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A systematic review of randomized controlled trials on exercise parameters in the treatment of patellofemoral pain: what works?

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Purpose: There is research evidence which supports the effectiveness of exercise in reducing pain and increasing function in patients with patellofemoral pain syndrome. However, what is unclear are the parameters underpinning this intervention. This has led to uncertainty when operationalizing exercises for patients with patellofemoral pain syndrome in clinical practice. The aim of this review was to evaluate the parameters of exercise programs reported in primary research, to provide clinicians with evidence-based recommendations for exercise prescription for patellofemoral pain.

Methods: A systematic review of randomized controlled trials was undertaken. Only trials that identified exercise to be effective in treating patellofemoral pain were included. Appropriate databases and reference lists were searched using established keywords. Data relating to common exercise parameters such as the type of exercise, length, and frequency of intervention, intensity, repetitions, sets, and specific technique were extracted, along with details of co-interventions that may have been used.

Results: A total of ten randomized controlled trials were included in this review and from these trials 14 interventions arms were evaluated. All 14 interventions focused on active exercises, all but two of which also included a passive stretching component. The current body of evidence demonstrates positive results with exercise interventions such as knee extension, squats, stationary cycling, static quadriceps, active straight leg raise, leg press, and step-up and down exercises for patients with patellofemoral pain syndrome. A progressive regime of daily exercises of two to four sets of ten or more repetitions over an intervention period of 6 weeks or more, combined with exercises to address flexibility of the lower limb musculature was commonly used.

Conclusion: Currently, the primary research on this topic supports the use of closed kinetic chain, strengthening exercises for musculature of the lower limb, combined with flexibility options. The current evidence base supports a prescription of daily exercises of two–four sets of ten or more repetitions over a period of 6 weeks or more.

Keywords: patellofemoral pain syndrome, PFPS, repetitions, lower limb, musculature

Introduction

Patellofemoral pain syndrome (PFPS) is one of the most common knee conditions seen by physiotherapists, affecting one in four people of the total population.¹ PFPS is characterized as a diffuse retro/peripatellar pain, aggravated with activities which load the patellofemoral joint, such as climbing stairs, squatting, running, and prolonged sitting.² Although its precise etiology is not currently universally accepted,² several neuromuscular deficits have been associated with its development, forming the basis for a plethora of different treatment options employed by researchers and clinicians alike.³ Conservative management remains the treatment of choice

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for frontline management of PFPS, with exercise therapy forming the mainstay.⁴ These treatments target neuromuscular deficits, including quadriceps, vastus medialis oblique (VMO), proximal strength deficits, tightness of soft tissues, or dynamic alignment/control abnormalities identified by the treating clinician.⁵ The range of exercises employed to target these deficits include various combinations and variations of open and closed kinetic chain exercises, exercises aimed at selectively or nonselectively recruiting muscles, and stretching.³

Systematic reviews on this topic have focused on the question of whether exercise is effective for PFPS and have reported mixed findings. Heintjes et al⁶ reported conflicting results; however, a more recent review by Fagan and Delahun³ revealed that some exercise interventions have been shown to reduce pain and increase function in PFPS patients. Since then several randomized controlled trials have demonstrated positive results in pain and function using exercise-based interventions.^{7–11}

The plethora of different exercise interventions reported in the literature suggests a lack of universally accepted exercise protocols for the management of PFPS. The aim of this systematic review was to analyze the exercise parameters associated with positive, statistically significant effects on PFPS, as reported in the primary research, in order to advise clinicians on the evidence-based recommendations for the treatment of patellofemoral pain.

Methods

Search strategy

Figure 1 provides a CONSORT (Consolidated Standards of Reporting Trials) diagram summary of the search strategy employed.

Databases

The following databases were searched using the devised PICO (patient, intervention, comparison, outcome) (Table 1) between January 13 and February 17, 2010: SPORTdiscus, MEDLINE, CINAHL, Science Direct, PEDro, EMBASE, and Google Scholar. The search terms used were: “patellofemoral pain syndrome” OR “patellofemoral pain” OR “retropatellar pain” AND “exercise” OR “exercise therapy” OR “strength” OR “rehabilitation.” The following limits were placed on the search where able: English language, humans, age 14–65, randomized controlled trials, and years 1996–2010. The reference lists of trials identified from the databases were manually searched for potentially relevant trials.

Inclusion

All randomized controlled trials from peer reviewed journals written in English, available in full text, and matching the above selection criteria were included in order to increase the rigor of the systematic review design. To address this study’s research question, only trials which demonstrated a positive outcome due to the intervention were included. This allowed analysis of the parameters of exercise, which led to positive outcomes in trials thus addressing the review aims. A positive outcome is defined as “a statistically significant improvement in one or more measure of pain and function.” Exercise interventions with nonsignificant outcomes when compared with other treatments were included if at least one arm showed significant improvement from baseline scores, irrespective of whether there was a significant difference between intervention groups.

Exclusion

A trial was excluded from this review if the trial’s primary intervention was a non-exercise based intervention, or the trial did not include at least one measure of pain and function.

Methodological assessment

All included trials were critically appraised by two independent reviewers using the PEDro scale,¹² an eleven-point scale commonly used to rate the methodology of randomized controlled trials. The inter-rater reliability of the PEDro score has previously been shown to be “fair to good.”¹³ See Supplementary material for the PEDro critical appraisal criteria.

Data extraction

Relevant data was extracted manually and entered into the data extraction table (see Table 2). The parameters used were: type of exercise (eg, open or closed chain), length of intervention, frequency, sets, repetitions of exercise, intensity (eg, 60% one-repetition maximum [1RM]), co-interventions (eg, taping), and instructions/specific technique where relevant (eg, alignment or avoidance of pain during exercise).

Results

Search findings

The literature search revealed ten studies meeting the systematic review criteria. Fourteen intervention arms reporting statistically significant improvements were included. All included trials were from peer reviewed journals. One study¹⁴ was excluded due to its poor methodological quality and high degree of bias.

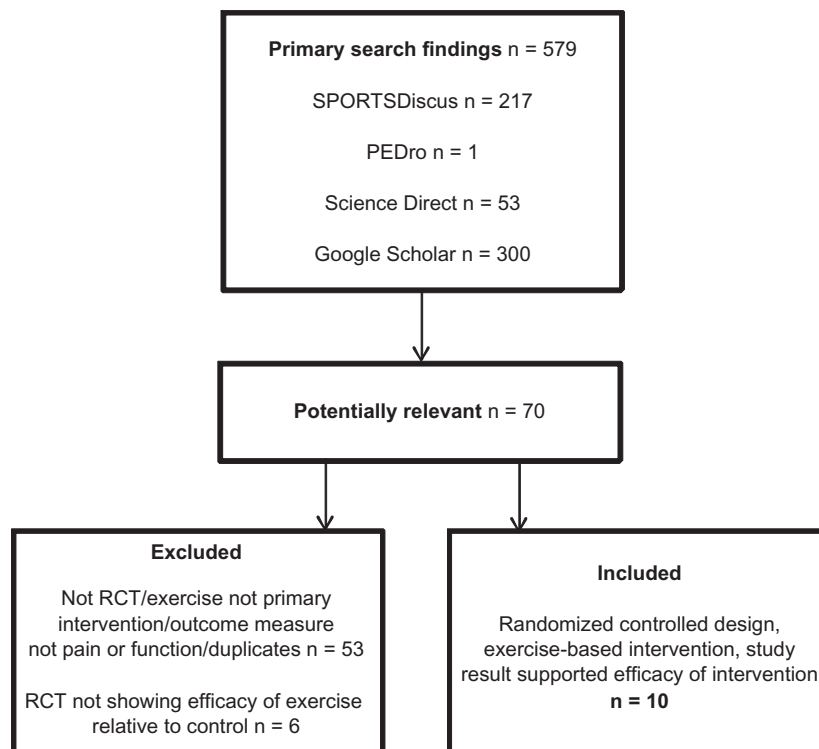


Figure 1 CONSORT (Consolidated Standards of Reporting Trials) diagram summarizing search and selection process.

Abbreviation: RCT, randomized controlled trial.

Quality of the studies included

Studies meeting the inclusion criteria were scored using the PEDro critical appraisal tool. Within an exercise intervention protocol it is not possible to blind either therapist or participant, leaving the maximum score possible as 9 out of 11. The included studies scored in the range of 6–9 on the PEDro scale (see Figure 2).

The interventions

Table 2 details the exercise parameters used in each of the studies. It shows the type of exercise done, the frequency, duration, intensity, and number of repetitions/sets that were performed.

Exercise type

The common interventions can be broadly categorized as “open” or “closed” kinetic chain and “selective” or “nonselective”

exercises. Open chain exercises were used in eight programs, while closed chain exercises were employed by eleven. Stretching was a feature of all but one protocol and was done concurrently with the strengthening program. “Proprioceptive/balance” exercise type^{11,15} and “proximal stability” were features of individual studies.¹⁹ Exercises were designed primarily to target strength and/or control at the knee or hip, and to correct local or peripheral muscle imbalance.

Program duration and frequency

All trials reported frequency per week and duration in weeks. The most common frequency of exercise was a 6-week period of daily exercise employed by four of the ten included trials.^{8,9,15,16} Three of the included studies employed 8-week rehabilitation periods,¹⁰ with the remaining three studies employing 3-week,⁷ 5-week,⁴ and 12-week¹¹ rehabilitation periods respectively. Although Bakhtiary and Fatemi⁷ had the shortest intervention period of 3 weeks, the frequency of exercise sessions were the greatest (twice daily), bringing the total volume of exercise sessions more in line with the remaining literature that reported positive effects of exercise on PFPS.

Specific exercises used

The exercises included in the randomized controlled trials were open kinetic chain (OKC), closed kinetic chain (CKC),

Table 1 The search PICO used to develop keywords

Population	Aged 14–65 years of either gender clinically diagnosed with PFJ pain
Intervention	Exercise-based rehabilitation for PFJ
Comparison	Other interventions including placebo/other exercise/nonexercise-based therapy
Outcome	Psychometrically sound measure of pain and function

Abbreviation: PFJ, patellofemoral joint.

Table 2 Characteristics of effective exercise interventions for patellofemoral pain

Study	Intervention				Program parameters		
	Type of exercise	Duration (weeks)	Frequency	Exercises	Intensity/resistance	Reps	Sets
Clark et al ¹⁵	CKC including proprioceptive/balance exercises	6	Daily	Stationary cycle (warm-up) Wall squats Sit to stand Progressive step down exercise Specific gluteus medius and maximus exercises Balance work using trampet	NR	NR 10 × 10-second holds, progressed to 3 minutes NR	NR 1 NR
Crossley et al ¹⁶	CKC, isometric exercises including selective VMO	6	Daily	Week 1–2: Isometric VMO (knee at 90°) Squats to 40° knee flexion + isometric gluteals Isometric abduction against a wall in standing Week 3–6: Step downs 10–20 cm depth Isometric hip abduction in standing All week 1–2 exercises	NR	10 10 15-second hold 5–10 30-second hold	4 4 4 3 4
Nakagawa et al ⁹	OKC and CKC including proximal stability	6	5×/week	Week 1–2: TrA contractions in quadruped kneel Isometric combined hip abduction and lateral rotation in side lying, hips and knees slightly flexed Isometric hip abduction with knees extended Isometric hip abduction and lateral rotation in quadruped Isometric quadriceps (knee at 90°) ASLR Squat to 40° flexion Week 3–4: Wall squat 0°–60° flexion Step up/down (20 cm depth) Lunges 0°–45° flexion Pelvic drop exercise on 20 cm step Single arm extension against elastic resistance in contralateral single leg stance Contralateral body rotation in single leg stance against elastic resistance, maintaining lower limb static Weeks 5–6: As for week 3 and 4 + balance exercises and additional elastic resistance around the affected leg in forward lunges, encouraging active lateral rotation and abduction of the hip. Begin progress walk or run program	NR	15 × 10-second holds 15 × 10-second holds 15 × 10-second holds 15 × 10-second holds 10 10 10 10 10 10 10 15 10 15 × 10-second holds As per week 3–4	2 2 2 2 3 4 3 3 3 2 4 2

(Continued)

Table 2 (Continued)

Study	Intervention				Program parameters		
	Type of exercise	Duration (weeks)	Frequency	Exercises	Intensity/resistance	Reps	Sets
Bakhtiary and Fatemi ⁷	Group 1: OKC	3	2×/day	Supine straight leg raise to 45° hip flexion	NR	Group 1 and 2: 20 × 3–4-second hold, increased by 5 reps every 2 days	1
	Group 2: CKC	3	2×/day	Single leg squat to 15°–20° to knee flexion whilst holding stable surface			
Witvrouw et al ¹⁹	Group 1: OKC	5	3×/week	Static quadriceps contractions in full knee extension Straight leg raise in supine Knee extension from 10° flexion to full extension Leg adduction exercises in side lying	Groups 1 and 2: 60% of 10RM, new 10RM established at the end of each week. "Maximal contractions" for static tasks	Group 1: 10 × 6-second hold	3
	Group 2: CKC	5	3×/week	Seated leg press Double or single leg squat 1/3 knee bend Stationary biking Rowing machine exercise Step up and down exercise			
Herrington and	Group 1: OKC	6	3×/week	Knee extension exercises in seated position from 90° of flexion to full extension	Groups 1 and 2: Set 1 50% 6RM Set 2 75% 6RM Set 3 100% 6RM Set 4 Progressed according set 3 max (Next session progressed based on set 4 max)	10 10 Max possible Max possible	4
Al-Sherhi ⁸	Group 2: CKC	6	3×/week	Leg press in seated position from 90° of knee flexion to full extension Group 1 and 2: 5-minute static cycle warm-up			
Syme et al ¹⁰	Group 1: General non-VMO selective	8	2×/week	3–5 lower limb exercises focusing on quadricep strengthening. Actual exercises not specified.	60%–70% of 1RM	10	1–3
	Group 2: VMO selective	8	Daily HEP + >6 EMG biofeedback sessions	Lower limb exercises focusing on selective activation and retraining of the VMO relative to the VL using a dual channel surface electromyographic (EMG) biofeedback unit. Daily home exercises			
Van Linschoten et al ¹¹	OKC and CKC including balance exercises	12	25 minutes daily	Stationary cycle (warm-up), static and dynamic strengthening exercises for quadriceps, adductors, and gluteal muscles and balance work	NR – though progressed fortnightly during the first 6 weeks	NR – though progressed fortnightly during the first 6 weeks	NR
Song et al ¹⁷	CKC	8	3×/week	SL leg press, 45°–0° flexion	60% 1RM (1RM reset every 2 weeks)	10	5
Kettunen et al ²³	OKC and CKC	8	Daily	Weeks 1–4: Standing hamstring curl	NR	Weeks 1–2: 10–20	2
				All fours, transverse plane single leg bent knee hip abduction		Weeks 2–4: 10–40 Weeks 4–6:	

(Continued)

Table 2 (Continued)

Study	Intervention				Program parameters		
	Type of exercise	Duration (weeks)	Frequency	Exercises	Intensity/resistance	Rep	Sets
				Knee extension		10–20	2
				Straight leg raise		Weeks 6–8:	
				Weeks 4–8:		10–40	4
				Standing hip extension against resistance band with straight knee			
				Standing hip extension against resistance band moving from knee flexion to extension			
				Lateral step down/up			
				Sit to stand			

Abbreviations: reps, repetitions; NR, not reported; CKC, closed kinetic chain; OKC, open kinetic chain; SLR, straight leg raise; ASLR, active straight leg raise; RM, repetition max; TrA, transversus abdominus; VMO, vastus medialis oblique.

selective, stability/proximal control, and general exercises. The specific exercises reported in the trials for open chain exercises were: active straight leg raise (n = 4), knee extension (n = 3), and static quadriceps (n = 3). Closed chain exercises were: double/single leg squats (n = 5), step up and step down (n = 5), seated leg press (n = 3), static quadriceps contraction in knee flexion (n = 2), stationary bike (n = 4), and static hip abduction +/- external rotation (n = 2), with several other exercises appearing just once (eg, lunges and rowing machine). Selective exercises were selective VMO exercises (n = 2). Stability/proximal control exercises included: balance work (n = 2) and proximal stability/transversus abdominus (TrA) (n = 1). General exercises included progressive walk/run program (n = 1).

Intensity

Intensity ranged from varying percentages of maximum effort to failure to report. Whilst there was variability in the prescribed exercise intensities, there was a trend to increase the intensity/resistance progressively throughout the rehabilitation period, with three studies^{4,8,10} reporting this parameter and also

describing its progression. The lowest frequency of exercise was two times a week but with the greatest intensity (60%–70% of 1RM) of all the included studies.¹⁰ Similar prescription was practiced by three other trials^{4,8,17} with an exercise frequency of three times a week, but with higher intensities of exercise than the remaining groups. Where intensity was given, it was always above 60% of ten-repetitions maximum (10RM).

Sets and repetitions

The included trials reported a minimum of ten repetitions, except two studies^{9,16} which involved lengthy isometric contractions repeated a lesser number of times. Studies included between one and four sets, with larger numbers of sets when the repetitions were lower (see Crossley et al¹⁶) or lower numbers of sets where the repetitions were higher (see Bakhtiary and Fatemi⁷).

Technique

Although the majority of studies included specific instructions for aspects of the techniques applied, the overall explanation of the interventions was not mentioned. Three trials^{4,8,9} recorded that exercises were performed with correction of dynamic/static alignment of pelvis/hip/knee/foot. Studies also detailed amount of pain (two studies⁸), depth of squat or lunge (two studies^{6,16}) and used biofeedback to enhance selective muscle recruitment (one study¹⁰).

Stretching

Stretching was included in eight of the ten trials. The majority of trials^{9–11,15,16,19} examined three repetitions of 30-second duration. The frequency of stretching varied as it was performed concurrently with strengthening; further details can be found in Table 2.

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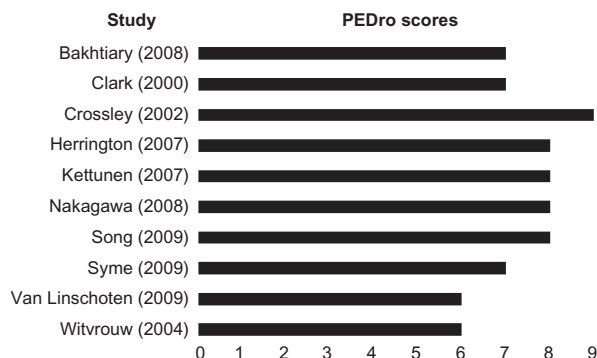


Figure 2 Graph showing PEDro scores for each of the included studies.

Co-interventions

Subjects participating in the exercise intervention of eight trials^{8–11,15,16,19} were also receiving/allowed to receive other treatments, concurrently or as a part of that trial. Table 3 summarizes these co-interventions. The additional interventions included advice to avoid symptom-producing activity, taping, education, nonsteroidal anti-inflammatory drugs, simple analgesics, bracing, and patella mobilizations. Taping and education were the two most common co-interventions.

Discussion

This review provides evidence-based recommendations to clinicians who wish to use exercise programs to improve pain and function in patients with patellofemoral pain.

Type of exercise

The high frequency of both OKC and CKC exercises employed by the included studies indicates support for the

use of both exercise types. The apparent low frequency of use of balance and proximal stability/TrA exercises questions the need to specifically train these components.

Program duration

The majority of the trials reported an intervention period of 6 weeks, except Witvrouw et al⁴ and Bakhtiary and Fatemi,⁷ which reported 5- and 3-week intervention periods, respectively. Therefore, an intervention period of 6 weeks could be considered the starting length for programs targeting PFPS, as the studies with intervention periods of 6 or more weeks were most commonly reported and associated with positive outcomes.

Frequency and intensity

The majority of studies (eight out of ten) prescribed 5 or more days of exercises per week. Thus, the choice of frequency is likely to be a reflection of goals of training, and

Table 3 Details of stretching and co-interventions reported

Study	Stretching parameters				Co-intervention	
	Muscle/stretch	Reps	Duration	Frequency	Nonmedical	Medical
Clark et al ¹⁵	H/S ITB Quadriceps gastrocnemius	10	10 seconds	Daily	Taping Education	NR
Crossley et al ¹⁶	Sitting H/S Anterior hip in prone	3	30 seconds	Daily	Taping (daily), PFJ mobilization	Allowed paracetamol only
Nakagawa et al ⁹	Sitting H/S Standing quadriceps Standing calf Standing ITB	3	30 seconds	5×/week	Sitting patella mobilization	NR
Bakhtiary and Fatemi ⁷	NR				NR	NR
Witvrouw et al ¹⁹	Quadriceps H/S Gastrocnemius	3	30 seconds	3×/week	Asked not to participate in sport	NR
Herrington and Al-Sherhi ⁸	NR				Nil	Nil
Syme et al ¹⁰	Quadriceps H/S ITB Gastrocnemius Soleus Anterior hip	3	30 seconds	2×/week	Taping Education Patellar mobilizations	Advised not to change current use
Van Linschoten et al ¹¹	Flexibility exercises for major thigh muscles, specifics NR	NR	NR	Daily	Education Brace/bandage 20% Insoles 26%	NSAIDs 6% Topical agents 3%
Song et al ¹⁷	Quadriceps H/S ITB Calf	3	30 seconds	3×/week	Hot pack to quadriceps for 15 minutes pre exercise, cold pack to knee for 10 minutes post exercise	Nil
Kettunen et al ²³	Calf H/S Quadriceps	3–5	20 seconds	2×/day	Avoidance of symptom producing activities	NR

Abbreviations: reps, repetitions; NR, not reported; H/S, hamstring; ITB, iliotibial band; NSAID, nonsteroidal anti-inflammatory drug; PFJ, patellofemoral joint.

the need for adequate recovery following higher intensity training. Syme et al,¹⁰ for example, aimed to improve aspects of motor control such as VMO/vastus lateralis (VL) timing and dynamic alignment, and therefore may have included daily exercises of low intensity so as to reinforce motor patterns and enhance motor learning, rather than improve raw strength. Based on these results, frequency of training should be chosen with respect to the type of exercise and the perceived goals of training, and principles of overload and progression should be considered where strength is a target of intervention.

Strength

Strength as a target of treatment was explicitly stated by nine of the ten studies. The exercise interventions incorporated into protocols demonstrating positive results (knee extension, squats, stationary cycling, static quadriceps, active straight leg raise, and step up and step down exercises) contain an implicit strengthening component. Targets of strengthening exercises varied according to the trial; however, frequently included quadriceps, gluteals, hip abductors, and external rotators, and occasionally included hip adductors. Nakagawa et al⁹ reported significant improvement with the addition of hip and core strengthening compared with controls receiving quadriceps strengthening only. The high reporting of exercises that strengthened both hip and knee muscle groups among programs which demonstrated positive outcomes supports their inclusion in exercise programs and reflects the hip and knee strength deficits that have been shown to exist in patients with PFPS.^{3,18}

Flexibility

Stretching of various lower limb musculatures was included as an adjunct to exercise in eight of the ten trials. Of these, seven trials specified the stretched muscles, with all seven including hamstring and quadriceps stretches, six including gastrocnemius, five including the iliotibial band (ITB), and two including anterior hip stretches. To date only one randomized controlled trial²⁰ has specifically investigated the effect of stretching on PFPS in isolation, concluding that although it seemed to improve flexibility and knee function there was no statistically significant improvement in pain or function with stretching alone. In a 2006 cohort study, Tyler et al²¹ reported that successful outcomes were correlated to demonstrated improvements in ITB and iliopsoas flexibility. The frequent inclusion of stretching in studies reporting positive outcomes further supports the use of stretching as an inclusion in exercise protocols.

Selective muscle recruitment/muscle timing

There has been a great emphasis on deficits in VMO strength and timing in interventions which selectively train this muscle.²² Fagan and Delahunt³ found that although one research study had shown improvements in VMO/VL timing with selective muscle VMO training, they did not investigate the effect of the training on symptoms. Interestingly, only two of the included studies^{10,16} showing positive effects of exercise incorporated selective VMO training. Syme et al¹⁰ found significant improvements with general and VMO selective strengthening compared with controls; however, there was no between-group difference. The authors¹⁰ recommend that it not be overly focused on for progressing rehabilitation.

Sets and repetitions

The review revealed a minimum of 20–40 total repetitions should be considered when prescribing exercises for patellofemoral pain.

Limitations

This review focused on exercises undertaken as part of a structured exercise program rather than general exercises (such as walking) and unstructured exercises (such as Pilates). As such, this review does not provide any insight into the role of general physical activity and unstructured exercises in the management of patients with PFPS. Like previous reviews, this review has highlighted risk of bias, due to poor methodology, in some of the primary research. One study did not report concealing of subject allocation, two did not report blinding of the primary outcome assessor, and intention to treat analysis was not reported in two of the eight studies. Co-interventions such as taping, education, and patella mobilization were also a common feature. Taping for example is reported to provide benefits independent of exercise,¹⁵ leading to opportunities for confounding. This does, however, reflect clinical practice where exercise is frequently combined with co-interventions.

Conclusion

Implications for practice

This systematic review builds on the current body of evidence which supports the use of exercise in reducing pain and increasing function ability in patients with PFPS. This review provides clinicians with specific parameters in order to devise an evidence-based exercise program to treat PFPS. Based on evidence from the literature, results are optimal when exercises are performed on a daily basis for 6 or more

weeks. The interventions shown to be most effective are knee extension, squats, stationary cycling, static quadriceps, active straight leg raise, and step up and step down exercises combined with flexibility exercises. The evidence suggests that a progressive program of two to four sets of ten or more repetitions has the most benefit. These myriad of exercise options provide clinicians with the flexibility to tailor their exercise programs to suit individual needs and requirements of their patients. The findings from this review also suggest that exercise programs can be effective when used independently, or in combination with other treatments such as patella mobilization, taping, and education. This, too, provides clinicians with options as part of their management strategies, which can then be incorporated into an exercise program for patients with PFPS.

Implications for research

Exercise as a therapy for PFPS is a well-researched area. However, there are still key gaps in the literature that need to be addressed. Further research is required to determine exercise programs which are specific goal oriented to reflect patient outcomes rather than generalized programs, as is currently reported in the literature. Compliance with exercise programs are poorly reported in the literature and this could be the focus of future research, as poor compliance may lead to poor outcomes.

Disclosure

The authors report no conflicts of interest in this work.

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Supplementary material

The PEDro critical appraisal criteria scale¹²

1. Eligibility criteria were specified
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)
3. Allocation was concealed
4. The groups were similar at baseline regarding the most important prognostic indicators
5. There was blinding of all subjects
6. There was blinding of all therapists who administered the therapy
7. There was blinding of all assessors who measured at least one key outcome
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analyzed by “intention to treat”
10. The results of between-group statistical comparisons are reported for at least one key outcome
11. The study provides both point measures and measures of variability for at least one key outcome

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht.²⁴ The list is based on “expert consensus” not, for the most part, on empirical data. Two

additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to “weight” scale items so that the PEDro score reflects the importance of individual scale items. The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomized clinical trials (ie, RCTs or CCTs) archived on the PEDro database are likely to be valid (criteria 2–9), and could have sufficient statistical information to make their results interpretable (criteria 10–11). An additional criterion (criterion 1) that relates to the external validity (or “generalizability” or “applicability” of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site. The PEDro scale should not be used as a measure of the “validity” of a study’s conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the “quality” of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

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