Fukuda TY, Melo WP, Zaffalon BM, and et al. Hip Posterolateral Musculature Strengthening in Sedentary Women with Patellofemoral Pain Syndrome: A Randomized Controlled Clinical Trial With 1-Year Follow-up. J Orthop Sports Phys Ther 2012;42(10):823-830.

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Design: Randomized clinical trial

Objective: To determine if adding hip strengthening exercises to a conventional knee exercise program produces better long-term outcomes than conventional knee exercises alone in women with patellofemoral pain syndrome (PFPS).

Population /sample size/setting:

- 54 female volunteers aged 20 to 40 years of age with unilateral PFPS participated in the study and were randomly assigned to 1 of 2 groups, a knee exercise group (KE; n = 26, mean age = 23) or a knee and hip exercise group (KHE; n = 28, mean age = 22). Two patients in the KE and 3 patients in the KHE group did not complete the study.
- The participants were recruited from the Rehabilitation Service, ISCMSP, Brazil by a single physical therapist experienced in knee rehabilitation.
- All patients included in the trial were sedentary, defined as not having practiced physical activity (aerobic and strengthening exercises) any day of the week for at least 6 months previously.
- Inclusion criteria included women 20 to 40 years of age, history of anterior knee pain for at least 3 months, and reported increasing pain in 2 or more activities that commonly provoke PFPS, such as 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.
- Exclusion criteria included history of any neurological disorders, injury to the lumbosacral region, hip, or ankle, rheumatoid arthritis, a heart condition, or surgery involving the lower extremities; or were pregnant or using corticosteroids or anti-inflammatory medication or had other knee pathologies, such as patellar instability, patellofemoral dysplasia, meniscal or ligament tears, osteoarthritis, or tendinopathies.

Interventions:

- The assignment of subjects to the 2 groups was performed randomly using opaque, sealed envelopes, each containing the name of one of the groups (KE or KHE). The envelopes were picked by an individual not involved in the study. Group assignment was performed following the initial baseline evaluation, but prior to the initial treatment session.
- Three physical therapists were trained in delivering the exercise protocols used for the study and provided all treatment. It was not possible to blind the therapists.
- A single examiner was responsible for the administration of all clinical tests and questionnaires before the initiation of treatment (baseline) and at 3, 6, and 12 months after intervention. The examiner was blind to the group assignment of the patients and did not participate in the intervention.

- The KE and KHE groups completed 12 treatment sessions, provided 3 times per week for 4 weeks. The patients performed exercises solely during physical therapy and did not perform exercises at home either during or after the 4-week treatment.
- The treatment for the individuals in the KE group emphasized stretching and strengthening of the knee musculature. The treatment protocol included;
  • Stretching (hamstrings, plantar flexors, quadriceps, and iliotibial band), 3 reps of 30 s
  • Seated knee extension from 90° to 45°, 3 sets of 10 repetitions
  • Leg press from 0° to 45°, 3 sets of 10 repetitions
  • Squatting from 0° to 45°, 3 sets of 10 repetitions
  • Single-leg calf raises, 3 sets of 10 repetitions
  • Prone knee flexion, 3 sets of 10 repetitions
- Individuals in the KHE group were treated using the same protocol as the KE group, but with the addition of exercises to strengthen the hip abductor, lateral rotator, and extensor muscles (the hip posterolateral musculature). The treatment protocol included;
  • Same protocol as the KE group
  • Hip abduction with weights (side-lying), 3 sets of 10 repetitions
  • Hip abduction against elastic band (standing), 3 sets of 10 repetitions
  • Hip lateral rotation against elastic band (sitting), 3 sets of 10 repetitions
  • Hip extension (machine), 3 sets of 10 repetitions
- The maximum load and resistance for all strengthening exercises were evaluated during the first treatment session and reviewed weekly to adjust as needed.
- The trial did not include a non-exercise control.
- All outcome measures were assessed before treatment at baseline and at 3, 6, and 12 months post-treatment.

Main outcome measures:

- Four primary outcome variables were included (3 were self-reported) to measure knee pain and function.
  - Numeric pain rating scale (NPRS) from 0 (no pain) to 10 (worst pain) with a minimal clinically important difference (MCID) of 2 points, similar to the visual analog scale (VAS). The NPRS was used to measure pain during ascending and descending stairs.
  - The Lower Extremity Functional Scale (LEFS) is a 20-item functional assessment questionnaire for PFPS patients that rates the level of difficulty of functional tasks from 0 (extreme difficulty) to 4 (no difficulty), yielding a maximum score of 80 points, with higher scores indicating better function. The MCID of the LEFS is 9 points in patients with PFPS.
  - The Anterior Knee Pain Scale (AKPS) is a 13-item assessment tool with items differentially weighted for a maximum score of 100, with higher scores indicating better function. The MCID of the AKPS is 13 points.
  - The single-limb single-hop test was also used to measure function.

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- Sample-size estimation calculations were based on detecting a 10-point difference in the LEFS, assuming a standard deviation of 13 points, a 2-sided 5% significance level, and 80% power. A sample size of 20 women per group was determined.
- **T**wo subjects in the KE group and 3 subjects in the KHE group were lost to follow-up at 3, 6, and 12 months, due to missing 2 or more treatment sessions. All analyses were performed with 24 subjects in the KE group and 25 subjects in the KHE group.
- At baseline, there was no statistically significant difference between the participants in the KE and KHE groups for age, height, body mass, duration of symptoms or any of the pain and functional outcome variables.
- For within group change scores, the results of the 4 outcome measures: the LEFS, AKPS, single-hop test, and NPRS during ascending and descending stairs indicated that the patients in the KHE group had significantly better function and decreased pain at 3, 6, and 12 months post-treatment compared to baseline. All change scores exceeded the MCID for each outcome measure.
- In contrast, for within group change scores of the 4 outcome measures: the KE group had significantly reduced pain (NPRS) only at the 3- and 6-month follow-ups, as well as some improvement on the single-hop test at 3, 6, and 12 months posttreatment, but no changes in LEFS or the AKPS on all 3 post-treatment assessments. All change scores did not attain the MCID for each outcome measure.
- Between group differences at 3, 6, and 12 months post-treatment indicated that the KHE group compared to the KE group, had significantly less pain and better function for all outcome measures on all 3 post-treatment assessments. On the Lower Extremity Functional Scale (LEFS), the between group difference in change scores from baseline at 3, 6, and 12 months post-treatment favored the KHE group by 22.0, 22.0, and 20.8 points, respectively. The MCID of the LEFS is 9 points in patients with PFPS. On the AKPS, the between group difference in change scores from baseline at 3, 6, and 12 months post-treatment favored the KHE group by 17.0, 15.6, and 14.9 points, respectively. The MCID of the AKPS is 13 points in patients with PFPS. In all 3 post-treatment comparisons between the 2 groups for the primary outcomes of pain and function (LEFS, AKPS, and NPRS), all differences were more than the MCID.
- An intention-to-treat analysis was performed using the last-value-carried-forward method to impute values for all missing data. The results of the intention-to-treat analysis were consistent with the per-protocol analysis, providing evidence that the missing data had no substantial influence on the overall results.

Authors' conclusions:

- **T**he results of this clinical trial demonstrated the long-term effectiveness of hip-strengthening exercises to supplement a conventional knee exercise program for improving function and reducing pain in sedentary women with PFPS. The group that performed a combination of hip and knee exercises showed significant improvements for all outcome measures at 3, 6, and 12 months post-treatment, in contrast to the group that performed knee exercises alone, which only showed significant improvement in pain at 3 and 6 months post-treatment.
- In the KHE group, all mean changes for pain and function as measured on the LEFS, AKPS, and NPRS at all 3 post-treatment time points surpassed the MCID's. In the KE

group, all mean changes on the LEFS, AKPS, and NPRS at all 3 post-treatment time points were below the MCID's.

- **F**our weeks of knee-strengthening exercises, supplemented by strengthening exercises for the hip abductors, lateral rotators, and extensors, was more effective in improving function and reducing pain over a 1-year period than knee strengthening alone in sedentary women with PFPS. In contrast to the long-term functional and pain benefits of those performing the combination of knee and hip exercises, those performing only knee-strengthening exercises showed no improvement at 12 months post-treatment.
- For functional evaluation using the single-hop test, the KHE group had a significant improvement at all 3 follow-up time points compared to pretreatment, which did not occur in the KE group.
- The KE group did not have a clinically meaningful or significant improvement on any measure of pain or function (with the exception of pain at 3 and 6 months over the 1-year study).
- This study provides strong evidence to support one form of exercise over the other. Exercise programs recommended for patients with anterior knee pain should incorporate strengthening of the posterolateral hip musculature.
- Since the recurrence rate of PFPS can be as high as 91%, these findings would suggest that, although a conventional knee-stretching and -strengthening program may produce successful short-term outcomes, the inclusion of hip strengthening may be needed to prevent recurrence of future symptoms.
- The physiological plausibility between hip muscle weakness and changes in kinematic patterns of the lower extremity can be explained by these strength deficits that may lead to excessive medial rotation and adduction of the femur, which in turn may lead to excessive dynamic valgus alignment of the knee in symptomatic patients with PFPS.

Comments:

- Primary outcome measures were clearly stated.
- Fukuda et al. (2010) concluded that in sedentary women with PFPS both treatment approaches were more effective than no treatment for improving function and reducing pain. However, the addition of hip strengthening to a knee-stretching /strengthening exercise program was more effective in improving function and decreasing pain than knee exercises alone. In that study, the authors only reported short-term outcomes.
- In the KHE group, reductions in pain and improvement in function compared to baseline at all 3 post-treatment time points were all of a clinically important magnitude that persisted for 1 year. Furthermore, this improvement was significantly greater than improvements seen in the KE group. In contrast, none of the reductions in pain and improvement in function compared to baseline at all 3 post-treatment time points were of a clinically important magnitude for the KE group.
- Sample sizes were accurately calculated and acquired and may have contributed to the significant findings between the 2 groups. The study was powered for between-group differences based on MCIDs in primary outcomes.
- Major strengths of this study include assessor blinding at all time-points, and the inclusion of a long-term assessment time point at 12 months.
- After the 4-week treatment program, the patients were instructed to maintain their normal daily activities without performing a home exercise program during the 1-year follow-up.

The study did not control or monitor the level of activity or exercises performed by the patients after treatment during the 1-year follow-up. It is therefore not known if one group exercised more than the other group during the 1-year follow-up which could affect the outcome, but does not distort the truth. Since all participants were sedentary before enlisting in the trial, complying with a non-exercise 1-year follow-up period may not be an issue.

- This study did not go beyond the 1-year time period for pain and functional outcomes, and it is possible that there are benefits of treatment beyond 1 year that this study did not capture.
- One limitation of this trial is that data were obtained from a population of sedentary women (those who did not perform repetitive or high-impact activities), which might limit the generalizability of the findings. However, sedentary women often present with excessive dynamic knee valgus, which can lead to patellofemoral overload in daily activities such as negotiating stairs, squatting, or walking.
- This study did not investigate or determine if similar results would have been obtained with hip exercises alone, or if continuing the exercises as a home exercise program after the 4-week treatment was completed would have been beneficial. However, three studies (Khayambashi et al. 2012, 2014, Dolak et al. 2011) have demonstrated that an exercise program of isolated posterolateral hip muscle strengthening was more effective in improving pain in persons with PFPS compared to a quadriceps strengthening program or compared to a no-exercise control group, and improvements were maintained at 6-month follow-up. Limiting the study protocol to a 4-week exercise program may have impacted the ability of the study to achieve the maximal therapeutic benefit of hip strengthening exercises. This would underestimate the effect of the intervention.

Assessment*:*

This adequate quality study supports some evidence that a treatment approach consisting of a combination of hip- and knee-strengthening exercises was more effective in improving function and reducing pain over a 1-year period than knee-strengthening exercises alone in sedentary women with PFPS.

References:

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