RESEARCH REPORT

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Short-Term Effects of Hip Abductors and Lateral Rotators Strengthening in Females With Patellofemoral Pain Syndrome: A Randomized Controlled Clinical Trial

nterior knee pain or patellofemoral pain syndrome (PFPS) is one of the most common disorders affecting the lower extremities. It frequently occurs among the physically active population, and its incidence is higher among women. Despite the high prevalence, the etiology of this painful syndrome and most effective approach to the treatment are still unclear.^{5,23,29}

A commonly accepted hypothesis for the etiology of PFPS is based on excessive patellofemoral joint pressure secondary to poor patellar tracking.^{13,33} Accordingly, many clinical interventions have focused directly on the patella, with the goal of trying to correct the patellar alignment and motion. These interventions with intended direct effect on patella alignment included quadriceps strengthening, especially the oblique fibers of the vastus medialis muscle, hamstring and iliotibial band stretching, patellar mobilization, and patellar tapSTUDY DESIGN: Randomized clinical trial.

 OBJECTIVE: To investigate the influence of strengthening the hip abductor and lateral rotator musculature on pain and function of females with patellofemoral pain syndrome (PFPS).

BACKGROUND: Hip muscle weakness in women athletes has been the focus of many recent studies and is suggested as an important impairment to address in the conservative treatment of women with PFPS. However, it is still not well established if strengthening these muscles is associated with clinical improvement in pain and function in sedentary females with PFPS.

METHODS: Seventy females (average ± SD age, 25 ± 07 years), with a diagnosis of unilateral PFPS, were distributed randomly into 3 groups: 22 females in the knee exercise group, who received a conventional treatment that emphasized stretching and strengthening of the knee musculature; 23 females in the knee and hip exercise group, who performed exercises to strengthen the hip abductors and external rotators in addition to the same exercises performed by those in the knee exercise group; and of the 25 females who did not receive any treatment. The females of the nontreatment group (control) were instructed to maintain their normal daily activities. An 11-point numerical pain rating scale (NPRS) was used to assess pain during stair ascent and descent. The lower extremity functional scale (LEFS) and the anterior knee pain scale (AKPS) were used to assess function. The single-limb single hop test was also used as a functional outcome to measure preintervention and 4-week postintervention function.

● RESULTS: The 3 groups were homogeneous prior to treatment in respect to demographic, pain, and functional scales data. Both the knee exercise and the knee and hip exercise groups showed significant improvement in the LEFS, the AKPS, and the NPRS, when compared to the control group (P<.05 and P<.001, respectively). But, when we considered minimal clinically important differences, only the knee and hip exercise group demonstrated mean improvements in AKPS and pain scores that were large enough to be clinically meaningful. For the single-limb single hop test, both groups receiving an intervention showed greater improvement than the control group, but there was no difference between the 2 interventions (P>.05).

• **CONCLUSION:** Rehabilitation programs focusing on knee strengthening exercises and knee strengthening exercises supplemented by hip strengthening exercises were both effective in improving function and reducing pain in sedentary women with PFPS. Improvements of pain and function were greater for the group that performed the hip strengthening exercises, but the difference was significant only for pain rating while descending stairs.

• LEVEL OF EVIDENCE: Therapy, level 1b-. J Orthop Sports Phys Ther 2010;40(11):736-742. doi:10.2519/jospt.2010.3246

• **KEY WORDS:** anterior knee pain, chondromalacia, gluteus medius, knee, patella

¹Associate Professor, Physical Therapist Staff, Irmandade da Santa Casa de Misericórdia (ISCMSP), Physical Therapy Department, São Paulo-SP, Brazil; Nucleus of Support to Research in Analysis of Movement (NAPAM), São Paulo-SP, Brazil. ²Postgraduate student, Irmandade da Santa Casa de Misericórdia (ISCMSP), Physical Therapy Department, São Paulo-SP, Brazil. ³Master of Science student, Federal University of São Paulo (UNIFESP), São Paulo-SP, Brazil. ⁴Associate Professor and Physical Therapist Staff, Irmandade da Santa Casa de Misericórdia (ISCMSP), Physical Therapy Department, São Paulo-SP, Brazil. ⁵Physical Therapist Staff, Universidade Nove de Julho, Einstein Movement Analysis Laboratory, São Paulo-SP, Brazil. The protocol for this study was approved by The Ethics Committee on Research of the Irmandade da Santa Casa de Misericórdia de São Paulo (ISCMSP). Address correspondence to Thiago Yukio Fukuda, Physical Therapy Department, Rua Dr Cesário Motta Jr, 112, 01221-020, São Paulo-SP, Brazil. E-mail: tfukuda10@yahoo.com.br ing, among others.^{16,29,31,36} Foot orthoses are also commonly used as an indirect approach to affect patellofemoral motion through control of foot pronation.¹¹

More recently, some researchers have recognized that the patellofemoral joint could be influenced by abnormal hip motion leading to excessive femoral movements in the transverse and frontal planes.^{23,29-31} Powers et al³⁰ demonstrated that during weight-bearing activities, individuals with PFPS exhibited excessive femoral medial rotation, leading to a relative lateral displacement of the patella. Based on this study and considering that complaints of pain with PFPS are typically during weight-bearing activities, a growing body of clinical and biomechanical literature has been published on the influence of the hip musculature to control knee motion.^{6,14,19,31,34}

Several authors have documented significant weakness of the hip lateral rotators and abductors in women with PFPS.^{5,28} Several researchers have also measured excessive internal rotation and adduction of the hip, leading to an excessive dynamic valgus alignment of the knee, in women with PFPS.^{12,28,32} Based on these reports, it has been suggested that strengthening of the hip musculature could help improve lower extremity alignment and tracking of the patella, reducing excessive retropatellar joint pressure and ultimately leading to decreased pain and improved function in individuals with PFPS.^{14,23,31,32} Most of these studies focused on young female athletes with PFPS, unlike the current study that investigated sedentary females.

Despite numerous studies showing weakness of the hip musculature and poor control of hip motion in females with PFPS, there is currently very limited information on the effectiveness of hip strengthening exercises to decrease pain and improve function in these individuals. Thus, the purpose of this study was to determine whether strengthening the hip abductors and lateral rotators in addition to the knee musculature would be superior to strengthening the knee musculature alone or no treatment at all for outcomes of pain and function in sedentary females with PFPS.

METHODS

Patients

S EVENTY FEMALE PATIENTS PARTICIpated in this randomized clinical trial. They were randomly assigned into 3 groups: 25 participants not receiving treatment in the control (CO) group, 22 participants in the knee exercise (KE) group, and 23 participants in the knee and hip exercise (KHE) group. Two patients in the KE group and 2 patients in the KHE group did not complete the study.

The sample size estimation calculations were based on detecting a 10-point difference in the Lower Extremity Functional Scale (LEFS), based on a 9-point minimal clinically important difference (MCID),^{4,35} assuming a standard deviation of 13 points, 2-tailed, an alpha level equal to .05, and 80% power. This generated a sample size of 20 females per group. Allowing for a conservative dropout rate and the intent to have 3 groups, we recruited 70 patients to participate in the study, while providing adequate protection against type II error.

The female patients were between 20 and 40 years of age and were included if they had a history of anterior knee pain for at least the past 3 months and reported pain in 2 or more daily activities listed by Thomee et al³³ (ascending and descending stairs, squatting, kneeling, jumping, long sitting, isometric knee extension contraction at 60° of knee flexion, and pain on palpation of the medial and/or lateral facet of the patella). The participants were recruited from the Rehabilitation Service, Irmandade da Santa Casa de Misericórdia de São Paulo, Brazil (ISCMSP) by a single physical therapist with more than 10 years of clinical experience in knee rehabilitation. All the females included in this trial

were sedentary, defined as individuals who had not practiced physical activity any day of the week, both aerobic and strengthening exercises, for at least the past 6 months.³⁷

Females were excluded if they were pregnant or had any neurological disorders, hip or ankle injuries, low back or sacroiliac joint pain, rheumatoid arthritis, used corticosteroids and/or antiinflammatory drugs, a heart condition that precluded performing the exercises, or previous surgery involving the lower extremities. We also excluded females who had other knee pathologies such as patellar instability, patellofemoral dysplasia, meniscal or ligament tears, osteoarthritis, tendinopathies, and epiphysitis. A standard knee clinical examination was performed to rule out concomitant pathology of the lower extremities.

All volunteers were informed about the procedures for the study and signed informed consent written in accordance with National Health Council Resolution CNS-196/96. This study was approved by the ISCMSP Research Ethics Committee.

After the inclusion of the participants, a single examiner was responsible for the administration of all tests and questionnaires performed before and after the intervention. This examiner was blind to the group assignment of the patients and did not participate in the intervention.

The assignment of patients in the 3 groups was performed randomly using opaque and sealed envelopes containing the names of the groups: CO, KE, and KHE. The envelopes were picked by an individual not involved in this study. Group assignment was performed following the initial evaluation and just minutes prior to the initial treatment session. Two therapists trained on the exercise protocol for the study provided all treatment. Both therapists were responsible for the 2 intervention protocols.

Interventions

The females of the KE and KHE groups completed 3 treatment sessions per week for 4 weeks, totaling 12 sessions (**FIGURE**

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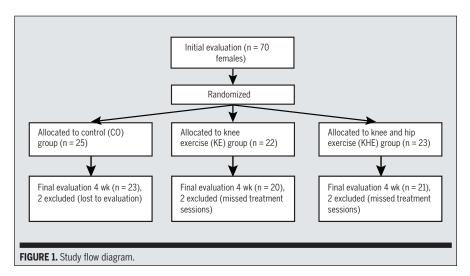
1). The treatment for the individuals in the KE group emphasized stretching and strengthening of the knee musculature. Individuals in the KHE group were treated using the same protocol, with the addition of performing exercises to strengthen the hip abductor and lateral rotator muscles.

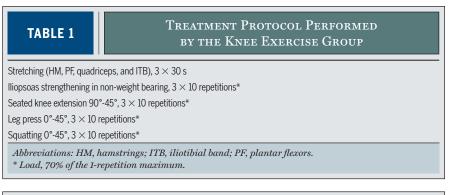
The load during training was standardized to 70% of the 1-repetition maximum, defined as the maximum load the person could use to complete 1 repetition of the exercise without pain. The maximum load was evaluated during the first treatment session and reviewed weekly for needed adjustments. Nonweight-bearing exercises were initiated using ankle weights and progressed to a knee extension machine, based on patient tolerance. These criteria were based on the protocol of previous studies.17 However, exercises utilizing elastic resistance were standardized to the maximum resistance that each patient was able to use and still complete 10 repetitions of the exercise. Resistance was also reviewed weekly for adequacy. Stretching of the hamstrings and ankle plantar flexors (straight leg raise in supine position), quadriceps, and iliotibial band (in sidelying) consisted of three 30-second stretches, assisted by the therapist, for each structure. It is important to highlight that the patients did not perform exercises at home.

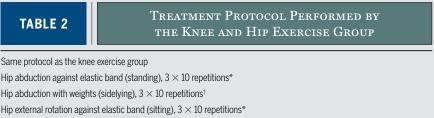
All patients in the CO group were instructed to maintain their daily activities and did not receive any form of treatment. The exercises performed by the individuals in the KE and KHE groups are shown in TABLE 1, TABLE 2, and FIGURE 2.

Evaluation

An 11-point Numerical Pain Rating Scale (NPRS),⁷ where 0 corresponded to "no pain" and 10 corresponded to "worst imaginable pain," was used to measure pain during ascending and descending stairs. The LEFS⁴ and Anterior Knee Pain Scale (AKPS)¹⁸ were used to measure function. The NPRS has been shown to be reliable and valid, with a MCID of 2 points.¹⁰







Side-stepping against elastic band, 3×1 min

* Maximum resistance that enables 10 repetitions. ⁺ Load, 70% of the 1-repetition maximum.

The LEFS and the AKPS have been used previously for clinical outcome studies and are recommended for use with the PFPS population. The LEFS is a 20-item functional assessment tool that rates the level of difficulty of functional tasks from 0 (extreme difficulty) to 4 points (no difficulty), yielding a maximum score of 80 points, with higher scores indicating better function. The MCID of the LEFS has been reported to be 9 points in patients with PFPS.^{4,35} The AKPS is a 13-item assessment tool, with items differentially weighted for a maximum score of 100 and higher scores indicating better function. The MCID of the AKPS has been reported to be 13 points.^{18,35} Both scales show high test-retest reliability, moderate responsiveness, and adequate validity.³⁵

The single-limb single hop test¹ was used as a functional test, and similar to all other outcome measures, was administered before and after the 4-week intervention.



FIGURE 2. Examples of hip strengthening exercises using elastic band or weights for resistance. (A) Hip abduction in standing position, (B) side-stepping, (C) hip external rotation, and (D) hip abduction in sidelying.

TABLE 3	Demographic Characteristics of the Control, Knee Exercise, and Knee and Hip Exercise Groups*							
	Control (n = 23)	Knee Exercise (n = 20)	Knee and Hip Exercise (n = 21)					
Age (y)	24.0 ± 7.0	25.0 ± 6.0	25.0 ± 7.0					
Body mass (kg)	57.8 ± 6.2	57.1 ± 7.3	61.3 ± 8.1					
Height (m)	1.60 ± 0.5	1.64 ± 0.6	1.62 ± 0.6					
* Values are mean \pm SD. Only those subjects remaining at the end of the study are included. There were no differences among groups (P>.05).								

Data Analysis

Data were analyzed with SPSS Version 13.0. Descriptive statistics for demographic data and all outcome measures were expressed as averages and standard deviations. Comparison between the groups was performed using separate 1-way analyses of variance (ANO-VAs) for age, body mass, height, pain score, and functional scales to determine homogeneity of the 3 groups at baseline. The data for the 2 functional scales (AKPS and LEFS), the singlelimb single hop test, and the NPRS were analyzed using separate 3-by-2 (group by time) mixed-model 2-way ANOVAs. The factor group had 3 levels (CO, KE, and KHE), and the repeated factor, time, had 2 levels (preintervention and postintervention).

RESULTS

Baseline and Demographic Data

HERE WERE NO STATISTICALLY SIGnificant differences (P>.05) for age, height, and body mass among the 3 groups (**TABLE 3**). There were also no statistically significant differences (P>.05) among groups for any of the outcome variables at baseline (preintervention) (**TABLE 4**).

Pain and Function

There was a statistically significant group-by-time interaction for the 3-by-2 mixed-model ANOVAs for the LEFS, the AKPS, and the single-limb single hop test (*P*<.0001, *P*<.0001, and *P*<.05, respectively). Planned pairwise comparisons for the LEFS and AKPS indicated that the individuals in both the KE (P < .05) and KHE groups (P < .01) had improved function at the 4-week evaluation when compared to baseline. Performance on the single-limb single hop test also improved for the KE and KHE groups (P < .05). No preinterventionto-postintervention differences were found for these outcomes measures for the CO group (P>.05). The analysis of differences among groups following the 4-week intervention showed that both the KE and KHE groups were statistically different when compared to the CO group for the LEFS (both, P < .05), AKPS (P < .05 and P < .01, respectively), and single-limb single hop test (both,

P<.05). There was no difference between the KE and KHE groups (P>.05) for all 3 outcome measures.

There was also a statistically significant group-by-time interaction for the 3-by-2 mixed-model ANOVAs for the NPRS during ascending and descending stairs (both, P < .01). Planned pairwise comparisons showed that only patients in the KHE group obtained a significant pain reduction at the 4-week evaluation when compared to baseline (ascending stairs, P < .001; descending stairs, P < .001). The analysis of differences among groups following the 4-week intervention showed that both the KE and KHE groups had statistically lower ratings of pain during ascending stairs in comparison to the CO group (both, P < .05). No statistically significant difference was found between the KE and KHE groups postintervention (P>.05). However, the analysis for NPRS during descending stairs showed that the individuals in the KHE group had statistically lower rating of pain postintervention when compared to those in the KE and CO groups (P < .05 and P < .01, respectively). The difference in NPRS between the KE and CO groups for descending stairs postintervention was not significant (P>.05). TABLE 4 summarizes within- and between-group differences, with associated 95% confidence intervals.

Intention-to-Treat Analysis

We performed an intention-to-treat analysis,²⁴ and the results were consistent with the per-protocol analysis as presented above. This parallel method was based on the imputation of the group mean to each missing value for each of the 3 groups (CO, KE, and KHE).

DISCUSSION

HE RESULTS OF THIS RANDOMIZED clinical trial demonstrated that a 4-week intervention either consisting of knee-strengthening exercises or knee-strengthening exercises supple-

Outcome Measures Preintervention and Postintervention for the CO, KE, and KHE Groups

Measure/Group (n) Prein		Postintervention*	Within-Group Change Score [†]	Between-Group Difference in Change Score		
	Preintervention*			KHE – CO Group [‡]	KE – CO Group‡	KHE – KE Group [‡]
LEFS (0-80)§				14.2 (6.4, 22.0)	7.6 (3.2, 12.0)	6.6 (-1.5, 14.7)
CO group (23)	48.8 ± 17.0	51.2 ± 15.1	2.4 ± 7.5 (-0.6, 5.4)			
KE group (20)	55.6 ± 15.9	65.6 ± 14.5	10.0 ± 6.5 (7.3, 12.7)			
KHE group (21)	49.1 ± 11.9	65.7 ± 13.5	16.6 ± 16.7 (9.4, 23.8)			
AKPS (0-100)§				14.3 (7.4, 21.2)	9.5 (2.9, 16.1)	4.8 (-2.9, 12.5)
CO group (23)	63.8 ± 15.5	64.5 ± 11.1	0.7 ± 9.9 (-3.2, 4.6)			
KE group (20)	70.4 ± 12.5	80.6 ± 13.9	$10.2 \pm 11.6 (5.4, 15.0)$			
KHE group (21)	63.9 ± 11.7	78.9 ± 16.0	15.0 ± 12.8 (9.8, 20.2)			
Single-limb hop test (cm)§				16.3 (8.3, 24.4)	11.1 (3.4, 18.8)	5.2 (-4.9, 15.3)
CO group (23)	81.0 ± 25.5	80.3 ± 16.0	-0.6 ± 9.1 (-4.2, 3.0)			
KE group (20)	76.1 ± 37.7	86.5 ± 32.0	$10.5\pm15.4~(4.1,16.9)$			
KHE group (21)	76.1 ± 33.8	91.8 ± 34.4	15.7 ± 16.6 (8.9, 22.5)			
NPRS ascending stairs				-2.3 (-3.4, -1.2)	-1.6 (-2.4, -0.8)	-0.7 (-2.0, 0.6)
CO group (23)	4.9 ± 2.5	5.0 ± 2.5	0.1 ± 1.1 (-0.3, 0.5)			
KE group (20)	4.9 ± 2.9	3.4 ± 2.3	-1.5 ± 1.6 (-2.2, 0.8)			
KHE group (21)	5.2 ± 1.6	3.0 ± 1.8	-2.2 ± 2.3 (-3.1, -1.3)			
NPRS descending stairs				-2.3 (-3.5, -1.1)	-0.7 (-1.9, 0.5)	-1.6 (-3.0, -0.2)
CO group (23)	4.4 ± 2.4	4.1 ± 2.3	-0.3 ± 1.5 (-0.9, 0.3)			
KE group (20)	4.5 ± 2.8	3.5 ± 2.5	-1.0 ± 2.2 (-1.9, -0.1)			
KHE group (21)	4.9 ± 1.6	2.3 ± 1.5	-2.6 ± 2.3 (-3.5, -1.7)			

Abbreviations: AKPS, Anterior Knee Pain Scale; CO, control; KE, knee exercise; KHE, knee and hip exercise; LEFS, Lower Extremity Functional Scale; NPRS, 11-point numerical pain rating scale.

* Values are mean \pm SD.

 $^+$ Values are mean \pm SD (95% confidence interval).

[‡] Values are mean (95% confidence interval)

[§] Higher scores on the LEFS, AKPS, and the single-limb single hop test represent better function.

NPRS (0-10 cm), where 0 means "no pain," and 10 means "worst imaginable pain."

mented by hip-strengthening exercises both led to improved function and reduced pain during stair negotiation in sedentary females with PFPS. For most outcome measures, greater improvement was noted in the group combining knee and hip exercises, but these differences were not statistically significant, except for NPRS while descending stairs, for which the individuals in the KHE group showed a significantly greater improvement than those in the KE group. There was no change in function or pain in the patients who received no intervention.

Despite the lack of statistically significant differences in improvement between the 2 groups receiving an intervention, analysis of the data, based on the published MCIDs9,15 of 9 points for the LEFS, 13 points for the AKPS, and 2 points for the NPRS, suggests greater clinical benefits for the combined hip and knee exercise program. The patients in the KHE group showed improvement above the MCID for all scales-LEFS (16.6 points), AKPS (15 points), and NPRS ascending and descending stairs (2.2 and 2.6 points, respectively)-compared to those in the KE group, who only showed improvement above the MCID for the LEFS (10 points). It could be postulated that a larger number of patients in each group could have led to significant difference between groups for all outcome measures.

The importance of hip abductor and lateral rotator muscle strengthening in

the treatment of PFPS has received increased attention in recent years. This approach is based on several studies that have demonstrated weakness of the hip abductors and lateral rotators in women with PFPS.^{8,14,31} Mechanically, weakness of the hip musculature could lead to increase femoral adduction and medial rotation during dynamic weight-bearing activities, which would increase the lateral patellofemoral joint vector, leading to patellar facet overload. 19,23,29,30 Despite the logical relationship that would appear to exist between hip weakness and excessive hip adduction and medial rotation, it is noteworthy that a direct association between hip strength^{2,19,27} and hip kinematics1,6,13,26 has not clearly been established.

This randomized controlled trial, using a blind examiner, was designed to evaluate the influence of hip abductor and lateral rotator strengthening in sedentary females with PFPS, when provided in conjunction to what may be perceived as more traditional knee exercises. The functional evaluations were performed by standardized and validated scales such as the LEFS, AKPS, and single-limb single hop test.^{1,4,18} The NPRS was used for pain assessment during ascending and descending stairs.⁷

Noteworthy is that, in this study, these concepts were applied to sedentary females with PFPS. This is in contrast to most reports in the literature that are almost exclusively based on the study of female athletes. In our study, sedentary females were investigated who lacked routine physical activity according to the criteria established by the American College of Sports Medicine.37 Some authors have reported that PFPS is related to overload during sports activities, especially in sports involving jumping.8 However, we disagree that this disease is present only with athletes. Accordingly, some authors have also speculated that simple daily activities were sufficient to lead to poor knee and hip kinematics, leading to a reduction of the patellofemoral contact area and increased joint stresses.^{20,30} In our clinical experience, there is a high incidence of PFPS in young and sedentary females, possibly due to the commonly noted hip muscle weakness that may change lower limb kinematics.22

Authors have shown that hip muscle weakness is frequently present in patients with PFPS.^{21,25,31,34} Tyler et al³⁴ proposed a 6-week therapeutic exercise program including hip flexor, abductor, and adductor muscle strengthening exercises, and stretching of the iliotibial band and iliopsoas muscle. These authors found a significant increase in hip flexor strength but did not observe a change in strength of the hip abductor and adductor muscles. Because the functional status and pain level of the individuals in the study improved, these findings may suggest that increased strength of the hip adductors and abductors is not essential for pain resolution of PFPS. Nevertheless, iliopsoas strengthening, which is a secondary lateral femoral rotator, would assist in controlling the orientation of the femur and trochlea in weight-bearing activities. In addition, flexibility of the hip flexors and iliotibial band could reduce the tension in the lateral retinaculum and allow an appropriate patellar glide.

In a separate study, Nakagawa et al²⁵ evaluated the effects of flexibility and strengthening exercises of the hip abductors and lateral rotators. One group focused on stretching the quadriceps, gastrocnemius, and iliotibial band, and performing quadriceps strengthening exercises. The other group added strengthening exercises for the transverse abdominal, and the hip abductors and rotators. These authors obtained very similar results for pain relief to those in the current study. However, their data should be considered with some reservation, because it was a pilot study that utilized a small number of patients and weekly supervised sessions. Another limitation of the Nakagawa et al²⁵ study was the lack of functional assessments.

In the current study, the protocol was based on 4 weeks of exercises with a frequency of 3 times a week, resulting in beneficial results based on pain reduction and improved function. While short-term improvements were achieved through this program, prospective and randomized clinical trials are needed to assess the long-term effects of hip muscle exercises, specifically, the abductor and lateral rotators in sedentary patients.

Based on the obtained results, it is thought that the muscles that directly influence the hip also affect the knee.^{3,28} Specifically, the abductor and lateral rotators can help control forces applied to the knee joint,²³ and help control femoral medial rotation and adduction during dynamic daily activities.²⁹ It is noteworthy that the study aimed to strengthen the specific muscles involved, without concern for sensorymotor training (ie, education on proper movement pattern, which might have influenced the results).

CONCLUSION

OUR WEEKS OF EITHER KNEE strengthening exercises or knee strengthening exercises supplemented by hip strengthening exercises were effective in improving function and reducing pain in sedentary women with PFPS. Improvements of pain and function were greater for the group who performed the combined knee and hip strengthening exercises, but the difference was significant only for pain rating while descending stairs. This improvement occurred without providing any instructions on optimal lower extremity alignment to be maintained during weight-bearing activities.

KEY POINTS

FINDINGS: After 4 weeks of a combined knee and hip strengthening exercise program, sedentary females with PFPS had a greater reduction in pain during stair descent compared to the group who performed knee strengthening exercises only. Both groups also showed significant improvement in function and pain during stair ascent. The improvement of the group doing the combined exercises was greater than the MCID for all outcome measures.

IMPLICATION: On the basis of our results, we suggest that strengthening of the hip abductors and lateral rotators should be used along with strengthening of the knee musculature for women with PFPS.

CAUTION: The data from this study were based on sedentary females. A longer follow-up is necessary in addition to future similar comparisons including a larger number of patients and possibly longer treatment period.

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