Archives of Rehabilitation Research and Clinical Translation (2024) 6, 100334

ACRM AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Rehabilitation Research and Clinical Translation

Archives of Rehabilitation Research and Clinical Translation 2024;6:100334

Available online at www.sciencedirect.com

OPEN ACCESS ARCHIVES of Rehabilitation Research & Clinical Translation

Original Research

Combined Hip and Knee Strengthening Compared With Knee Strengthening for Individuals With Lateral Patellar Dislocation: A Single-blind, Superiority, Randomized Controlled Trial

Lucas Simões Arrebola, PhD [a,b], Toby O. Smith, PhD [c,d], Vanessa Gonçalves Coutinho de Oliveira, MSc [a,b], Pedro Rizzi de Oliveira, MSc [a,b], Paloma Yan Lam Wun [b], Rogério Teixeira de Carvalho, PhD [e], Carlos Eduardo Pinfildi, PhD [a]

[a] *Department of Human Movement Sciences, Federal University of São Paulo (UNIFESP), Baixada Santista Campus, São Paulo, Brazil*
[b] *Physical Therapy Department, Institute of Medical Assistance to the State Public Servant (IAMSPE), São Paulo, Brazil*
[c] *Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, United Kingdom*
[d] *Faculty of Medicine and Health Sciences, University of East Anglia, Norwich, United Kingdom*
[e] *Department of Orthopaedics, Institute of Medical Assistance to the State Public Servant (IAMSPE), São Paulo, Brazil*

KEYWORDS
Clinical trial;
Conservative treatment;

Abstract *Objective:* To investigate whether a combined hip and knee muscle strengthening program is superior to a knee strengthening program for people after lateral patellar dislocation (LPD).

Disclosures: Dr Toby Smith is supported by funding from the National Institute for Health Research (NIHR) Oxford Health Biomedical Research Centre. The views expressed are those of the author(s) and not necessarily those of the NIHR. All other authors declare no potential conflicts of interest with respect to the research, authorship, and publication of this manuscript.
List of abbreviations: AKPS, anterior knee pain scale; ES, effect size; HQSG, hip and quadriceps strengthening group; KBSG, Knee-based strengthening group; LEFS, lower extremity functional scale; LPD, lateral patellar dislocation; LR, lateral rotators; MPFL, medial patellofemoral ligament; MR, medial rotators; MRI, magnetic resonance imaging; NPI Score, Norwich Patellar Instability Score; NPRS, numerical pain rating scale; PD, patellar dislocation; PFP, patellofemoral pain; PROM, Patient-Reported Outcome Measure; RCT, randomized controlled trial; WHOQOL, World Health Organization quality of life assessment.
Trial Registration Number: Registered in Brazilian Clinical Trials Registry: RBR-8kf6ks, on January 21, 2018.
Cite this article as: Arch Rehabil Res Clin Transl. 2024;000:100334

https://doi.org/10.1016/j.arrct.2024.100334

Patellar dislocation;
Rehabilitation;
Resistance training

Design: Single-blind, superiority, randomized controlled trial with 48 weeks follow-up.
Setting: Physiotherapy out-patient clinic.
Participants: Forty individuals aged 16 or older, with a history of non-traumatic LPD were randomized to a knee-based strengthening (KBSG) or quadriceps and hip strengthening exercise (HQSG) program (N=40). Inclusion criteria included a positive apprehension sign, pain on palpation along the medial retinaculum, and J sign. Exclusion criteria included restricted range of motion (<90° knee flexion), and traumatic or postsurgical LPD.
Interventions: Concealed randomization was performed using random permuted blocks of size 4. Individuals received their corresponding exercise program according to randomization and group allocation: knee-based strengthening (n=20) or combined hip and quadriceps strengthening (n=20) twice weekly for 8 weeks over 16 appointments.
Main Outcome Measures: Primary outcome was the Lysholm Knee Score. Secondary outcomes included Numerical Pain Ratings Scale (NPRS) at rest and during effort, Norwich Patellar Instability Score (NPIS), Kujala Anterior Knee Pain Scale (AKPS), Lower Extremity Functional Scale (LEFS), 4 domains of the WHOQOL-Bref, and recurrence rate. Patient-reported outcome measures were assessed from the baseline to 48 weeks. Assessments were performed by a physiotherapist who was blinded to the group allocation. Data were analyzed by using a repeated-measures ANOVA model with Tukey's post hoc test after an intention-to-treat principle.
Results: At the primary time-point of 8 weeks, there were no substantial between-group differences in the Lysholm Knee Score: mean difference=-6.8 (95% CI -14.3 to 3.7); NPIS: mean difference=23.5 (95% CI 5.6 to 41.3); AKPS: mean difference=-1.54 (95% CI -8.6 to 5.6), NPRS at rest and during effort (mean difference=0.32 (95% CI -0.37 to 1); and mean difference=0.68 (95% CI -0.9 to 1.86); LEFS mean difference=-1.08 (95% CI -5.9 to 2.4), WHOQOL-Bref domains (physical health: mean difference=-0.12, (95% CI -1.26 to 1.02); psychological: mean difference=-0.32 (95% CI -2.04 to 1.4); social relations: mean difference=-0.7 (95% CI -2.2 to 0.82); environment: mean difference=0.44 (95% CI -1 to 1.9), and recurrence rate (P=.69).
Conclusion: This study indicates that combined hip and knee muscle strengthening is not superior to knee-based strengthening for LPD treatment. The limitations stemming from the underpowered nature of the trial must be acknowledged, concerning the potential oversight of moderate intervention effects.

Lateral patellar dislocation (LPD) is a prevalent orthopedic condition[1] characterized by the lateral displacement of the patella away from the trochlear groove, often accompanied by a rupture of the medial patellofemoral ligament (MPFL).[2]

Recurrent LPD occurs in approximately 7.7%-13.8% of cases in the absence of any risk factors.[3] This incidence can increase substantially, reaching up to 70% of cases when 3 or more risk factors are present.[3,4] Individuals with recurrent dislocations commonly face a diminished quality of life, characterized by persistent symptoms such as pain, instability, reduced activity, and the potential for chondral injury to the patellofemoral joint.[5,6]

Several anatomic factors have been attributed to first-time LPD, such as trochlear dysplasia, tibial tuberosity to trochlear groove distance greater than 20 mm, patella alta, lateral patellar tilt exceeding 20°, skeletal immaturity, and ligamentous laxity.[6,7]

Conservative treatment stands as the primary approach for managing first-time LPD in the absence of osteochondral fracture.[8] This frequently focuses on vastus medialis and general quadriceps strengthening, quadriceps electrical stimulation, and proprioceptive exercises.[9,10]

The recommendation to incorporate a hip muscle strengthening program alongside quadriceps muscle strengthening for individuals after LPD is rooted in the evidence base for patellofemoral pain (PFP).[11-13] Despite recent findings suggesting an association between hip muscles weakness and recurrent instability,[14] the efficacy of a combined hip muscle and quadriceps strengthening program remains unexplored in the context of LPD. Moreover, while such programs have been investigated in the context of PFP,[13] the distinct nature of LPD as compared with PFP suggests caution in generalizing these findings. Accordingly, the objective of this trial was to evaluate the superiority of a hip muscle strengthening (extensors, abductors, and lateral rotators [LR]) in conjunction with a quadriceps strengthening program compared with a program focusing on knee-based strengthening exercises.

Methods

Study design

This was a single-blinded, superiority, parallel, randomized controlled trial (RCT). This has been reported in accordance to the Consolidated Standards of Reporting Trials (CONSORT) reporting statement.

Participants

Participants with a prior history of non-traumatic LPD requiring emergency care were recruited from the Institute of

Medical Assistance to the State Public Servant (IAMSPE) under the supervision of a medical doctor responsible for diagnosing these cases (RTdC). All participants signed an informed consent form or assent form depending on age. The study was approved by the Federal University of São Paulo Ethics and Research Committee on October 05, 2017 (reference: 2.317.503) and the IAMSPE Ethics and Research Committee on December 18, 2017 (reference: 2.445.222). It was prospectively registered in the Brazilian Clinical Trials Registry (RBR-8kf6ks).

This study was conducted in compliance with the principles of the Declaration of Helsinki.

Eligibility criteria

The eligibility of participants was evaluated by the medical doctor (RTdC) who was responsible for diagnosing these cases.

Inclusion criteria

We included men and women, aged 16 or older, with a history of nontraumatic LPD — whether it was their initial occurrence or a recurrent event. This encompassed both unilateral cases and those with a prior history of dislocation in either leg (bilateral) requiring emergency care. The interval between the latest LPD episode and enrolment was required to be a minimum of 6 weeks. Participants were required to exhibit a positive apprehension sign to the lateralization of the patella, pain on palpation along the medial retinaculum, and increased patellar inclination in knee-flexion-extension (J sign).[15]

Exclusion criteria

We excluded participants who had used knee immobilization for more than 48 hours after their emergency care visit, or those with restricted range of motion hindering compliance with the exercise protocol at the time of approach (less than 90° of knee flexion). We excluded participants with a history of traumatic or patellar dislocation (PD) after surgery, prior traumatic meniscal injury, prior complete tear of the anterior cruciate ligament, posterior cruciate ligament, and/or collateral ligament, a history of radiological evidence of knee osteoarthritis, and those who had undergone lower limb surgery during the previous 12 months.

Setting

This study occurred at a physiotherapy out-patient clinic at a tertiary hospital.

Randomization

Concealed randomization was performed using randomly permuted blocks of size 4, generated on Microsoft Excel, employing a simple randomization method, in a 1:1 allocation ratio. The randomization process was performed by a physiotherapist uninvolved in enrolment, assessments or treatment (PYLW). Opaque, closed, numbered envelopes were used and stored in a locked cabinet. The randomized groups comprised the knee-based strengthening group (KBSG) and the hip and quadriceps strengthening group (HQSG). Group assignment occurred post-consent and completion of baseline questionnaires. This allocated group information was subsequently communicated to the physiotherapist responsible for the intervention (VGCdO).[16]

Intervention

After randomization, each individual received their corresponding exercise program: isolated quadriceps strengthening or combined hip and quadriceps strengthening. Both programs commenced a minimum of 6 weeks after the last episode of LPD and were delivered by an experienced physiotherapist (VGCdO), face-to-face, twice weekly for 8 weeks over 16 appointments. The 8-week duration was chosen to align with the predominant treatment period identified in routine physiotherapy practices for this specific population.[17] The exercises prescribed, the load progression, and the type of exercises and equipment used are described in table 1 and illustrated in figures 1-6. The load was measured and progressed weekly, tailored in dosage to participants.

The KBSG had treatment sessions lasting 30 minutes for the first 2 weeks, 45 minutes for weeks 2-4, and 60-70 minutes for weeks 4-8. The HQSG's sessions were 60 minutes for the first 2 weeks, 75 minutes for weeks 2-4, and 90-100 minutes for weeks 4-8.

The KBSG and the HQSG programs were developed based on the frameworks proposed in prior studies involving participants with PFP.[11,12,18,19]

At the end of each program, participants from both groups were instructed to conduct strengthening exercises at a gym on their own, for a minimum of 3 times per week.[20] Exercise compliance was recorded at each follow-up appointment using the following question: "did you continue the muscle strengthening exercises at a gym at least 3 times per week?"

Outcome measures

Data were collected at the following time-points: baseline (pre-randomization), 4 weeks, 8 weeks (primary endpoint), 12 weeks, 24 weeks, and 48 weeks post-randomization. The selection of the 8-week primary endpoint was based on aligning with the established 8-week discharge timeframe and considering the practical transition of patients to gym-based activities. The isometric hip and knee muscle strength evaluation was collected at baseline (pre-randomization) and the end of the treatment (8 weeks post-randomization). The primary outcome measure was the Lysholm Knee Score.[21] The Lysholm Knee Score is a Patient-Reported Outcome Measure (PROM) designed to evaluate the functional status of individuals with knee conditions. Scores range from 0 to 100, with higher scores reflecting better knee function. It was chosen as the primary outcome because it was validated for patients with patellar instability, demonstrating high internal consistency and test-retest reliability.[22] The secondary outcomes were as follows:

Numerical pain rating scale (NPRS) at rest and during effort[23]: Numerical scale comprising 11 points, where 0 denoted the absence of pain, and 10 represented the worst pain imaginable. The term "rest pain" referred to discomfort experienced when the individual was stationary, while

Table 1 Protocol description of Knee-based Strengthening Group and Hip and Quadriceps Strengthening Group according to TIDieR guideline

Group	Time	Exercise	Load	Sets	Equipment
KBSG	0-2 weeks	Hamstrings stretching	30 seconds	3 sets for each leg	Inelastic belt
KBSG		Quadriceps strengthening in OKC	Elastic resistance	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Exercise band of medium resistance
		Quadriceps strengthening in CKC with low feet positioning and protected angle (0°-60°/70° of knee flexion)	60% of 1RM	3 sets of 15 repetitions using both legs with 30 seconds of rest between sets	Leg-press
		Quadriceps strengthening in CKC with protected angle (0°-60°/70° of knee flexion)	60% of 1RM	3 sets of 15 repetitions using both legs with 30 seconds of rest between sets	Hack squat
	2-4 weeks	Hamstrings stretching	1 minute	3 sets for each leg	Inelastic belt
		Quadriceps strengthening in OKC	80% of 1RM	3 sets of 12 repetitions using both legs with 60 seconds of rest between sets	Quadriceps bench
		Quadriceps strengthening in CKC with low foot positioning and protected angle (0°-60°/70° of knee flexion)	80% of 1RM	3 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Leg-press
		Quadriceps strengthening in CKC with protected angle (0°-60°/70° of knee flexion)	80% of 1RM	3 sets of 12 repetitions using both legs with 60 seconds of rest between sets	Hack squat
		Balance exercise — static control of medial femoral rotation in a stable surface	Bodyweight	3 sets of 30 seconds for each leg with 30 seconds of rest between sets	Step
	4-8 weeks	Hamstrings stretching	1 minute	3 sets for each leg	Inelastic belt
	4-8 weeks	Quadriceps strengthening in OKC	80% of 1RM	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Quadriceps bench
		Quadriceps strengthening in CKC with low foot positioning and protected angle (0°-60°/70° of knee flexion)	80% of 1RM	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Leg-press
		Quadriceps strengthening in CKC with protected angle (0°-60°/70° of knee flexion)	80% of 1RM	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Hack squat
		Balance exercise — dynamic valgus control on a step-down task	Bodyweight	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Step
		Balance exercise — static control of medial femoral rotation in an unstable surface	Bodyweight	3 sets of 30 seconds for each leg with 30 seconds of rest between sets	Bosu ball
HQSG		Hamstrings stretching	30 seconds	3 sets for each leg	Inelastic belt
HQSG	0-2 weeks	Quadriceps strengthening in OKC	Elastic resistance	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Exercise band of medium resistance
HQSG	0-2 weeks				
HQSG		Quadriceps strengthening in CKC with low feet positioning and protected angle (0°-60°/70° of knee flexion)	60% of 1RM	3 sets of 15 repetitions using both legs with 30 seconds of rest between sets	Leg-press
HQSG					
		Quadriceps strengthening in CKC with protected angle (0°-60°/70° of knee flexion)	60% of 1RM	3 sets of 15 repetitions using both legs with 30 seconds of rest between sets	Hack squat
		Hip abductors strengthening in OKC (SLR)	60% of 1RM	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Ankle weights
		Hip abductors strengthening in OKC — Side-lying clam	Elastic resistance	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Exercise band of medium resistance
		Hip extensors strengthening in OKC (SLR)	60% of 1RM	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Ankle weights
		Hip lateral rotators at 90° strengthening	Elastic resistance	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Exercise band of light resistance
		Hip lateral rotators at 0° strengthening	Elastic resistance	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Exercise band of light resistance
	2-4 weeks	Hamstrings stretching	1 minute	3 sets for each leg	Inelastic belt
	2-4 weeks	Quadriceps strengthening in OKC	80% of 1RM	3 sets of 12 repetitions using both legs with 60 seconds of rest between sets	Quadriceps bench
		Quadriceps strengthening in CKC with low foot positioning and protected angle (0°-60°/70° of knee flexion)	80% of 1RM	3 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Leg-press

(*continued*)

Table 1 (*Continued*)

Group	Time	Exercise	Load	Sets	Equipment
		Quadriceps strengthening in CKC with protected angle (0°-60°/70° of knee flexion)	80% of 1RM	3 sets of 12 repetitions using both legs with 60 seconds of rest between sets	Hack squat
		Hip abductors strengthening in OKC (SLR)	80% of 1RM	3 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Ankle weights
		Hip abductors strengthening in OKC — Side-lying clam	Elastic resistance	3 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Exercise band of medium-heavy resistance
		Hip extensors strengthening in OKC (SLR)	80% of 1RM	3 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Ankle weights
		Hip lateral rotators at 90° strengthening	Elastic resistance	3 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Exercise band of light-medium resistance
		Hip lateral rotators at 0° strengthening	Elastic resistance	3 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Exercise band of light-medium resistance
		Balance exercise — static control of medial femoral rotation in a stable surface	Bodyweight	3 sets of 30 seconds for each leg with 30 seconds of rest between sets	Step
		Hamstrings stretching	1 minute	3 sets for each leg	Inelastic belt
	4-8 weeks 4-8 weeks	Quadriceps strengthening in OKC	80% of 1RM	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Quadriceps bench
		Quadriceps strengthening in CKC with low foot positioning and protected angle (0°-60°/70° of knee flexion)	80% of 1RM	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Leg-press
		Quadriceps strengthening in CKC with protected angle (0°-60°/70° of knee flexion)	80% of 1RM	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Hack squat
		Hip abductors strengthening in OKC (SLR)	80% of 1RM	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Ankle weights
		Hip abductors strengthening in OKC — Side-lying clam	Elastic resistance	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Exercise band of heavy resistance
		Hip extensors strengthening in OKC (SLR)	80% of 1RM	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Ankle weights
		Hip lateral rotators at 90° strengthening	Elastic resistance	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Exercise band of medium resistance
		Hip lateral rotators at 0° strengthening	Elastic resistance	4 sets of 12 repetitions for each leg with 60 seconds of rest between sets	Exercise band of medium resistance
		Balance exercise — dynamic valgus control on a step-down task	Bodyweight	3 sets of 15 repetitions for each leg with 30 seconds of rest between sets	Step
		Balance exercise — static control of medial femoral rotation in an unstable surface	Bodyweight	3 sets of 30 seconds for each leg with 30 seconds of rest between sets	Bosu ball

Abbreviations: 1RM, 1-repetition maximum; CKC, Closed Kinetic Chain; OKC, Open Kinetic Chain.

Fig 1 Exercises performed from 0 to 2 weeks — Knee-based Strengthening Group. (A) Hamstring stretching; (B) Quadriceps strengthening in open kinetic chain with elastic resistance; (C) Quadriceps strengthening in closed kinetic chain on a leg-press machine; (D) Quadriceps strengthening in closed kinetic chain on a hack squat.

"effort pain" encompassed the pain during activities such as squatting, kneeling, and climbing stairs.

Norwich Patellar Instability (NPI) Score:[24] The NPI Score was designed to assess the effect of patellar instability on an individual's daily life. It includes domains related to symptoms and functional limitations. The score ranges from 0 to 250, with lower scores indicating better outcomes.[22]

Kujala Anterior Knee Pain Scale (AKPS):[25] The AKPS is a PROM specifically focused on evaluating individuals with anterior knee pain. The score ranges from 0 to 100, with higher scores indicating better knee function.[23]

Lower Extremity Functional Scale (LEFS):[26] The LEFS is a PROM that gauges the functional status of individuals with lower extremity musculoskeletal conditions. It encompasses various daily activities, ranging from basic functions to more complex movements. The score ranges from 0 to 80, with higher scores indicating better functional status.[24]

World Health Organization Quality of Life Assessment (WHOQOL-BREF):[27] The WHOQOL-BREF is composed of 4 domains: physical health, psychological, social relations, and environmental. For statistical purposes, the domains were interpreted separately. The mean scores obtained per domain were multiplied by 4 to compare the results with the WHOQOL-100 scores and better interpret the findings.[28]

Frequency of recurrent PD requiring emergency or health care management. The analysis encompasses instances involving either patella in individuals with a history of bilateral dislocation.[15]

Isometric hip and knee muscle strength evaluation assessed using the Lafayette Manual Muscle Testing System Model-01165,[a] factory calibrated.[14] The hand-held dynamometer was stabilized with assessor counter-resistance and externally with an inelastic belt to assess the hip and the knee muscles, respectively. The following muscle groups were assessed: hip flexors, hip extensors, hip abductors, hip adductors, hip LR at 90°and 0°, hip medial rotators (MR) at 90° and 0°, and femoral quadriceps at 60°. All patients were evaluated in sequence, alternating measurements between lower limbs to minimize fatigue. Before the evaluation, 2 submaximal contractions were performed to familiarize individuals. Subjects were verbally encouraged to perform the contractions at maximum capacity. For each muscle group, 3 measurements were performed with an interval of 30 seconds between tests. If the difference between measurements was greater than 10%, the result was discarded and remeasurement occurred. The muscle strength values obtained were normalized by body mass, employing the following formula: strength (kgf)/mass

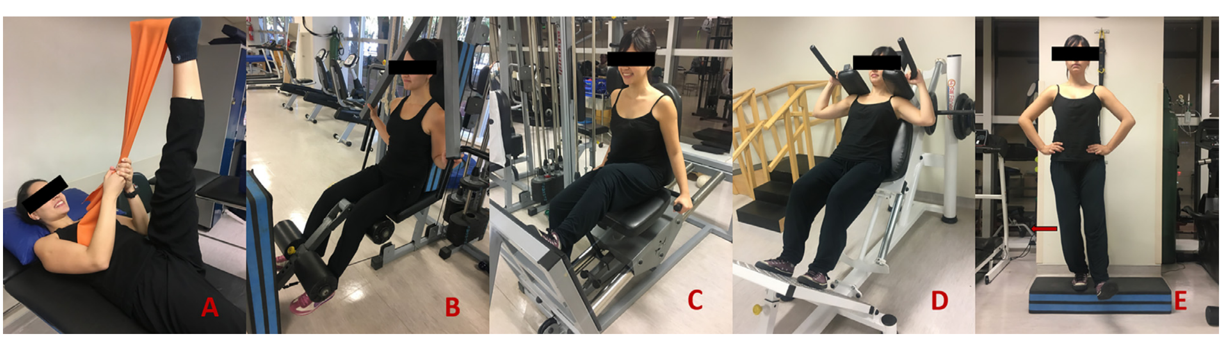

Fig 2 Exercises performed from 2 to 4 weeks — Knee-based Strengthening Group. (A) Hamstring stretching; (B) Quadriceps strengthening in open kinetic chain on a quadriceps bench; (C) Quadriceps strengthening in closed kinetic chain on a leg-press machine; (D) Quadriceps strengthening in closed kinetic chain on a hack squat; (E) Static control of medial femoral rotation on a stable surface.

Fig 3 Exercises performed from 4 to 8 weeks — Knee-based Strengthening Group. (A) Hamstring stretching; (B) Quadriceps strengthening in open kinetic chain on a quadriceps bench; (C) Quadriceps strengthening in closed kinetic chain on a leg-press machine; (D) Quadriceps strengthening in closed kinetic chain on a hack squat; (E) Dynamic valgus control on a step-down task; (F) Static control of medial femoral rotation on an unstable surface.

Fig 4 Exercises performed from 0 to 2 weeks — Hip and Quadriceps Strengthening Group. (A) Hamstring stretching; (B) Quadriceps strengthening in open kinetic chain with elastic resistance; (C) Quadriceps strengthening in closed kinetic chain on a leg-press machine; (D) Quadriceps strengthening in closed kinetic chain on a hack squat; (E) Hip abductors strengthening on a straight leg raise (SLR) exercise with ankle weights; (F) Hip abductors strengthening on a side-lying clam exercise with elastic resistance; (G) Hip extensors strengthening on a SLR exercise with ankle weights; (H) Hip LR at 90° strengthening with elastic resistance; (I) Hip LR at 0° strengthening with elastic resistance.

Fig 5 Exercises performed from 2 to 4 weeks — Hip and Quadriceps Strengthening Group. (A) Hamstring stretching; (B) Quadriceps strengthening in open kinetic chain on a quadriceps bench; (C) Quadriceps strengthening in closed kinetic chain on a leg-press machine; (D) Quadriceps strengthening in closed kinetic chain on a hack squat; (E) Hip abductors strengthening on a straight leg raise (SLR) exercise with ankle weights; (F) Hip abductors strengthening on a side-lying clam exercise with elastic resistance; (G) Hip extensors strengthening on a SLR exercise with ankle weights; (H) Hip LR at 90° strengthening with elastic resistance; (I) Hip LR at 0° strengthening with elastic resistance; (J) Static control of medial femoral rotation on a stable surface.

(kg) × 100. The mean of the 3 contractions was used for comparisons.

All assessments were performed by the same experienced physiotherapist (PRdO) who was blinded to the group allocation.

Sample size calculation

The sample size was based on a Lysholm Knee Score[21] at the end of the treatment (8 weeks; primary endpoint), where a 10-point clinical difference[29] was considered significant

Fig 6 Exercises performed from 4 to 8 weeks — Hip and Quadriceps Strengthening Group. (A) Hamstring stretching; (B) Quadriceps strengthening in open kinetic chain on a quadriceps bench; (C) Quadriceps strengthening in closed kinetic chain on a leg-press machine; (D) Quadriceps strengthening in closed kinetic chain on a hack squat; (E) Hip abductors strengthening on a straight leg raise (SLR) exercise with ankle weights; (F) Hip abductors strengthening on a side-lying clam exercise with elastic resistance; (G) Hip extensors strengthening on a SLR exercise with ankle weights; (H) Hip LR at 90° strengthening with elastic resistance; (I) Hip LR at 0° strengthening with elastic resistance; (J) Dynamic valgus control on a step-down task; (K) Static control of medial femoral rotation on an unstable surface.

between groups, assuming Cohen's *d* effect size (ES) of 1.06, a power of 0.80, and a statistical significance level of $P<.05$ (2-sided). This resulted in a sample size of 30 individuals, 15 per group, increased by 25% for attrition, resulting in a total of 40 participants, 20 per group.[15]

Statistical analysis

Descriptive data were represented by the mean ± SD and frequency. Prior to analysis, the data distribution was assessed for normality and homogeneity by visual inspection of histograms and Shapiro-Wilk and Levene tests.

The analysis followed an intention-to-treat principle. Missing data were addressed through multiple imputations and analyzed through sensitivity analysis.[30] Ten imputations of missing values were generated through the fully conditional specification. The imputations were analyzed through descriptive statistics (mean ± SD, interquartile ranges, and confidence intervals [CI]) to verify the imputed data did not deviate significantly from the original.

At each time-point, descriptive analyses, including means, mean differences, and 95% CI, were employed to assess between-group differences. Additionally, a repeated-measures ANOVA model with Tukey's post hoc test was applied for further analysis. The recurrence rate was presented as both frequency and percentage, and inter-group differences at each time-point were scrutinized through Log Rank (Mantel-Cox) and Kaplan-Meier survival analyses. This post hoc analysis was conducted to enhance the interpretability of our findings. Exercise compliance was conveyed in terms of frequency and percentage.

A significance level of 0.05 was used in all statistical tests.

All analyses were performed using IBM SPSS software version 20.0 for Windows.[b]

Results

Flow of the participants and cohort characteristics

From 24 September 2018 through 7 January 2020, 43 individuals were screened for eligibility, with 3 ineligible for inclusion. Forty individuals (11 men; 29 women) with a mean age of 20.3 years underwent randomization with 20 assigned to KBSG and 20 to HQSG. The characteristics of the participants and baseline data are presented in table 2, while the Consort Flow Diagram is provided in figure 7.

Primary outcome

Lysholm Knee Score

As illustrated in table 3, the mean differences observed between the KBSG and HQSG during the treatment period were -9.7 (95% CI -19.4 to 4.8) at 4 weeks, and -6.8 (95% CI -14.3 to 3.7) at 8 weeks. The mean differences for the follow-up periods were -5.4 (95% CI -14 to 3.2) at 12 weeks, -5.5 (95% CI -13.9 to 2.8) at 24 weeks, and -1.64 (95% CI -13.6 to 10.3) at 48 weeks, as illustrated in table 4. No statistically significant differences were observed between the KBSG and HQSG in the Lysholm Knee Score at any time point.

Secondary outcomes

NPRS at rest and during effort

The mean differences between the KBSG and HQSG during the treatment period for the NPRS at rest were 1.4 (95% CI 0.45 to 2.4) at 4 weeks, and 0.32 (95% CI -0.37 to 1) at 8 weeks. Likewise, for the NPRS during effort during the same period, the mean differences between groups were 2.2 (95% CI 0.62 to 3.8), and 0.68 (95% CI -0.9 to 1.86), respectively. These findings are presented in table 3.

During the follow-up periods, the mean differences between groups for the NPRS at rest were 0.59 (95% CI -0.2 to 1.34) at 12 weeks, 0.23 (95% CI -0.6 to 1.12) at 24 weeks, and 0.25 (95% CI -0.9 to 1.43) at 48 weeks. For the NPRS during effort, the mean differences were 0.95 (95% CI -0.42 to 2.3) at 12 weeks, 0.77 (95% CI -0.56 to 2.1) at 24 weeks, and 0.9 (95% CI -0.74 to 2.5) at 48 weeks. These findings are presented in table 4.

While no statistical difference was observed between the KBSG and HQSG for the NPRS at rest and during effort at any time point, a clinically meaningful distinction between the groups emerged for the NPRS during effort at the 4-week mark.[23]

NPI Score

As shown in table 3, the mean differences between groups for the NPI Score during the treatment period were 8.6 (95% CI -19.1 to 36.3) at 4 weeks and 23.5 (95% CI 5.6 to 41.3) at 8 weeks. In table 4, mean differences between groups during follow-up were 15.7 (95% CI -1.8 to 33.2) at 12 weeks, 18.9 (95% CI 0.2 to 37.6) at 24 weeks, and 10.8 (-9.2 to 30.7) at 48 weeks. While the NPI Score demonstrated no significant difference between the KBSG and HQSG at any time point, the 95% CI for the group differences did not cross the zero mark, potentially indicating a difference favoring the HQSG. This information is depicted in tables 3 and 4.

Kujala AKPS

As presented in table 3, the mean differences between the KBSG and HQSG for the Kujala AKPS during the treatment period were -2.8 (95% CI -12.4 to 6.8) at 4 weeks, and -1.54 (95% CI -8.6 to 5.6) at 8 weeks. Table 4 illustrates the follow-up periods, where the mean differences between groups were -1.6 (95% CI -9.9 to 6.6) at 12 weeks, -3.2 (-11.6 to 5.2) at 24 weeks, and -1.2 (-10.2 to 7.9) at 48 weeks. No substantial differences between the KBSG and HQSG were found at any time point.

LEFS

The mean differences between KBSG and HQSG for the LEFS during the treatment period were -6.8 (95% CI -13.9 to 0.28) at 4 weeks, and -1.08 (95% CI -5.9 to 2.4) at 8 weeks, as illustrated in table 3. In the follow-up periods, the mean differences between groups were -3.1 (95% CI -8.4 to 2.3) at 12 weeks, -5 (95% CI -10.4 to 0.28) at 24 weeks, and -2.7 (95% CI -10.6 to 5.2) at 48 weeks, as shown in table 4.

The LEFS demonstrated no substantial difference between the KBSG and HQSG at any time point.

WHOQOL-Bref

As indicated in table 3, the mean differences between groups during the treatment period for the 4 domains of the

Table 2 Characteristics of the participants and baseline data

Variable	KBSG (n=20) Mean ± SD	HQSG (n=20) Mean ± SD
Women	13	16
Men	7	4
Age (y)	18.85 (4.67)	21.75 (7.79)
Weight (kg)	68.5 (16.4)	61.6 (12.29)
Height (m)	1.67 (0.07)	1.66 (0.09)
BMI (kg/m^2)	24.2 (4.65)	22.34 (4.05)
Number of episodes	3.05 (2.01)	3.4 (3.01)
Age at first episode (y)	14.50 (4.19)	14.30 (4.57)
Bilateral dislocation	8	6
Unilateral dislocation	12	14
Lysholm Knee Score	59.85 (17.2)	59.25 (21.2)
NPRS at rest	1.82 (2.69)	2.4 (2.78)
NPRS during effort	4.62 (2.74)	5.1 (3.05)
NPIS	94.45 (51.3)	94.80 (51.2)
Kujala AKPS	66.15 (14.7)	64.95 (16.6)
LEFS	52.2 (15.21)	56.3 (12.75)
WHOQOL-BREF physical health	12.22 (2.45)	12.72 (2.56)
WHOQOL-BREF psychological	14.66 (3.10)	14.88 (2.30)
WHOQOL-BREF social relations	15.78 (3.01)	15.98 (3.33)
WHOQOL-BREF environment	13.94 (2.72)	13.58 (2.12)
Isometric hip flexors strength (kgf/kg × 100)	31 (7.42)	30.36 (7.90)
Isometric hip extensors strength (kgf/kg × 100)	26.68 (7.67)	26.74 (7.51)
Isometric hip abductors strength (kgf/kg × 100)	17.33 (3.77)	17.23 (4.55)
Isometric hip adductors strength (kgf/kg × 100)	15.81 (4.58)	14.18 (4.96)
Isometric hip LR 90° strength (kgf/kg × 100)	13.54 (3.27)	14.42 (4.29)
Isometric hip LR 0° strength (kgf/kg × 100)	13.29 (3.91)	11.53 (2.62)
Isometric hip MR 90° strength (kgf/kg × 100)	16.70 (5.55)	17.18 (5.36)
Isometric hip MR 0° strength (kgf/kg × 100)	11.14 (3.28)	10.8 (2.66)
Isometric quadriceps strength (kgf/kg × 100)	43.72 (10)	38.28 (13.8)

Abbreviations: BMI, body mass index.

WHOQOL-BREF were as follows: -0.56 (95% CI -2.1 to 1) at 4 weeks and -1.08 (95% CI -5.9 to 2.4) at 8 weeks for physical health; -0.34 (95% CI -2.2 to 1.5) at 4 weeks and -0.32 (95% CI -2.04 to 1.4) at 8 weeks for psychological health; -0.84 (95% CI -2.5 to 0.8) at 4 weeks and -0.7 (95% CI -2.2 to 0.82) at 8 weeks for social relations; -0.16 (95% CI -1.5 to 1.1) at 4 weeks and 0.44 (-1 to 1.9) at 8 weeks for the environment. No substantial differences between the KBSG and HQSG were observed for the 4 domains of the WHOQOL-Bref at any time point.

Frequency of recurrent patellar dislocation

As in tables 3 and 4 and figure 8, there was no substantial difference between the QS and HQS in the frequency of recurrent PD requiring health care management at any time, as indicated by the Log Rank (Mantel-Cox) and Kaplan-Meier survival analyses. At the 4-week follow-up, 1 participant from the HQSG experienced an episode of recurrent PD managed conservatively. Similarly, at the 12-week follow-up, 1 participant from the KBSG experienced an episode of recurrent PD managed surgically through MPFL reconstruction. Furthermore, at the 24-week follow-up, 1 participant from the KBSG faced recurrent PD and opted for conservative treatment (early mobilization and strengthening exercises). At the 48-week follow-up, 3 participants from the HQSG and 1 participant from the KBSG experienced recurrent PD. Among the HQSG, 1 opted for surgical treatment (MPFL reconstruction), while the remaining 2 chose conservative treatment (early mobilization and strengthening exercises). Overall, the prevalence of recurrent PD over the 48-week study period was 17.5% (7/40; KBSG=3; HQSG=4). Five of the 7 participants who experienced recurrent PD were not engaged in the exercises at the time of the recurrence.

Isometric hip and knee muscle strength

As depicted in table 3, the mean differences between the KBSG and HQSG for the hip and knee strength at the end of the treatment (8 weeks) were as follows: -0.5 kgf/kg × 100 (95% CI -6.7 to 5.7) for hip flexors, 1.83 kgf/kg × 100 (95% CI -3.4 to 7) for hip extensors, 1.3 kgf/kg × 100 (95% CI -1.4 to 4) for hip abductors, 2 kgf/kg × 100 (95% CI -1.06 to 5) for hip adductors, -0.4 kgf/kg × 100 (95% CI -3.5 to 2.7) for hip LR at 90°, 1.18 kgf/kg × 100 (95% CI -0.9 to 3.3) for hip LR at 0°, -0.61 kgf/kg × 100 (95% CI -4.08 to 2.8) for hip MR at 90°, 0.48 kgf/kg × 100 (95% CI -1.24 to 2.2) for MR at 0°, and 0.62 kgf/kg × 100 (-7.9 to 9.2) for femoral quadriceps at 60°. There was no substantial difference between the KBSG and HQSG in hip and knee muscle strength at 8 weeks for the assessed muscle groups.

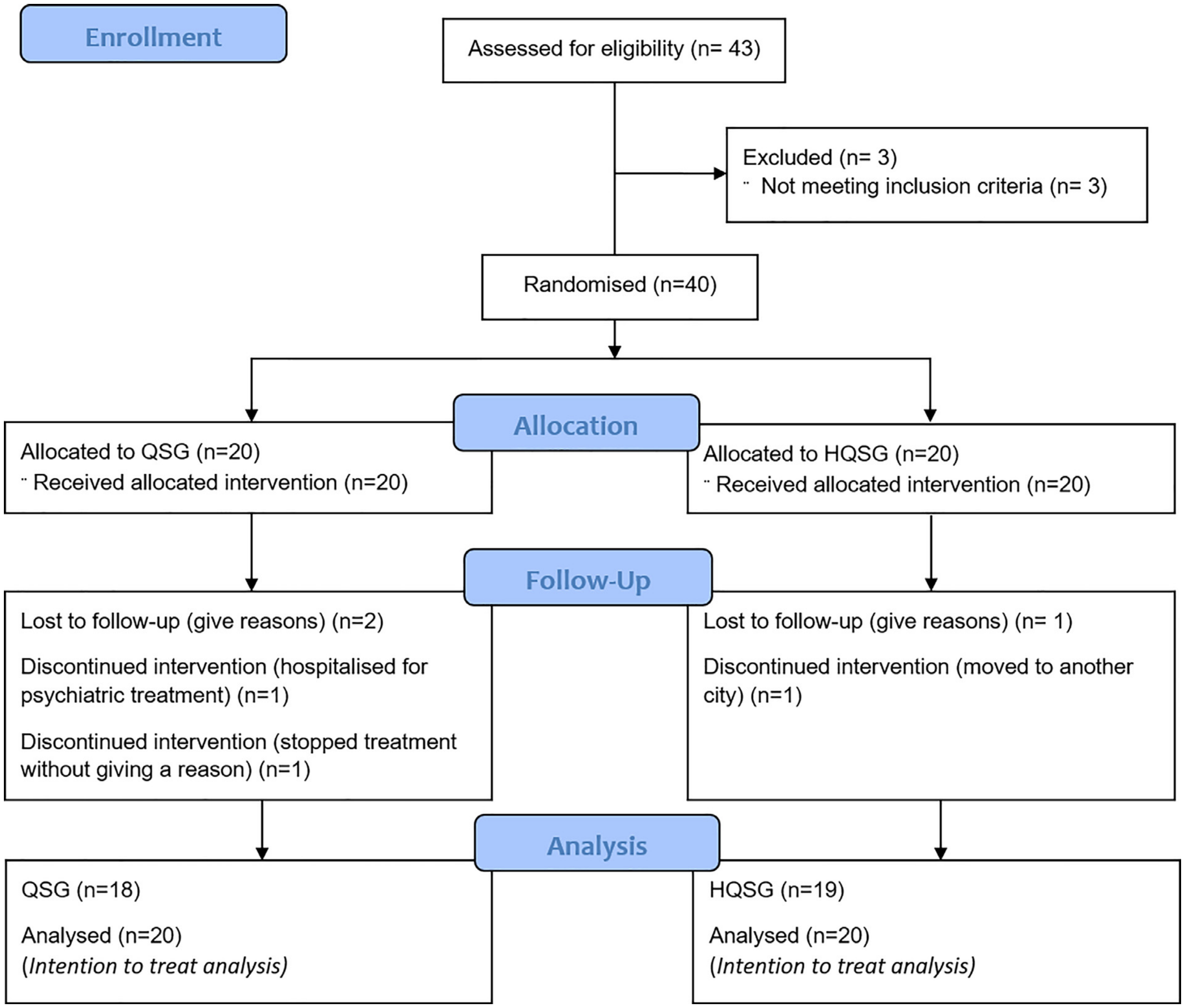

Fig 7 Consolidated standards of reporting trials flowchart.

Exercise adherence after discharge

At the 12- and 24-week follow-ups, 11 out of 18 participants (61%) from the KBSG and 13 out of 19 participants (68%) from the HQSG adhered to the strengthening exercises at least 3 times per week after discharge. By the 48-week follow-up, the number of participants adhering to the strengthening exercises in the KBSG remained the same (11 out of 18; 61%), whereas there was a slight decrease in participants adhering to the HQSG strengthening exercises (11 out of 19; 58%).

Discussion

This study is the first single-blind RCT to investigate whether combined intervention targeting HQSG is superior to the knee-based strengthening approach to treat LPD. The main findings were (1) there is no statistical difference between a combined hip and quadriceps muscle strengthening program and a knee-based strengthening program for the Lysholm Knee Score at the 8-week evaluation (primary outcome); (2) there is no statistical difference between a combined hip and quadriceps muscle strengthening program and a knee-based strengthening program for improving pain (NPRS at rest and during effort), function (NPI Score, Kujala AKPS, and LEFS), quality of life (WHOQOL-Bref), frequency of recurrent PD and lower limb muscle strength for any time point; (3) While no statistical differences emerged, notable between-group differences for NPRS during effort at 4 weeks and for the NPI Score at the primary endpoint (8 weeks) further supports the possibility of a meaningful difference favoring the HQSG.

While combined hip and quadriceps exercises are widely advocated for enhancing pain and function in individuals with PFP in both short- and long-term,[13] our study diverges from this established narrative for LPD.[11,12,18] The anatomic and biomechanical distinctions, as well as variations in injury mechanisms and natural histories, between PFP and LPD[7,31,32] underscore the importance of tailoring interventions to the specific condition at hand. After PD, many people have generalized hip and knee weakness compared with healthy subjects,[14] and similarly with women with PFP,[33] this population could benefit from a combined hip and knee strengthening program. Notably, our findings suggest that individuals with LPD may not experience substantial differences in patellofemoral joint-related scores (Lysholm,

Table 3 Primary and secondary outcomes at weeks 4 (during treatment) and 8 (primary endpoint; end of treatment)

	4 weeks			8 weeks			
	KBSG Mean (95% CI)	HQSG Mean (95% CI)	Mean Difference (95% CI)	KBSG Mean (95% CI)	HQSG Mean (95% CI)	Mean Difference (95% CI)	*P* Value*
Lysholm Knee Score	72.5 (64 to 81)	82.2 (76.9-87.5)	−9.7 (−19.4 to 4.8)	82.9 (77 to 88.7)	89.7 (84.7-94.7)	−6.8 (−14.3 to 3.7)	0.22
NPRS at rest	1.7 (0.75-2.7)	0.3 (−0.5 to 0.6)	1.4 (0.45-2.4)	0.7 (0.2-1.2)	0.38 (−1.2 to 0.9)	0.32 (−0.37 to 1)	0.30
NPRS during effort	3.6 (2.2-5.1)	1.4 (0.6-2.2)	2.2 (0.62-3.8)	1.9 (0.9-2.8)	1.4 (0.3-2.5)	0.68 (−0.9 to 1.86)	0.16
NPI Score	57 (37.5-76.6)	48.4 (27.5-69.4)	8.6 (−19.1 to 36.3)	42.2 (27.3-57)	18.7 (7.8-29.6)	23.5 (5.6-41.3)	0.11
Kujala AKPS	75.8 (69 to 82.7)	78.6 (71.4-85.9)	−2.8 (−12.4 to 6.8)	87.4 (83 to 91.8)	89 (83 to 94.8)	−1.54 (−8.6 to 5.6)	0.68
LEFS	61.3 (55.8-66.9)	68.1 (63.4-72.9)	−6.8 (−13.9 to 0.28)	70.7 (67.1-74.3)	71.8 (68.3-75.2)	−1.08 (−5.9 to 2.4)	0.16
WHOQOL-BREF physical health	14.4 (13.3-15.5)	15 (13.8-16.2)	−0.56 (−2.1 to 1)	15.7 (14.8-16.7)	15.9 (15.1-16.6)	−0.12 (−1.26 to 1.02)	0.89
WHOQOL-BREF psychological	15.1 (13.6-16.6)	15.4 (14.3-16.6)	−0.34 (−2.2 to 1.5)	15.5 (14.1-17)	15.9 (14.8-16.9)	−0.32 (−2.04 to 1.4)	0.98
WHOQOL-BREF social relations	16.5 (15.3-17.6)	17.3 (16 to 18.6)	−0.84 (−2.5 to 0.8)	16.2 (15.1-17.4)	16.9 (15.8-18)	−0.7 (−2.2 to 0.82)	0.63
WHOQOL-BREF environment	15 (13.9-16)	15.1 (14.2-16.1)	−0.16 (−1.5 to 1.1)	15 (14 to 16.1)	14.6 (13.6-15.7)	0.44 (−1 to 1.9)	0.40
Recurrence of LPD — cumulative N (%)	0 (0%)	1 (5%)	1	0 (0%)	1 (5%)	1	0.69
Isometric hip flexors strength (kgf/kg × 100)	-	-	-	35.6 (31 to 40.2)	36.1 (31.5-40.7)	−0.5 (−6.7 to 5.7)	0.97
Isometric hip extensors strength (kgf/kg × 100)	-	-	-	35.7 (31.8-39.6)	33.8 (30.2-37.5)	1.83 (−3.4 to 7)	0.67
Isometric hip abductors strength (kgf/kg × 100)	-	-	-	20.5 (18.8-22.2)	19.2 (16.9-21.4)	1.3 (−1.4 to 4)	0.54
Isometric hip adductors strength (kgf/kg × 100)	-	-	-	18.5 (16.2-20.8)	16.5 (14.3-18.7)	2 (−1.06 to 5)	0.15
Isometric hip LR at 90° strength (kgf/kg × 100)	-	-	-	17.7 (15.4-20)	18.1 (16 to 20.3)	−0.4 (−3.5 to 2.7)	0.56
Isometric hip LR at 0° strength (kgf/kg × 100)	-	-	-	16.3 (14.4-18.2)	15.1 (14 to 16.2)	1.18 (−0.9 to 3.3)	0.1
Isometric hip MR at 90° strength (kgf/kg × 100)	-	-	-	22.9 (20.1-25.6)	23.5 (21.2-25.7)	−0.61 (−4.08 to 2.8)	0.72
Isometric hip MR at 0° strength (kgf/kg × 100)	-	-	-	13.9 (12.8-14.9)	13.4 (12 to 14.8)	0.48 (−1.24 to 2.2)	0.61
Isometric femoral quadriceps at 60° strength (kgf/kg × 100)	-	-	-	56.8 (50.8-62.9)	56.2 (49.7-62.7)	0.62 (−7.9 to 9.2)	0.39

* The *P* values represent the time-group interaction, assessed through the application of the repeated-measures ANOVA model. Given the absence of statistical differences in both primary and secondary outcomes, no specific *P* value is associated with any particular time point.

Table 4 Primary and secondary outcomes at weeks 12, 24, and 48 (follow-ups)

	Week 12			Week 24			Week 48			
	Mean (95% CI)		Mean Difference (95% CI)	Mean (95% CI)		Mean Difference (95% CI)	Mean (95% CI)		Mean Difference (95% CI)	P Value*
	KBSG	HQSG		KBSG	HQSG		KBSG	HQSG		
Lysholm Knee Score	85.3 (78.3-92.3)	90.7 (85.2-96.3)	−5.4 (−14 to 3.2)	87.1 (80.7-93.5)	92.6 (86.8-98.5)	−5.5 (−13.9 to 2.8)	85.2 (77.2-93.2)	86.8 (77.4-96.2)	−1.64 (−13.6 to 10.3	0.22
NPRS at rest	0.79 (0.12-1.45)	0.2 (−0.21 to 0.62)	0.59 (−0.2 to 1.34)	0.7 (0.2-1.2)	0.5 (−0.3 to 1.2)	0.23 (−0.6 to 1.12)	0.88 (−0.9 to 1.85)	0.62 (−0.11 to 1.36)	0.25 (−0.9 to 1.43)	0.30
NPRS during effort	2 (0.8-3.2)	1 (0.31-1.83)	0.95 (−0.42 to 2.3)	1.8 (0.7-2.9)	1 (0.15-1.9)	0.77 (−0.56 to 2.1)	2.2 (0.9-3.5)	1.3 (0.27-2.4)	0.9 (−0.74 to 2.5)	0.16
NPI Score	32 (16.2-47.8)	16.3 (7.4-25.2)	15.7 (−1.8 to 33.2)	29.1 (11.8-46.4)	10.2 (1.5-19)	18.9 (0.2-37.6)	25.3 (8.7-41.8)	14.5 (2.1-26.9)	10.8 (−9.2 to 30.7)	0.11
Kujala AKPS	88.4 (82.4-94.3)	90 (83.9-96.1)	−1.6 (−9.9 to 6.6)	88.8 (83.5-94.1)	92 (85 to 99)	−3.2 (−11.6 to 5.2)	89.6 (84 to 95.3)	90.8 (83.3-98.3)	−1.2 (−10.2 to 7.9)	0.68
LEFS	70.7 (66.5-75)	73.8 (70.2-77.4)	−3.1 (−8.4 to 2.3)	71.2 (66.4-76.1)	76.3 (73.7-78.9)	−5 (−10.4 to 0.28)	70.6 (65 to 76.2)	73.3 (67.4-79.2)	−2.7 (−10.6 to 5.2)	0.16
WHOQOL-BREF physical health	16.1 (15 to 17.2)	16 (14.8-17.3)	0.1 (−1.6 to 1.6)	16.4 (15.4-17.4)	16 (14.9-17.1)	0.4 (−1 to 1.88)	16.6 (15.6-17.5)	16.1 (14.9-17.2)	0.5 (−0.97 to 2)	0.89; 0.02
WHOQOL-psychological	15.8 (14.4-17.2)	15.7 (14.6-16.9	0.1 (−1.6 to 1.8)	16.2 (15.1-17.3)	16 (15 to 17)	0.2 (−1.3 to 1.7)	16.3 (15.1-17.6)	15.8 (14.8-16.8)	0.5 (−1 to 2)	0.98
WHOQOL-BREF social relation	16.7 (15.4-18)	16.9 (15.2-18.5)	−0.18 (−2.2 to 1.9)	17.1 (15.9-18.3)	17.1 (16 to 18)	0.06 (−1.45 to 1.57)	16.4 (15.3-17.5)	16.5 (15.1-17.8)	−0.1 (−1.8 to 1.6)	0.63
WHOQOL-BREF environment	15.2 (14.1-16.3)	14 (12.7-15.3)	1.2 (−0.5 to 2.8)	15.5 (14.3-16.6)	14.7 (13.6-15.7)	0.8 (−0.7 to 2.3)	15.4 (14.2-16.6)	14.7 (13.6-15.8)	0.72 (−0.8 to 2.3)	0.40
Recurrence of LPD – cumulative N (%)	1 (5%)	1 (5%)	0	2 (10%)	1 (5%)	−1	3 (15%)	4 (20%)	1	0.69

* The *P* values represent the time-group interaction, assessed through the application of the repeated-measures ANOVA model. Given the absence of statistical differences in both primary and secondary outcomes, no specific *P* value is associated with any particular time point.

Kujala AKPS, and NPI Score) between the combined and isolated strengthening programs at any time point.

Considering the potential role of femoral quadriceps in patellofemoral joint stabilization as indicated by our results, aligns with previous work by Smith et al.[15] Their study, demonstrating favorable outcomes with specific-VM and general quadriceps exercises for LPD, echoes our findings where participants in both KBSG and HQSG groups achieved similar Lysholm Knee Score ranges (83-90 points at 8 weeks, with the highest mean scores at 24 weeks). Additionally, Wong et al[34] demonstrated improvements in quadriceps muscle strength and patellar stability after an 8-week quadriceps strengthening program in healthy subjects and a hip strengthening program with loads of 80% of 1-repetition maximum, similar to our study, seemed to lack any effect on the improvement of the dynamic knee valgus,[35] the main mechanism of injury of LPD.[36]

While no statistical differences emerged between the groups regarding 3 patellofemoral joint-related scores, there were notable between-group mean differences of 2.2 and 23.5 observed for NPRS during effort at 4 weeks and NPI Score at 8 weeks, all favoring the HQSG. These differences suggest a potentially clinically meaningful finding,[37] and the 95% CI of the mean difference in the NPI Score, excluding 0 at the primary endpoint (8 weeks), further supports the possibility of a meaningful difference favoring the HQSG.

This aligns with existing evidence highlighting the efficacy of combined hip and knee-targeted exercises in improving pain and function in individuals with PFP.[13] Interestingly, comparable improvements in lower limb strength (hip and knee) were observed in both KBSG and HQSG, despite only the latter receiving specific hip strengthening exercises, hinting at exercise-induced hypoalgesia, potentially stemming from the higher exercise volume in the HQSG.[38]

Furthermore, despite the lack of information on the sensitivity of the NPI Score to our study population, this specific tool tailored for individuals after LPD appears to exhibit greater sensitivity than the Lysholm Knee Score in discerning differences between the 2 interventions. While the 95% CI of the mean difference and the ES suggest a meaningful advantage for the HQSG, caution should be exercised in drawing conclusions. Notably, we did not conduct an adequate sample size calculation for these secondary outcomes, and the absence of information regarding the minimally clinically important difference complicates interpretation. This emphasizes the necessity for further investigation to validate and substantiate these findings.

The total recurrence rate observed in our study at the 48-week follow-up was 17.5%, with 7 participants experiencing recurrence — 3 in the KBSG and 4 in the HQSG, mirroring rates documented in prior studies (16% at 2 years follow-up).[9] Notably, 5 of the 7 participants experiencing recurrent PD did not adhere to the prescribed exercise regimen after discharge. It is conceivable that the gains achieved in patellar instability through the 8-week strengthening protocol may not be sustained over the 48-week follow-up period, particularly in the absence of consistent exercise engagement. This sedentary behavior likely contributed to a decline in strength, potentially influencing the recurrence rate of LPD as reported in our study.[39] Further exploration is warranted to elucidate the interplay between post-

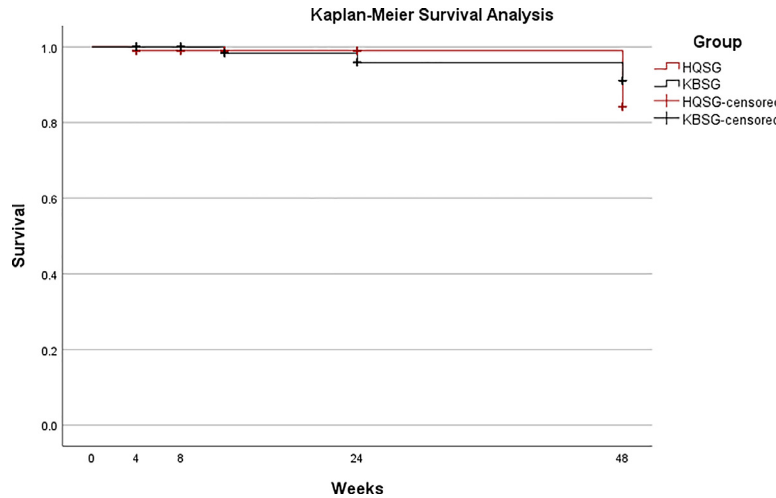

Fig 8 Kaplan-Meier survival analysis: recurrence of lateral patellar dislocation over follow-up periods.

discharge exercise compliance, sedentary behavior, and their effect on recurrence rates and perceived instability in LPD.

Study limitations

This study presents some limitations. Firstly, the absence of magnetic resonance imaging (MRI) assessment of participants' patellofemoral joint anatomy represents a potential influence on our study outcomes. Various anatomic factors contribute to recurrence rate and perceived instability,[7] and the lack of MRI data may limit a comprehensive understanding of these dynamics. Unfortunately, because of constraints at the hospital where the study was conducted and limited patient access to imaging during treatment, MRI evaluation was not feasible.

Secondly, the NPI Score, a tool tailored for assessing individuals with patellar instability and potentially more sensitive than the Lysholm Knee Score in capturing changes was not employed as a primary outcome. This decision stemmed from the absence of information on its Minimally Clinically Important Difference and SD for a sample size calculation of during the design of our RCT. Additionally, at the inception of our study, no Brazilian Portuguese translated version of the Norwich Patellar Instability Score (NPI Score) was available. Our research group took the initiative to translate, cross-culturally adapt and validate the NPI Score in 2018, with the results being published in early 2019.[24]

Thirdly, the ES employed in determining our sample size calculation, Cohen's *d* of 1.06, is deemed excessively large and not practically applicable in the context of human subjects' research. Consequently, the sample size used in our study lacks statistical power. Additionally, the small sample size in our study underscores the need for caution when extending the implications of our findings to a wider population. Despite the implementation of a sample size calculation and adherence to a methodological framework aimed at minimizing potential biases, further investigations with larger and more diverse cohorts are warranted to corroborate and extend the applicability of our findings to a more comprehensive demographic spectrum.

Lastly, our study did not include an evaluation of kinesiophobia, an aspect relevant to individuals with PFP and recurrent LPD. Women with PFP have been reported to exhibit greater kinesiophobia,[40] possibly linked to altered movement patterns (dynamic valgus) rather than muscle strength.[41] Given the potential effect on perceived function, future studies should consider incorporating kinesiophobia assessments in individuals with recurrent LPD who may share similar patterns of movement-related fear.[42]

Conclusions

This randomized controlled trial, while revealing no statistical differences in various outcome measures (including Lysholm Knee Score, NPI Score, Kujala AKPS, NPRS at rest and during effort, LEFS, WHOQOL-Bref, isometric hip and knee muscle strengthening, recurrence rate of LPD, and exercise adherence after discharge) between KBSG and HQSG, presents findings that need cautious interpretation. Acknowledging the study's limitations, particularly its underpowered nature, is crucial. The sample size may not have provided sufficient statistical power to detect moderate effects of the interventions on these outcomes, especially for the NPRS during effort and the NPI Score.

Therefore, clinicians should consider both approaches, with the choice potentially influenced by co-existing pathologies at either the knee or the hip joint. Further research is warranted to generalize these findings to a broader population and should focus on optimizing conservative treatment strategies, exploring exercise volume, load, and post-discharge adherence to enhance recovery, and minimizing LPD recurrence in this specific population.

Suppliers

a. Lafayette Manual Muscle Testing System Model-01165; Lafayette Instrument Company.
b. IBM SPSS software version 20.0 for Windows; IBM

Corresponding author

Lucas Simões Arrebola, PT, PhD, Department of Human Movement Sciences, Federal University of São Paulo (UNIFESP), Rua Silva Jardim, 136 Vila Matias, Santos, São Paulo 11015-020, Brazil. *E-mail address:* lucas.arrebola@unifesp.br.

Acknowledgments

We thank the chief of Physical Therapy Department of IAMSPE, Aparecida Cristina Chrispim Pires, for providing the necessary structure and equipment for developing this work.

References

1. 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;10:146-51.
2. Petri M, Ettinger M, Stuebig T, et al. Current concepts for patellar dislocation. Arch Trauma Res 2015;4:1-7.
3. Huntington LS, Webster KE, Devitt BM, Scanlon JP, Feller JA. Factors associated with an increased risk of recurrence after a first-time patellar dislocation: a systematic review and meta-analysis. Am J Sports Med 2020;48:2552-62.
4. Jaquith BP, Parikh SN. Predictors of recurrent patellar instability in children and adolescents after first-time dislocation. J Pediatr Orthop 2017;37:484-90.
5. Christensen TC, Sanders TL, Pareek A, Mohan R, Dahm DL, Krych AJ. Risk factors and time to recurrent ipsilateral and contralateral patellar dislocations. Am J Sports Med 2017;45:2105-10.
6. Shubin Stein BE, Gruber S, Brady JM. MPFL in first-time dislocators. Curr Rev Musculoskelet Med 2018;11:182-7.
7. Balcarek P, Oberthür S, Hopfensitz S, et al. Which patellae are likely to redislocate? Knee Surg Sports Traumatol Arthrosc 2014;22:2308-14.
8. Liu JN, Steinhaus ME, Kalbian IL, et al. Patellar instability management: a survey of the International Patellofemoral Study Group. Am J Sports Med 2018;46:3299-306.
9. 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. Orthop J Sports Med 2018;6:1-17.
10. 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;96:269-81.
11. McConnell J. Rehabilitation and nonoperative treatment of patellar instability. Sports Med Arthrosc Rev 2007;15:95-104.
12. Ménétrey J, Putman S, Gard S. Return to sport after patellar dislocation or following surgery for patellofemoral instability. Knee Surg Sports Traumatol Arthrosc 2014;22:2320-6.
13. Willy RW, Hoglund LT, Barton CJ, et al. Clinical practice guidelines patellofemoral pain. J Orthop Sports Phys Ther 2019;49:1-95.
14. Arrebola LS, Smith T, Silva FF, et al. CE Pinfildi, Hip and knee weakness and ankle dorsiflexion restriction in individuals following lateral patellar dislocation: a case-control study. Clin J Sport Med 2021;31:e385-91.
15. Smith TO, Chester R, Cross J, Hunt N, Clark A, Donell ST. Rehabilitation following first-time patellar dislocation: a randomised controlled trial of purported vastus medialis obliquus muscle versus general quadriceps strengthening exercises. Knee 2015;22:313-20.
16. Schulz KF, Altman DG, Moher D. CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c332.
17. 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;97:327-38.
18. Tscholl PM, Koch PP, Fucentese SF. Treatment options for patellofemoral instability in sports traumatology. Orthop Rev (Pavia) 2013;5:23.
19. Na Y, Han C, Shi Y, Zhu Y, Ren Y, Liu W. Is isolated hip strengthening or traditional knee-based strengthening more effective in patients with patellofemoral pain syndrome? A systematic review with meta-analysis. Orthop J Sports Med 2021;9.
20. Garber CE, Blissmer B, Deschenes MR, et al. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. Med Sci Sports Exerc 2011;43:1334-59.
21. Stella Peccin M, Ciconelli R, Cohen M. Specific questionnaire for knee symptoms —"The Lysholm Knee Scoring Scale"-translation and validation into Portuguese. Acta Ortop Bras 2006;14:268-72.
22. Hiemstra LA, Page JL, Kerslake S. Patient-reported outcome measures for patellofemoral instability: a critical review. Curr Rev Musculoskelet Med 2019;12:124-37.
23. Piva SR, Gil AB, Moore CG, Fitzgerald GK. Responsiveness of the activities of daily living scale of the knee outcome survey and numeric pain rating scale in patients with patellofemoral pain. J Rehabil Med 2009;41:129-35.
24. Arrebola LS, Campos TV de O, Smith T, Pereira AL, Pinfildi CE. Translation, cross-cultural adaptation and validation of the Norwich Patellar Instability score for use in Brazilian Portuguese. Sao Paulo Med J 2019;137:148-54.
25. da Cunha RA, Costa LOP, Hespanhol Junior LC, Pires RS, Kujala UM, Lopes AD. Translation, cross-cultural adaptation, and clinimetric testing of instruments used to assess patients with patellofemoral pain syndrome in the Brazilian population. J Orthop Sports Phys Ther 2013;43:332-9.
26. Castanhas LG, Menacho MO, Mazuquin BF, Cardoso JR, Dias JM, Pereira LM. Translation, cross-cultural adaptation and analysis of the psychometric properties of the lower extremity functional scale (LEFS): LEFS-BRAZIL. Braz J Phys Ther 2013;17:272-80.
27. Fleck MPA, Louzada S, Xavier M, et al. Aplicação da versão em português do instrumento abreviado de avaliação da qualidade de vida "WHOQOL-bref" Universidade de São Paulo, Revista de saúde pública. Rev Saude Publica 2000;34:178-83.
28. WHO. WHOQOL-BREF. Introduction, administration, scoring and generic version of the assessment. Field Trial Version. Geneva: World Health Organization; 1996.
29. Collins N, Crossley KM, Misra D, Felson D, Roos E. Measures of knee function: International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS). Knee Ou. Arthritis Care Res 2015;63:15-8.
30. Joseph R, Sim J, Ogollah R, Lewis M. A systematic review finds variable use of the intention-to-treat principle in musculoskeletal randomized controlled trials with missing data. J Clin Epidemiol 2015;68:15-24.
31. Crossley KM, Stefanik JJ, Selfe J, et al. 2016 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;50: 839-43.
32. Seitlinger G, Ladenhauf HN, Wierer G. What is the chance that a patella dislocation will happen a second time: update on the natural history of a first time patella dislocation in the adolescent. Curr Opin Pediatr 2018;30:65-70.

33. Van Cant J, Pineux C, Pitance L, Feipel V. Hip muscle strength and endurance in females with patellofemoral pain: a systematic review with meta-analysis. Int J Sports Phys Ther 2014;9:564–82.
34. Wong YM, Chan ST, Tang KW, Ng GYF. Two modes of weight training programs and patellar stabilization. J Athl Train 2009;44:264–71.
35. Palmer K, Hebron C, Williams JM. A randomised trial into the effect of an isolated hip abductor strengthening programme and a functional motor control programme on knee kinematics and hip muscle strength. BMC Musculoskelet Disord 2015;16:1–8.
36. Vetrano M, Oliva F, Bisicchia S, et al. I.S.Mu.L.T. First-time patellar dislocation guidelines. Muscles Ligaments Tendons J 2017;7:1—10.
37. Lininger M, Riemann BL. Statistical primer for athletic trainers: using confidence intervals and effect sizes to evaluate clinical meaningfulness. J Athl Train 2016;51:1045–8.
38. Straszek CL, Rathleff MS, Graven-Nielsen T, Petersen KK, Roos EM, Holden S. Exercise-induced hypoalgesia in young adult females with long-standing patellofemoral pain — a randomized crossover study. Eur J Pain 2019;23:1780–9.
39. Correa CS, Cunha G, Marques N, Oliveira-Reischak Ã, Pinto R. Effects of strength training, detraining and retraining in muscle strength, hypertrophy and functional tasks in older female adults. Clin Physiol Funct Imaging 2016;36:306–10.
40. Priore LB, Azevedo FM, Pazzinatto MF, et al. Influence of kinesiophobia and pain catastrophism on objective function in women with patellofemoral pain. Phys Ther Sport 2019;35:116–21.
41. de Oliveira Silva D, Barton CJ, Briani RV, et al. Kinesiophobia, but not strength is associated with altered movement in women with patellofemoral pain. Gait Posture 2019;68:1–5.
42. Kadowaki M, Tadenuma T, Kumahashi N, Uchio Y. Brain activity changes in somatosensory and emotion-related areas with medial patellofemoral ligament deficiency. Clin Orthop Relat Res 2017;475:2675–82.