, Stone ML, Dobson BE, Mendelsohn C. Characteristics of patients with primary acute lateral patellar dislocation and their recovery within the first 6 months of injury. Am J Sports Med. 2000 Jul-Aug;28(4):472-9.
10. Magnussen, R.A., Verlage, M., Stock, E., Zurek, L., Flanigan, D.C., Tompkins, et al. Primary patellar dislocations without surgical stabilization or recurrence: how well are these patients really doing? Knee Surg Sports Traumatol Arthrosc. 2017 Aug;25(8):2352-2356. doi: 10.1007/s00167-015-3716-3.
11. Sanders TL, Pareek A, Johnson NR, Stuart MJ, Dahm DL, Krych AJ. Patellofemoral arthritis after lateral patellar dislocation: a matched population-based analysis. Am J Sports Med. 2017 Apr;45(5):1012-1017. doi: 10.1177/0363546516680604.
12. Smith TO, Donell ST, Chester R, Clark A, Stephenson R. What activities do patients with patellar instability perceive makes their patella unstable? Knee. 2011 Oct;18(5):333-9. doi: 10.1016/j.knee.2010.07.003.

13. Smith To, Donell S, Song F, Hing CB. Surgical versus non-surgical interventions for treating patellar dislocation. Cochrane Database of Systematic Reviews. 2015 2 doi: 10.1002/14651858.CD008106.pub3
14. Liu JN, Steinhaus ME, Kalbian IL, Post WR, Green DW, Strickland SM, at al. Patellar instability management: a survey of the international patellofemoral study group. Am J Sports Med. 2017 doi: 10.1177/0363546517732045
15. Smith TO, Chester R, Clark A, Donell ST, Stephenson R. A national survey of the physiotherapy management of patients following first-time patellar dislocation. Physiotherapy. 2011 Dec;97(4):327-38. doi: 10.1016/j.physio.2011.01.003.
16. Smith TO, Davies L, Chester R, Clark A, Donell ST. Clinical outcomes of rehabilitation for patients following lateral patellar dislocation: a systematic review. Physiotherapy. 2010 Dec;96(4):269-81. doi: 10.1016/j.physio.2010.02.006.
17. Moiz M, Smith N, Smith TO, Chawla A, Thompson P, Metcalfe A. Clinical Outcomes After the Nonoperative Management of Lateral Patellar Dislocations: A Systematic Review. Orthopaedic Journal of Sports Medicine. 2018;6(6):2325967118766275. doi:10.1177/2325967118766275.
18. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008 Sep 29;337:a1655. doi: 10.1136/bmj.a1655.
19. 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 Sep;22(4):313-20. doi: 10.1016/j.knee.2015.03.013
20. 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 Oct;19(5):696-702. doi: 10.1016/j.knee.2011.08.004
21. Ratamess N, Alvar B, Evetoch T, Housh T, Kibler W, Kraemer W. Progression models in resistance training for healthy adults [ACSM position stand]. Med Sci Sports Exerc. 2009 Mar;41(3):687-708. doi: 10.1249/MSS.0b013e3181915670.

22. Fithian DC, Paxton EW, Stone ML, Silva P, Davis DK, Elias DA, et al. Epidemiology and natural history of acute patellar dislocation. Am J Sports Med. 2004 Jul-Aug;32(5):1114-21.
23. Ménétrey J, Putman S, Gard S. Return to sport after patellar dislocation or following surgery for patellofemoral instability. Knee Surg Sports Traumatol Arthrosc. 2014 Oct;22(10):2320-6. doi: 10.1007/s00167-014-3172-5.
24. Monson J, Arendt EA. Rehabilitative protocols for select patellofemoral procedures and nonoperative management schemes. Sports Med Arthrosc Rev. 2012 Sep;20(3):136-44. doi: 10.1097/JSA.0b013e318263db1c.
25. NIHR. Feasibility and pilot studies, in NIHR NETSCC glossary. Available at: www.netscc.ac.uk/glossary/#glos6 (Accessed 12/02/2018)
26. Tanaka MJ. The anatomy of the medial patellofemoral complex. Sports Med Arthrosc Rev. 2017 Jun;25(2):e8-e11. doi: 10.1097/JSA.0000000000000143.
27. Tanaka MJ, Elias JJ, Williams AA, Demehri S, Cosgarea AJ. Characterization of patellar maltracking using dynamic kinematic CT imaging in patients with patellar instability. Knee Surg Sports Traumatol Arthrosc. 2016 Nov;24(11):3634-3641. Epub 2016 Jun 29.
28. Lee TQ, Morris G, Csintalan RP. The influence of tibial and femoral rotation on patellofemoral contact area and pressure. J Orthop Sports Phys Ther. 2003 Nov;33(11):686-93
29. Jamison ST, Pan X, Chaudhari AM. Knee moments during run-to-cut maneuvers are associated with lateral trunk positioning. J Biomech. 2012 Jul 26;45(11):1881-5. doi: 10.1016/j.jbiomech.2012.05.031
30. Powers CM. The influence of abnormal hip mechanics on knee injury: a biomechanical perspective. J Orthop Sports Phys Ther. 2010 Feb;40(2):42-51. doi: 10.2519/jospt.2010.3337.
31. Weiss K, Whatman C. Biomechanics associated with patellofemoral pain and ACL injuries in sports. Sports Med. 2015 Sep;45(9):1325-1337. doi: 10.1007/s40279-015-0353-4.
32. Dix, J., Marsh, S., Dingenen, B. and Malliaras, P. The relationship between hip muscle strength and dynamic knee valgus in asymptomatic females: A systematic

review. Phys Ther Sport. 2018 May 25. pii: S1466-853X(17)30358-9. doi: 10.1016/j.ptsp.2018.05.015.

33. Crossley KM, Stefanik JJ, Selfe J, Collins NJ, Davis IS, Powers CM, et al. Patellofemoral pain consensus statement from the 4th International Patellofemoral Pain Research Retreat, Manchester. Part 1: Terminology, definitions, clinical examination, natural history, patellofemoral osteoarthritis and patient-reported outcome measures. Br J Sports Med. 2016 Jul;50(14):839-43. doi: 10.1136/bjsports-2016-096384
34. Riebe D, Ehrman JK, Ligouri G, Magal M. et al., ACSM's guidelines for exercise testing and prescription. 10th ed. Reibe D, editor. Philadelphia: Wolters Kluwer. 2017.
35. Peek K, Sanson-Fisher R, Mackenzie L, Carey M. Interventions to aid patient adherence to physiotherapist prescribed self-management strategies: a systematic review. Physiotherapy. 2016 Jun;102(2):127-35. doi: 10.1016/j.physio.2015.10.003.
36. Meade LB, Bearne LM, Sweeney LH, Alageel SH, Godfrey EL. Behaviour change techniques associated with adherence to prescribed exercise in patients with persistent musculoskeletal pain: Systematic review. Br J Health Psychol. 2018 Jun 17. doi: 10.1111/bjhp.12324
37. Michie S, Rumsey N, Fussell A, Hardeman W, Johnston M, Newman S, et al. Improving health: changing behaviour. NHS health trainer handbook; 2008
38. Peek K, Carey M, Sanson-Fisher R, Mackenzie L. Aiding patient adherence to physiotherapist-prescribed self-management strategies: an evidence-based behavioural model in practice. Physical Therapy Reviews. 2016 Mar 3;21(2):124-30.
39. Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. Clinical orthopaedics and related research. Clin Orthop Relat Res. 1985 Sep;(198):43-9.
40. Paxton EW, Fithian DC, Lou Stone M, Silva P. The reliability and validity of knee-specific and general health instruments in assessing acute patellar dislocation outcomes. Am J Sports Med. 2003 Jul-Aug;31(4):487-92.
41. Buchner M, Baudendistel B, Sabo D, Schmitt H. Acute traumatic primary patellar dislocation: long-term results comparing conservative and surgical treatment. Clin J Sport Med. 2005 Mar;15(2):62-6.
42. Lysholm J, Gillquist J. Evaluation of knee ligament surgery results with special emphasis on use of a scoring scale. Am J Sports Med. 1982 May-Jun;10(3):150-4.

43. Arnbjornsson AR, Egund NI, Rydling OL, Stockerup RO, Ryd LE. The natural history of recurrent dislocation of the patella. Long-term results of conservative and operative treatment. J Bone Joint Surg Br. 1992 Jan;74(1):140-2.
44. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011 Dec;20(10):1727-36. doi: 10.1007/s11136-011-9903-x.
45. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot and feasibility studies. BMJ. 2016 Oct 24;355:i5239. doi: 10.1136/bmj.i5239.
46. Le Corroller T, Dediu M, Champsaur P. Transient medial patellar dislocation: injury patterns at US and MR imaging. Skeletal Radiol. 2009 May;38(5):519-23. doi: 10.1007/s00256-009-0657-2
47. Smits A, Lopes A, Das N, Bekkers R, Massuger L, Galaal K. Exercise Programme in Endometrial Cancer; Protocol of the Feasibility and Acceptability Survivorship Trial (EPEC-FAST). BMJ Open. 2015 Dec 16;5(12):e009291. doi: 10.1136/bmjopen-2015-009291..
48. Lang TA, Altman DG. Basic statistical reporting for articles published in biomedical journals: the “Statistical Analyses and Methods in the Published Literature” or the SAMPL Guidelines”. Handbook, European Association of Science Editors. 2013;256:256.
49. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014 Mar 7;348:g1687. doi: 10.1136/bmj.g1687.
50. International Committee of Journal Editors (2018) Defining the Role of Authors and Contributors. Available at: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html (Accessed: 12/02/2018)