■ KNEE

Supervised versus self-managed rehabilitation for patients with an acute first-time or recurrent patellar dislocation: the Physiotherapy Rehabilitation Post Patellar Dislocation (PRePPeD) external pilot randomized controlled trial and embedded qualitative study

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Aims

The aim of this study was to determine the feasibility of a full-scale randomized controlled trial (RCT) comparing two exercise-based rehabilitation interventions for patients with an acute patellar dislocation.

Methods

A two-group external pilot RCT and embedded qualitative study was conducted in five English NHS hospitals. Patients were aged ≥ 14 years with an acute (recruited ≤ 21 days of injury) first-time or recurrent patellar dislocation. Randomization was 1:1 to supervised rehabilitation (between four and six physiotherapy sessions of tailored advice and prescribed home exercises) or self-managed rehabilitation (one physiotherapy session of advice, exercise instruction, and the provision of materials to guide self-management). Quantitative feasibility objectives were: patients' willingness to be randomized; patient recruitment; adherence to the intervention (overall proportion of supervised rehabilitation patients who attended at least four physiotherapy sessions and self-managed rehabilitation patients who attended at least one session); and retention. Follow-up was at three, six, and nine months after randomization. There was no blinding. Semistructured interviews aimed to understand patients' experience of recovery, and the acceptability to them of the interventions and the methods of follow-up.

Results

A total of 50 of 88 eligible patients (57% (95% CI 46 to 67)) were willing to be randomized. Sites recruited a mean of 1.4 patients per month (95% CI 0.6 to 1.8), the rate of adherence to the intervention was 72% (95% CI 58 to 83), and the rate of retention at nine months was 62% (95% CI 48 to 74). During follow-up, three patients redislocated the index patella and another underwent patellar stabilization surgery. Interviews with nine patients showed that the experience of recovery was conveyed through the themes 'coming to terms with the initial injury' and 'regaining my former self'. Interviews also indicated that the interventions and methods of follow-up were generally acceptable to patients.

Conclusion

A full-scale RCT comparing two exercise-based rehabilitation interventions for patients with an acute patellar dislocation is feasible with minor modifications. Modifications should prioritize improving retention and attendance at physiotherapy sessions.

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Introduction

Patellar dislocations are common injuries, mostly affecting adolescents and young adults.[1] The incidence of first-time patellar dislocations in Denmark is 42 per 100,000 person-years.[1] If this incidence was seen in the UK, it would result in 28,671 first-time dislocations annually.[2] The average risk of recurrent patellar dislocation after a first-time dislocation is 27%,[1] but this risk is even higher in younger patients and those with multiple dislocations.[3]

Currently, guidelines recommend that patients with an isolated first-time dislocation should be treated non-surgically.[4,5] This includes referral to physiotherapy for rehabilitation once the initial injury has been managed. The treatment of recurrent dislocation is more controversial, but many recommend surgery only if initial rehabilitation is unsuccessful.[6,7] If surgery is undertaken, it usually occurs several months after the patient's initial presentation to acute injury services.[8,9] Therefore, rehabilitation remains the first-line treatment for patients with acute first-time or recurrent patellar dislocation in most healthcare systems.

There is, however, little high-quality evidence to guide rehabilitation in these patients, and outcomes vary.[10] Previously, we tested a prototype intervention which included several physiotherapy sessions of tailored advice and home exercises, which showed promise. It appeared acceptable to patients and deliverable in the UK NHS.[11] However, there is no evidence that this type of supervised rehabilitation is effective. Attending a course of physiotherapy can also be inconvenient, particularly for these younger patients, who are often in education or work. A full-scale randomized controlled trial (RCT) comparing a supervised rehabilitation intervention with one which enables self-management would provide high-quality evidence to guide the provision of rehabilitation for these patients. Whether such a RCT is feasible is uncertain. Previous RCTs investigating this injury in the UK had problems with recruitment and retention.[8,12,13] Thus, the aim of the Physiotherapy Rehabilitation Post Patellar Dislocation (PRePPeD) study was to assess the feasibility of undertaking a full-scale RCT investigating these two different rehabilitation approaches.

Methods

PRePPeD was a parallel, two-group, external pilot RCT and embedded qualitative study conducted in five English NHS hospitals which varied in size, research experience and location. The East of Scotland Research Ethics Service provided ethical approval (reference: 22/ES/0035). The study was registered prospectively (ISRCTN 14235231). The protocol and a description of the interventions and their development have been published,[14,15] so the methods and interventions are only summarized here.

The peak incidence of first-time patellar dislocation is in mid-adolescence.[1] It is uncertain when the incidence of recurrent dislocation peaks, but it has been reported that young adults are mostly affected.[3] Aiming to recruit a representative sample, patients were therefore aged ≥ 14 years and had an acute first-time or recurrent dislocation confirmed if: 1) the patella was reduced by a healthcare professional; or 2) 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. Exclusion criteria were those: who were > 21 days from injury; who had undergone previous patellar stabilization surgery on the affected knee; those who required acute surgery, such as for an associated osteochondral fracture; contraindications to participating in the study; and those who were unable to adhere to the study procedures.

Potentially eligible patients were identified in fracture or knee clinics. After confirmation of eligibility, informed consent was obtained from patients aged ≥ 16 years or from the parent (here and throughout, a 'parent' also refers to someone with parental responsibility) of patients aged < 16 years.

Patient characteristics. Between January and August 2023, 115 potentially eligible patients were approached, 88 were eligible, and 50 were randomized (Figure 1). Eligible adults were more likely to participate (44/68; 65%) than eligible patients aged < 16 years (6/20; 30%). Eligible patients who declined to participate were mostly male (23/37; 62%) and their median age was 17 years (IQR 15 to 28). The most common reason for declining participation was a preference for supervised rehabilitation (13/37; 35%). One withdrew because they were unhappy with a delay in arranging their first physiotherapy session.

Patients' characteristics were generally well balanced at baseline (Table I). The median age was 22 years (IQR 18 to 29), 58% (29/50) were female, and 42% (21/50) had a previous ipsilateral dislocation.

Randomization and blinding. Patients were randomly allocated 1:1 to either intervention by a researcher at the study site using an encrypted web-based service provided by Oxford Clinical Trials Research Unit. The computer-generated randomization sequence was stratified by: 1) study site; and 2) first-time versus recurrent dislocation of the study patella (judged strongest prognostic clinical factor),[3] with permuted blocks of varying length. The nature of the interventions meant that patients, physiotherapists, and researchers were not blinded.

Interventions. After randomization, patients were given a paper workbook containing advice and basic initial exercises, which they were encouraged to implement immediately. Those with an email address were also given access to an online version of this workbook. They were then referred for physiotherapy which ideally began within three weeks after randomization.

'Self-managed rehabilitation' involved one session with a physiotherapist who reinforced the advice in the workbook and introduced a progressively challenging self-guided programme of knee range of motion, leg muscle strengthening, and motor control exercises. Patients then continued their recovery independently following guidance in the workbook. Those with difficulties could contact their physiotherapist for advice or to book one follow-up session. 'Supervised rehabilitation' involved between four and six physiotherapy sessions provided over a maximum of six months. Follow-up sessions enabled physiotherapists to reassess patients and tailor the advice and exercise they provided accordingly.

Both interventions used simple strategies to help patients adhere to the prescribed exercise, e.g. goal setting. Physiotherapists could provide both interventions, but the delivery of the

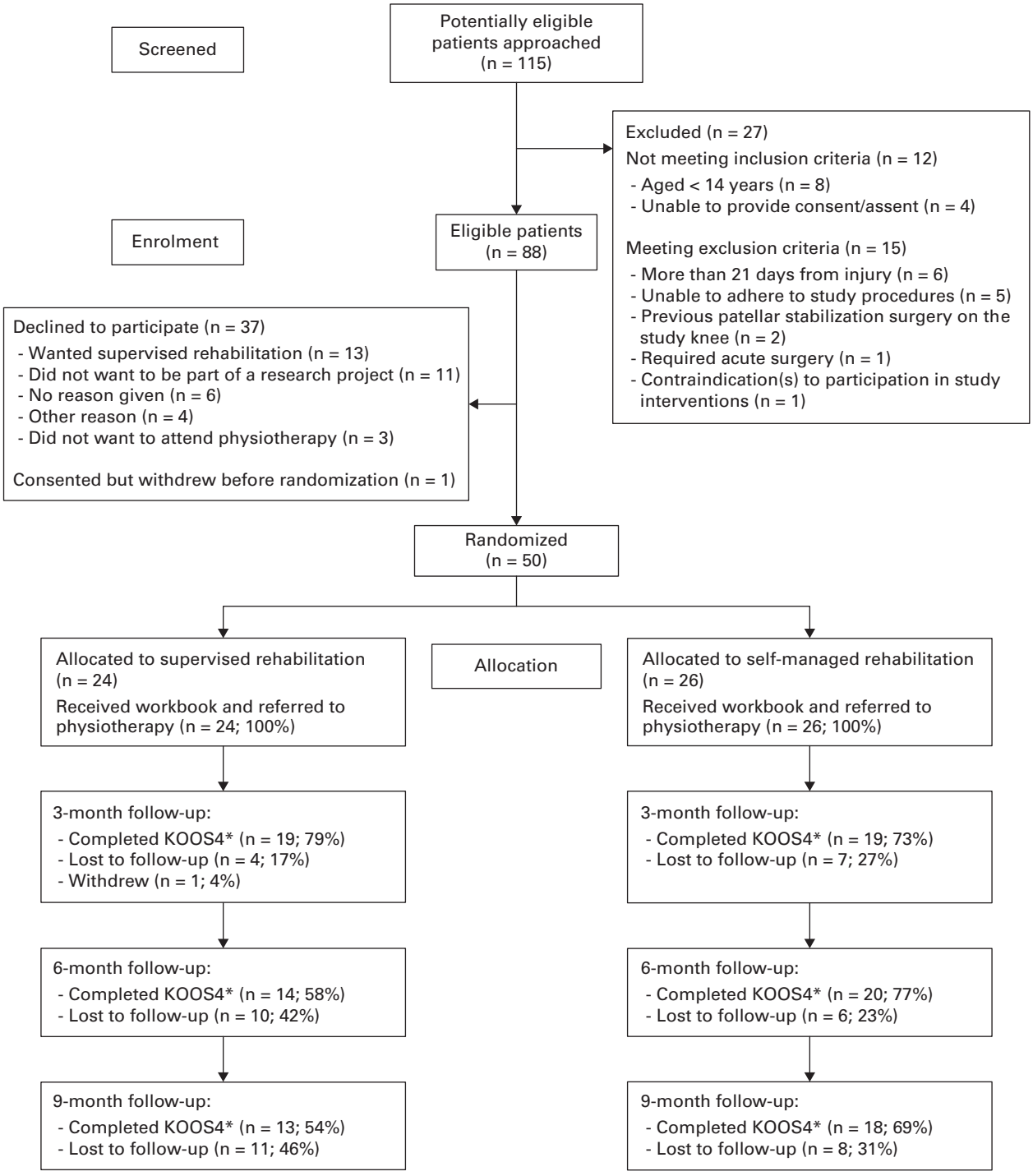

Fig. 1

CONSORT flow diagram. *The planned primary clinical outcome for the full-scale trial. KOOS4, four domain version of the Knee injury and Osteoarthritis Outcome Score.

interventions was monitored for treatment contamination (see Quality Assurance).

Outcomes. Primary quantitative outcomes were: the willingness to be randomized (proportion of eligible patients approached who were randomized); the rate of recruitment (the number of patients who were recruited per site per month); adherence to the intervention (overall proportion of patients allocated to supervised and self-managed rehabilitation who attended at least four physiotherapy sessions and one physiotherapy session, respectively); and retention (the proportion of patients who returned nine-month outcome data for the four domain version of the Knee injury and Osteoarthritis

Table I. Patients' baseline characteristics.

Characteristic	Total	Supervised rehabilitation	Self-managed rehabilitation
Patients, n	50	24	26
Median age, yrs (IQR)	22 (18 to 29)	20 (18 to 27)	26 (17 to 31)
Age < 16 yrs, n (%)	6 (12)	1 (4)	5 (19)
Sex, n (%)			
Male	21 (42)	10 (42)	11 (42)
Female	29 (58)	14 (58)	15 (58)
Median IMD decile (IQR)*	6.0 (4.0 to 8.0)	5.5 (2.8 to 8.0)	6.0 (4.3 to 8.0)
Median BMI, kg/m^2 (IQR)	25.4 (20.9 to 32.0)	24.8 (22.1 to 31.5)	27.1 (19.7 to 32.0)
Ethnicity, n (%)			
White	44 (88)	23 (96)	21 (81)
Asian or Asian British	4 (8)	1 (4)	3 (12)
Black, African, Caribbean, or Black British	1 (2)	0 (0)	1 (4)
Mixed or multiple ethnic groups	1 (2)	0 (0)	1 (4)
Other ethnic group	0 (0)	0 (0)	0 (0)
Education, n (%)†			
Higher professional or university education	25 (50)	13 (54)	12 (46)
Secondary education	25 (50)	11 (46)	14 (54)
Employment, n (%)			
Full-time employed	22 (44)	10 (42)	12 (46)
Full-time student	16 (32)	8 (33)	8 (31)
Part-time employed	11 (22)	5 (21)	6 (23)
Unemployed	1 (2)	1 (4)	0 (0)
Affected knee, n (%)			
Left	31 (62)	16 (67)	15 (58)
Right	19 (38)	8 (33)	11 (42)
Median duration from injury to randomization, days (IQR)	10 (5 to 15)	10 (5 to 14)	10 (2 to 16)
Mechanism of injury, n (%)			
Sporting activity	14 (28)	6 (25)	8 (31)
Direct blow to knee	9 (18)	4 (17)	5 (19)
Main pre-injury sport or physical activity, n (%)			
Walking or none	24 (48)	12 (50)	12 (46)
Multidirectional sport	19 (38)	9 (38)	10 (39)
Linear sport	7 (14)	3 (13)	4 (15)
Previous ipsilateral patellar dislocation, n (%)	21 (42)	10 (42)	11 (42)
1	4 (8)	1 (4)	3 (12)
2	5 (10)	4 (17)	1 (4)
3	3 (6)	2 (8)	1 (4)
4	1 (2)	0 (0)	1 (4)
5	2 (4)	0 (0)	2 (8)
6	1 (2)	0 (0)	1 (4)
7	1 (2)	1 (4)	0 (0)
≥ 10	4 (8)	2 (8)	2 (8)
Physiotherapy for any previous ipsilateral patellar dislocation, n (%)	13 (62)	7 (70)	6 (55)
Previous contralateral patellar dislocation, n (%)	9 (18)	5 (21)	4 (15)
1	4 (8)	2 (8)	2 (8)
2	4 (8)	2 (8)	2 (8)
≥ 10	1 (2)	1 (4)	0 (0)
Previous surgery on the affected knee, n (%)‡	1 (2)	0 (0)	1 (4)
Concurrent knee injury not affecting patellofemoral joint, n (%)	2 (4)	0 (0)	2 (8)
Complete ACL tear, grade 2 MCL sprain, and lateral meniscus tear	1 (2)	0 (0)	1 (4)
Lateral meniscus tear	1 (2)	0 (0)	1 (4)
Splint, n (%)§			
Knee immobilizer/cricket pad splint	34 (68)	14 (58)	20 (77)
Laterally stabilizing soft knee brace	8 (16)	5 (21)	3 (12)
Hinged knee brace, angle not fixed	1 (2)	0 (0)	1 (2)
Other	1 (2)	1 (4)	0 (0)

Continued

Table I. Continued

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

*Lower scores mean higher deprivation.
†Highest level patient is completing or has completed.
‡Medial growth plate arrest for valgus knee.
§Provided at baseline or most recently.
¶Routine data checks detected perfect or near perfect baseline KOOS scores for four patients (three allocated to self-managed rehabilitation), suggesting that these patients completed the KOOS according to 'pre-injury' rather than 'current' symptoms and function, though this could not be confirmed.
ACL, anterior cruciate ligament; ADL, activities of daily living; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; IMD, index of multiple deprivation; KOOS, Knee injury and Osteoarthritis Outcome Score; MCL, medial collateral ligament; QoL, quality of life; VAS, visual analogue scale.

Outcome Score (KOOS4; full-scale trial's planned primary outcome)).[16]

We collected the following clinical outcomes (see protocol for full details)[14] electronically, or by phone or post if necessary, three, six, and nine months after randomization to assess if they could be collected in the full-scale trial. Outcomes were patient-reported unless specified otherwise.

1) The KOOS4 and the five individual KOOS subscales were reported separately. The KOOS4 and individual KOOS subscales are scored from 0 to 100, with higher scores indicating better outcomes. 2) Return to pre-injury sport/physical activity level was measured on a study-specific visual analogue scale (VAS) from 0% to 100%, with higher scores indicating better outcomes. 3) Health-related quality of life was measured using the EuroQol five-dimension five-level questionnaire (EQ-5D-5L).[17] 4) The global rating of change in the affected knee since entering the study was measured on a seven-point Likert scale. 5) The frequency of performing the exercises was also recorded. 6) Harms were collected from patient-reported questionnaires and verified with patients (and sites where required). New dislocations were defined as those for which the patients required hospital or general practitioner attendance, or if there was a documented new dislocation in their medical records. After follow-up was completed, sites checked their patients' medical records for any patellar dislocations or related knee surgery which occurred during follow-up.

Patients completed the KOOS, EQ-5D-5L, and return to pre-injury sport/physical activity level questionnaires at baseline based on their current symptoms. Additionally, we collected health resource data from a range of sources to aid the development of the case report forms for the full-scale trial.

Sample size. The key uncertainty of the full-scale RCT is retention, so this informed the sample size calculation. A sample size of ≥ 50 patients enabled us to estimate 80% retention to within a 95% CI of ± 11% using Wilson's method.[18]

Statistical analysis. The recruitment rate was summarized as the mean number of patients recruited per site per month, and a 95% exact Poisson CI was calculated. Other quantitative feasibility outcomes were expressed as proportions with 95% CIs, calculated using Wilson's method.[19] All other quantitative data were analyzed using descriptive statistics with appropriate summary statistics (e.g. medians and IQRs). Categorical data were expressed as counts and proportions. EQ-5D-5L domain responses were mapped onto the EQ-5D-3L value set to provide one utility score following published methods (an age of 16 years was used for patients aged < 16 years).[20] Patients were analyzed according to their allocated treatment group regardless of the treatment they received. A per-protocol analysis was performed for the KOOS and global rating of change questionnaire, although this was not pre-specified in the study protocol, to demonstrate what this could look like for the full-scale trial. The per-protocol population included those who adhered to their allocated intervention ('supervised rehabilitation' patients who attended at least four physiotherapy sessions and 'self-managed rehabilitation' patients who attended at least one physiotherapy session) and did not access out-of-trial NHS physiotherapy. No inferences about intervention effectiveness were made. Stata v. 17 (StataCorp, USA) was used for the analysis.

Table II. Primary quantitative feasibility outcome results.

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

*Mean recruitment per month.

Patient and public involvement and engagement. In addition to the patient and public involvement and engagement (PPIE) activities described in the protocol,[14] one PPIE member with a previous patellar dislocation gave feedback on the qualitative interview topic guide and our interpretation of the qualitative data.

Embedded qualitative study. The embedded qualitative study aimed to understand patients' experience of recovering from an acute patellar dislocation, and the acceptability to them of the RCT interventions and methods of follow-up. We planned to conduct one semistructured interview with up to 20 patients sampled for variation in age (< 16 years and ≥ 16 years), allocated intervention, and completed or lost to follow-up, to obtain a breadth of experience. Eligible patients who declined to participate in the pilot RCT could also participate. Patients or their parents were invited to interviews by email or phone, or both. The lead author (CPF), an experienced, male musculoskeletal physiotherapist, conducted the interviews assisted by a pilot-tested topic guide (Supplementary Figure a). Patients were interviewed after their three-month follow-up for the RCT so that the acceptability of the follow-up methods could be explored. Informed consent was obtained before interviews as for the RCT.

Interviews were digitally audio recorded, transcribed verbatim, and the transcripts verified against the recording. The lead author led the analysis, which drew on Braun and Clarke's thematic analysis method.[21] Rigour was demonstrated by recording analysis decisions to show how findings were derived from the data. Regular reflexive discussions between the authors (CPF, ET) explored emerging interpretations, and the overall interpretation of the data was discussed with a PPIE partner. The findings are supported by de-identified patient quotations.

Results

The results according to prespecified progression criteria are shown in Table II.

A total of 57% of eligible patients who were approached were randomized (95% CI 46 to 67; n = 50/88). Recruitment, averaged over the period of time that all sites were open, was 1.4 patients per site per month (95% CI 0.6 to 1.8). All sites averaged recruitment of ≥ 1.0 patient each month.

The rate of adherence to the intervention was 72% (95% CI 58 to 83), driven by the higher adherence to self-managed rehabilitation (Table III).

Seven patients (14%) did not attend any physiotherapy session. For 6/7 who partially completed supervised rehabilitation (i.e. attended at least one session but fewer than four), this was because the patient stopped attending sessions or did not want to attend further sessions due to work or moving out of area. Video physiotherapy appointments were allowed, but none were used.

Six in the self-managed group had an additional contact with the site physiotherapy team, but two of these were for reasons unrelated to their patellar dislocation. Of the other four, three were for a lack of progress and one for rehabilitation after a subsequent tibial tuberosity osteotomy.

No patient in the supervised rehabilitation group attended more than six physiotherapy sessions or received treatment for more than six months, as intended in the protocol. A total of 15 physiotherapists (NHS agenda for change band 5 = one; band 6 = six; band 7 = six; band 8 = two) provided the interventions and reported high fidelity to delivering the core components (Supplementary Table i).

A total of 31 patients (62%; 95% CI 48 to 74) returned nine-month KOOS4 data. Retention was higher in the 'self-managed rehabilitation' group (Table II). In January 2024, in order to address falling retention, we reworded the emails, text messages, and letters sent with follow-up questionnaires, drawing on a theory-informed letter shown to improve retention.[22] Nine-month retention before implementation was 56% (15/27) and after implementation was 70% (16/23). We also posted patients a newsletter to update them about the study's progress and to explain why completing questionnaires was important, based on a theory-informed proposal that this information can improve retention.[23] Nine-month retention before implementation was 58% (7/12) and after implementation was 63% (24/38). We posted follow-up questionnaires and a prepaid return envelope to 16 patients who had not completed nine-month follow-up despite receiving electronic invitations and automated reminders. Only two of these subsequently completed their questionnaires, both electronically, and for one this was following a phone call encouraging completion of the questionnaire.

KOOS, EQ-5D-5L, and return to pre-injury sport/physical activity scores improved from baseline to six months and then generally plateaued, and indicated that patients usually had ongoing problems (Table IV). The return to pre-injury sport/physical activity questionnaire demonstrated a ceiling effect, with 11/34 patients (33%) recording maximum scores at six months, as did 12/29 (41%) at nine months. The global rating of change questionnaire had a spread of responses at follow-up timepoints (Supplementary Table ii). Patient-reported frequency of performing the exercises is shown in Supplementary Table iii.

Table III. Adherence to allocated interventions.

Variable	Supervised rehabilitation	Self-managed rehabilitation
Patients, n	24	26
Completed physiotherapy treatment, n (%)*	13 (54)	23 (88)
Partially completed supervised rehabilitation, n (%)†	7 (29)	N/A
Patient wished to stop sessions due to work/moving out of area	3 (15)	N/A
Did not attend and/or unable to contact	3 (15)	N/A
Clinician decided that no further treatment required	1 (5)	N/A
Did not attend any physiotherapy intervention session, n (%)	4 (17)	3 (12)
Did not attend and/or unable to contact	4 (17)	3 (12)
Total number 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)
Median number of physiotherapy intervention sessions attended (IQR)	4 (3 to 5)	1 (1 to 1)
Number of physiotherapy intervention sessions attended by patients, n (%)		
1	2 (8)	23 (89)
2	2 (8)	N/A
3	3 (13)	N/A
4	6 (25)	N/A
5	3 (13)	N/A
6	4 (17)	N/A
Patients receiving additional physiotherapy sessions at site, n (%)‡	0 (0)	6 (23)
Patient-reported out-of-trial physiotherapy, n (%)		
Private physiotherapy	2 (8)	2 (8)
NHS community physiotherapy§	0 (0)	2 (8)
Median days from randomization to first treatment session (IQR)	15 (6 to 23)	16 (11 to 27)
Median days from injury to first physiotherapy session (IQR)	22 (16 to 36)	29 (18 to 41)
Median first treatment session duration, mins (IQR)	45 (43 to 60)	45 (40 to 50)
Median follow-up session duration, mins (IQR)	30 (30 to 30)	N/A
Median physiotherapy duration, days (IQR)	88 (46 to 117)	N/A

*Attended ≥ four physiotherapy sessions for supervised rehabilitation or attended ≥ one physiotherapy session for self-managed rehabilitation.
†Attended ≥ one but < four physiotherapy sessions.
‡Some patients received more than one additional physiotherapy session.
§These were the same self-managed rehabilitation patients who also had private physiotherapy.
N/A, not applicable.

The occurrence of verified pre-specified harms is shown in Supplementary Table iv. No other harms were recorded. Six patients reported eight recurrent ipsilateral dislocations and one contralateral dislocation in follow-up questionnaires, but only three dislocations met our definition of a new dislocation. A fourth dislocation was identified from the review of the medical notes by the study sites.

The results of the per-protocol analysis are shown in Supplementary Tables v and vi.

Quality assurance. We monitored intervention fidelity by reviewing physiotherapist-completed treatment logs, which recorded intervention session details, and by observing treatment sessions at three study sites. Only minor intervention deviations were identified. On 19 June 2023, we sent an infographic summarizing the core intervention components to sites to address these deviations and in response to a physiotherapist's feedback that this would be useful.

Qualitative study. A total of 36 patients who were approached for the pilot RCT gave permission to be contacted about interviews. A convenience sample of nine patients from four sites were interviewed. Their characteristics are shown in Supplementary Table vii. Three interviews were face-to-face, three were by telephone, and three by audio-video. The median length of an interview was 29 minutes (IQR 25 to 39).

Themes. The experience of recovery after an acute dislocation was conveyed through the themes of 'coming to terms with the initial injury' and 'regaining my former self'. Two other themes addressed pre-specified objectives: 'acceptability of the interventions to patients' and 'acceptability of the follow-up methods to patients'. Supplementary Table viii contains key supporting quotations from patients within categories, and categories within themes.

1: Coming to terms with the initial injury. The physical response involved initial severe pain which was greatest while the patella was dislocated. Others described feeling nauseous or vomiting, feeling that they were having a panic attack, or fainting. After the patella was reduced, patients continued to have pain and swelling, but their primary concern was impaired mobility. There was variation in the extent and duration of impaired mobility in the early recovery period, but for most it meant difficulty with everyday tasks like driving, childcare, and work. However, for one patient, the disruption to everyday life

Table IV. Clinical outcomes at different timepoints.

Variable	Total			Supervised rehabilitation		Self-managed rehabilitation	
	n	Median (IQR)	Mean (SD)	n	Median (IQR)	n	Median (IQR)
KOOS4							
Baseline	50	48.6 (32.4 to 64.7)	50.2 (21.0)	24	48.2 (31.9 to 61.7)	26	52.2 (35.5 to 64.7)
3 mths	38	65.2 (51.0 to 86.0)	66.3 (19.8)	19	73.6 (53.1 to 84.5)	19	64.1 (44.6 to 87.3)
6 mths	34	75.0 (55.9 to 85.7)	70.4 (19.4)	14	74.5 (69.4 to 86.6)	20	76.9 (53.7 to 85.6)
9 mths	31	79.4 (52.2 to 89.4)	70.5 (21.1)	13	84.3 (68.4 to 88.8)	18	64.7 (49.6 to 89.4)
KOOS symptoms*							
Baseline	50	50.0 (42.9 to 60.7)	51.9 (11.2)	24	50.0 (42.9 to 57.1)	26	53.6 (46.4 to 64.3)
3 mths	38	57.1 (42.9 to 67.9)	54.9 (13.3)	19	53.6 (42.9 to 67.9)	19	60.7 (46.4 to 67.9)
6 mths	35	60.7 (50.0 to 71.4)	58.1 (11.6)	14	57.1 (53.6 to 67.9)	21	60.7 (50.0 to 71.4)
9 mths	31	60.7 (50.0 to 67.9)	60.1 (10.5)	13	67.9 (60.7 to 67.9)	18	58.9 (50.0 to 67.9)
KOOS pain*							
Baseline	50	66.7 (55.6 to 83.3)	66.1 (22.7)	24	59.7 (50.0 to 81.9)	26	73.6 (55.6 to 83.3)
3 mths	38	83.3 (69.4 to 100)	81.6 (16.8)	19	80.6 (66.7 to 100)	19	83.3 (75.0 to 97.2)
6 mths	35	91.7 (80.6 to 97.2)	84.8 (17.7)	14	91.7 (83.3 to 100)	21	88.9 (80.6 to 94.4)
9 mths	31	91.7 (72.2 to 100)	84.2 (18.4)	13	94.4 (88.9 to 100)	18	88.9 (66.7 to 100)
KOOS ADL							
Baseline	50	72.1 (44.1 to 88.2)	66.7 (25.8)	24	65.4 (42.6 to 83.1)	26	75.0 (54.4 to 91.2)
3 mths	38	91.2 (72.1 to 100)	85.2 (15.8)	19	91.2 (72.1 to 100)	19	92.6 (70.6 to 100)
6 mths	34	95.6 (83.8 to 100)	88.1 (17.7)	14	94.9 (88.2 to 100)	20	95.6 (81.6 to 100)
9 mths	31	95.6 (80.9 to 100)	86.4 (18.2)	13	98.5 (85.3 to 100)	18	88.2 (67.6 to 100)
KOOS sport/rec							
Baseline	50	30.0 (5.0 to 65.0)	37.8 (33.2)	24	30.0 (10.0 to 62.5)	26	40.0 (5.0 to 65.0)
3 mths	38	70.0 (45.0 to 100)	67.2 (29.2)	19	75.0 (50.0 to 95.0)	19	70.0 (40.0 to 100)
6 mths	34	80.0 (60.0 to 100)	74.0 (27.8)	14	80.0 (60.0 to 100)	20	82.5 (62.5 to 100)
9 mths	31	85.0 (55.0 to 100)	74.0 (28.6)	13	90.0 (70.0 to 100)	18	72.5 (50.0 to 100)
KOOS QoL							
Baseline	50	43.8 (25.0 to 62.5)	45.0 (27.9)	24	43.8 (25.0 to 59.4)	26	40.6 (18.8 to 62.5)
3 mths	38	62.5 (37.5 to 87.5)	61.5 (28.5)	19	68.8 (43.8 to 93.8)	19	50.0 (31.3 to 81.3)
6 mths	34	71.9 (43.8 to 93.8)	65.8 (28.5)	14	71.9 (56.3 to 100)	20	65.6 (37.5 to 93.8)
9 mths	31	75.0 (37.5 to 93.8)	63.7 (32.5)	13	81.3 (56.3 to 93.8)	18	50.0 (37.5 to 87.5)
EQ-5D-5L utility score†							
Baseline	50	0.63 (0.44 to 0.73)	0.55 (0.29)	24	0.63 (0.46 to 0.74)	26	0.63 (0.44 to 0.73)
3 mths	36	0.81 (0.63 to 0.94)	0.79 (0.19)	18	0.87 (0.76 to 0.98)	18	0.75 (0.61 to 0.98)
6 mths	34	0.84 (0.63 to 0.98)	0.75 (0.27)	14	0.93 (0.73 to 0.98)	20	0.73 (0.54 to 0.93)
9 mths	30	0.85 (0.69 to 0.98)	0.78 (0.24)	13	0.98 (0.76 to 0.98)	17	0.80 (0.68 to 0.98)
EQ-5D-5L VAS							
Baseline	50	75.0 (50.0 to 85.0)	68.1 (21.1)	24	80.0 (50.0 to 87.5)	26	72.5 (50.0 to 80.0)
3 mths	36	75.0 (63.0 to 92.0)	74.3 (20.7)	18	76.5 (70.0 to 95.0)	18	75.0 (52.0 to 91.0)
6 mths	34	77.5 (70.0 to 90.0)	75.9 (19.2)	14	85.0 (74.0 to 90.0)	20	75.0 (68.5 to 86.5)
9 mths	29	82.0 (75.0 to 94.0)	79.4 (17.6)	13	82.0 (79.0 to 95.0)	16	82.5 (72.5 to 88.5)
% Return to main pre-injury sport/physical activity							
Baseline	50	50.0 (0.0 to 75.0)	40.7 (35.5)	24	50.0 (24.5 to 77.5)	26	10.0 (0.0 to 75.0)
3 mths	36	75.5 (34.5 to 90.0)	61.9 (34.2)	18	80.0 (50.0 to 99.0)	18	50.0 (30.0 to 85.0)
6 mths	34	73.5 (35.0 to 100)	66.6 (33.9)	14	75.0 (50.0 to 100)	20	71.0 (32.5 to 100)
9 mths	29	91.0 (70.0 to 100)	74.0 (36.4)	13	91.0 (87.0 to 100)	16	85.0 (25.0 to 100)

*One patient allocated to self-managed rehabilitation only completed the KOOS symptoms and pain subscales at six months, so the number of patients in self-managed rehabilitation that completed the other KOOS subscales is different at this timepoint.
†One patient allocated to self-managed rehabilitation only completed the domains section of the EQ-5D-5L questionnaire at nine months, so the number of patients self-managed rehabilitation that completed the EQ-5D-5L VAS is different at this timepoint.
ADL, activities of daily living; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, quality of life; VAS, visual analogue scale.

was relatively minor and brief. Generally, the impact was less for those whose daily tasks did not depend on higher physical function, e.g. those who could work from home.

The patella dislocated during simple day-to-day activities in all but one patient. Patients were often unsure how the injury occurred, reflecting their sense that there was no obvious pre-

cipitating event. The emotional response was therefore disbelief that the patella could dislocate during activities perceived as safe and routine. Disbelief was followed by concern for the potential disruption to everyday life. While some patients described a fear of reinjury, this was more pronounced during later recovery, suggesting that the restriction of activity in the early recovery period is mainly driven by physical impairment. Of note, one patient reported that the injury had minimal emotional impact.

2: Regaining my former self. Getting better was the experience of wanting to return to normal pre-injury life and actively pursuing this by progressively testing the knee's physical capacity. Initially, this mainly involved increasing activity levels gradually. Improving physical performance reinforced the belief that activity was helpful. Recovery was also aided by physiotherapists' reassurance that resuming certain activities and removing the splint was safe, and performing rehabilitation exercises which built confidence. The importance patients placed on physical activity was influenced by their own beliefs, their previous experience of injury and the experience of others, and advice from healthcare professionals.

Looking to the future was patients' experience of considering their injury's impact on their life going forward. Recovery varied widely, with some patients recovering fully, which included returning to multidirectional sport. For others, confidence had improved but they remained wary that the patella would dislocate again. Wariness was driven by the sudden and unexpected nature of their dislocation during routine activities, resulting in a lack of trust in the knee, and a desire to avoid reliving the experience of the injury which was unpleasant and inconvenient. Wariness manifested itself in being careful by modifying or avoiding activities to reduce the risk of reinjury. Being vigilant by keeping physically fit, maintaining a healthy weight, and strengthening the surrounding muscles was also deemed important to reduce the risk of reinjury.

Those with several patellar dislocations felt that their injury would probably recur. Despite this, some felt that their experience of rehabilitation equipped them to reduce the risk of reinjury and manage any future dislocations. For others, uncertainty over whether the injury would recur made future life choices difficult. Of note, physical symptoms, like pain, rarely drove the modification of activity during later recovery.

3: Acceptability of the interventions to patients. Patients felt that participation in the pilot RCT was low-risk because both interventions involved physiotherapy. Any preferred treatment before randomization was usually for self-managed rehabilitation because this did not require attending several physiotherapy sessions, which was initially perceived as burdensome.

Patients valued physiotherapists' guidance on when they could resume activities and remove their knee splint, feeling that this accelerated recovery and increased confidence. Those in supervised rehabilitation also valued their physiotherapist's expertise in prescribing sufficiently challenging exercises which were tailored to their functional goals. The prescription of new, more challenging exercises at follow-up sessions reinforced a sense of progression and that the adherence to the exercises was helping. Knowing that physical performance would be reassessed at follow-up also motivated them to adhere to the prescribed exercise. Those allocated to self-managed rehabilitation found this intervention acceptable, but expressed concerns that some people may require more support.

The workbooks were initially thought to be large, but patients valued the structured guidance on what to do and when. They rarely accessed the online version, feeling that this was unnecessary. The exception was exercise videos, which were valued by some for initially learning or refreshing the techniques of the exercises; once achieved, paper exercise sheets were then used for the time efficiency.

While most patients read the advice in their workbook before starting physiotherapy, initial exercises were rarely performed. They felt that these exercises were unsafe, the knee was not ready, or that the physiotherapist's expertise was necessary to decide which exercises were appropriate. Instead, before starting physiotherapy, patients focused on improving their mobility, influenced by a desire to regain functional independence.

4: Acceptability of the follow-up methods. Completing follow-up questionnaires was straightforward. It required little time and was aided by receiving the questionnaires electronically. Automated electronic reminders were helpful, as it was easy to forget to complete questionnaires. There was one exception: one patient found completing electronic questionnaires frustrating, mainly due to suboptimal formatting.

For some, questionnaires offered a chance for reflection on their progress and aspects of recovery which still required attention. Patients generally felt that the questionnaires assessed outcomes which were important to them, particularly their ability to perform day-to-day and preinjury activities.

Discussion

These results suggest that a full-scale RCT comparing exercise-based rehabilitation interventions for patients with an acute patellar dislocation is feasible. The proportion of patients willing to be randomized and the rate of recruitment met prespecified criteria for progression to the full-scale trial. Qualitative interviews also showed that patients generally found that the interventions and methods of follow-up were acceptable. However, the proportion of patients who were retained and who attended the intended number of physiotherapy sessions was lower than planned. These areas need to be addressed as part of refinements for the full-scale trial.

Retention was an issue in a previous patellar dislocation rehabilitation RCT, which used face-to-face follow-up.[13] Therefore, follow-up was remote and could be completed electronically as recommended by PPIE partners. Despite this, the retention at nine months was only 62%, with a 15% differential loss to follow-up between the intervention groups. This would seriously reduce the credibility of the results if reproduced in the full-scale trial. Optimizing the design and formatting of follow-up questionnaires is recommended to improve retention,[23] and was a refinement which was identified in qualitative interviews. Clarifying what participation in the study involves in patient-facing information and discussions about consent could also help. While patients know that follow-up is part of participation, they often cannot recall the number or frequency of follow-up questionnaires.[23] Questionnaires may then be seen as unexpected and repetitive, reducing retention,[23] which could have been an

issue in this study. Revising the messages sent with follow-up questionnaires and sending a newsletter appeared to improve retention and could be used from the outset in future. There is also some evidence that paying patients an unconditional monetary incentive improves retention compared with no incentive,[24] and this should also be considered.

The other main area of refinement would be improving patients' attendance at physiotherapy sessions. This would help to maintain a clear difference between the intervention groups in a full-scale RCT, enhancing the credibility of the results. A total of seven patients (14%) did not attend any physiotherapy sessions which exceeds the rates in comparable RCTs,[25,26] and only 13 (54%) of the supervised rehabilitation group attended the minimum of four physiotherapy sessions. Initial sessions were usually within three weeks of randomization, so this raises further questions about whether all patients understood what participation involved. Potentially, clarifying what participation involves in patient-facing information and consent discussions could improve physiotherapy session attendance as well as retention. Possibly, having received the workbook after randomization, some patients may have felt that subsequently attending physiotherapy was unnecessary. Giving patients more basic intervention materials on randomization and providing the remainder at the first physiotherapy session could encourage attendance. These basic materials could focus on the restoration of function, which was a priority for the patients who were interviewed, who were also reluctant to perform exercises before seeing a physiotherapist. For the supervised rehabilitation group, encouraging sites to offer remote follow-up appointments is another potential strategy.

Despite our efforts to recruit a representative sample, patients who declined participation were more often male and younger than those who were recruited. 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, mainly due to a preference for supervised rehabilitation. Whether patients aged < 16 years should be included in the full-scale trial requires careful thought. The results may not be generalizable to these patients if only a minority participate. In future, capturing other patient characteristics at the time of screening will improve the assessment of the study sample's representativeness. This is important because little is known about the characteristics of patients with patellar dislocation in the UK. Another trial by our group is collecting patients' ethnicity and socioeconomic characteristics on screening logs, indicating that this can be done.[27]

We included patients with acute and recurrent patellar dislocation because initial rehabilitation with later surgery, if required, is a common approach to treatment for these patients in the NHS. In this pilot, 21 patients (42%) had a recurrent dislocation. This demonstrates that they represent a significant proportion of patients with a patellar dislocation presenting to acute NHS injury services. Qualitative findings also indicated that some patients with a recurrent dislocation felt that 'supervised rehabilitation' equipped them to manage their injury long-term, though the small number of patients who were interviewed limits its confidence in this finding. In other healthcare systems, surgical stabilization is more routinely recommended for patients with a recurrent dislocation.[28,29] Thus, including these patients in a full-scale trial could limit the wider uptake of the results. The full-scale trial's eligibility criteria will therefore need to be carefully considered to avoid unnecessarily excluding patients who may benefit from the interventions, while ensuring that the study sample is sufficiently homogeneous to ensure that the findings are clinically useful.

This study's strengths included the use of five sites with variable characteristics which increases confidence that the study was a good assessment of feasibility. Mixed-methods were also used which enhanced judgements about feasibility; the qualitative interviews helping to understand which elements of the pilot RCT's design could be improved. To our knowledge, the embedded qualitative study is the first of its type to be conducted in patients with an acute patellar dislocation, and this also provides a valuable contribution to our understanding of the experience of recovery after this injury. Methodological limitations include not interviewing physiotherapists to understand their experience of providing the interventions. However, regular email contact and site visits were opportunities to obtain physiotherapists' informal feedback which was valuable at this feasibility stage.[30] Further interviews would also have increased confidence that the qualitative themes were saturated.

In conclusion, this study's findings indicate that a full-scale RCT comparing exercise-based rehabilitation interventions for patients with an acute patellar dislocation is feasible, but modifications are required, particularly to improve retention and patients' attendance at physiotherapy sessions. Wider stakeholder consultation to inform these refinements would be beneficial and funding has been secured to conduct this work. We plan to apply for the full-scale trial in 2026.

Take home message

- This study showed that a full-scale randomized controlled trial comparing different exercise-based rehabilitation interventions for people with an acute first-time and recurrent patellar dislocation is feasible with minor modifications to improve retention and patient attendance at physiotherapy sessions.
- This full-scale trial would provide much needed high-quality evidence to guide rehabilitation provision for this patient population.

Social media

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Supplementary material

Supplementary material includes the qualitative interview topic guide, intervention fidelity data, additional outcome data including per-protocol analysis results, and qualitative interview patient characteristics and supporting patient quotations.

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