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Effectiveness of Inclusion of Dry Needling in a Multimodal Therapy Program for Patellofemoral Pain: A Randomized Parallel-Group Trial

STUDY DESIGN: Randomized controlled trial.

BACKGROUND: Evidence suggests that multimodal interventions that include exercise therapy may be effective for patellofemoral pain (PFP); however, no study has investigated the effects of trigger point (TrP) dry needling (DN) in people with PFP.

OBJECTIVES: To compare the effects of adding TrP DN to a manual therapy and exercise program on pain, function, and disability in individuals with PFP.

METHODS: Individuals with PFP (n = 60) recruited from a public hospital in Valencia, Spain were randomly allocated to manual therapy and exercises (n = 30) or manual therapy and exercise plus TrP DN (n = 30). Both groups received the same manual therapy and strengthening exercise program for 3 sessions (once a week for 3 weeks), and 1 group also received TrP DN to active TrPs within the vastus medialis and vastus lateralis muscles. The pain subscale of the Knee injury and Osteoarthritis Outcome Score (KOOS; 0-100 scale) was used as the primary outcome. Secondary outcomes included other subscales of the KOOS, the Knee Society Score, the International Knee Documentation Committee Subjective Knee Evaluation Form (IKDC), and the numeric pain-rating scale. Patients were assessed at baseline and at 15-day (posttreatment) and 3-month follow-ups. Analysis was conducted with mixed analyses of covariance, adjusted for baseline scores.

RESULTS: At 3 months, 58 subjects (97%) completed the follow-up. No significant between-group differences (all, $P>.391$) were observed for any outcome: KOOS pain subscale mean difference, −2.1 (95% confidence interval [CI]: −4.6, 0.4); IKDC mean difference, 2.3 (95% CI: −0.1, 4.7); knee pain intensity mean difference, 0.3 (95% CI: −0.2, 0.8). Both groups experienced similar moderate-to-large within-group improvements in all outcomes (standardized mean differences of 0.6 to 1.1); however, only the KOOS function in sport and recreation subscale surpassed the prespecified minimum important change.

CONCLUSION: The current clinical trial suggests that the inclusion of 3 sessions of TrP DN in a manual therapy and exercise program did not result in improved outcomes for pain and disability in individuals with PFP at 3-month follow-up.

LEVEL OF EVIDENCE: Therapy, level 1b. Prospectively registered July 27, 2015 at www.clinicaltrials.gov (NCT02514005). *J Orthop Sports Phys Ther 2017;47(6):392-401. doi:10.2519/jospt.2017.7389*

KEY WORDS: *dry needling, exercise, manual therapy, patellofemoral pain*

Patellofemoral pain (PFP) is one of the most common conditions in sports medicine, ranging from 25% to 40% of knee complaints and affecting 25% of the general population,[32,35] although there are limited epidemiological data. Patellofemoral pain is mainly characterized by diffuse retropatellar and peripatellar pain that is aggravated with squatting, prolonged sitting, and stair activities. Patellofemoral pain often lacks a clear medical diagnosis and is diagnosed in the absence of other pathologies, for example, patellar tendinopathy, chondral defects, or knee osteoarthritis.[32]

Individuals suffering from PFP often seek physical therapy for the management of their symptoms. Clinical practice

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guidelines for management of patients with PFP recommend multimodal intervention programs, including strengthening exercises of the hip and knee musculature, patellar taping, patient education, and activity modification.[2] There is strong evidence supporting the use of exercise programs, with or without other conservative interventions, for management of individuals with PFP to reduce pain and improve function.[5,23,24] Yet, there is insufficient evidence to determine the most optimal form of exercises.[40]

It appears that knee and hip musculature plays a relevant role in PFP; therefore, soft tissue interventions targeting muscles, in combination with exercises, may be effective for the management of this condition. One potential rationale for soft tissue interventions is related to the hypothesis that trigger points (TrPs) can be involved in the production of pain in patients with PFP.[38] Trigger points are defined as hypersensitive spots within taut bands of a skeletal muscle that are painful on palpation and usually elicit referred pain.[38] Trigger points are clinically classified as active or latent. If they are active, TrPs cause spontaneous pain, and the elicited referred pain reproduces the patient's symptoms. If they are latent, TrPs do not reproduce any symptoms.[38] Torres-Chica et al[39] observed that the referred pain elicited by active TrPs reproduced symptoms in individuals with postmeniscectomy knee pain. Simons et al[38] suggested that active TrPs in the knee muscles, particularly the vastus medialis and lateralis, may contribute to pain experienced by patients with PFP; however, no epidemiological data on the prevalence of TrPs in the knee muscles in patients with PFP are currently available. The only study that has investigated the presence of TrPs in this population reported that individuals with PFP exhibited a higher prevalence of TrPs in the gluteus medius and quadratus lumborum muscles in association with a reduction in hip abduction strength.[33] A potential role of active TrPs in patients with PFP may be related to better outcomes after their treatment, but there is no clinical trial investigating this topic.

Several therapeutic approaches are proposed for the management of TrPs, with manual therapies and dry needling (DN) being the most commonly used.[8,9] The only study that has investigated the effects of TrP manual therapy on PFP showed that application of manual compression to TrPs surrounding the knee area reduced symptoms in the short and medium term.[13] However, this study did not include any other intervention for PFP, such as exercise. Dry needling is defined as a "skilled intervention using a thin filiform needle to penetrate the skin that stimulates TrPs, muscle and connective tissue for the management of musculoskeletal pain disorders."[1] There is evidence suggesting that TrP DN may be effective for upper-quadrant pain immediately after treatment and at medium-term follow-up.[22] Similarly, a recent review concluded that TrP DN was effective for lower-quarter pain syndromes in the short term; however, its effects on function have been questioned.[29] Some studies included in this review support the use of TrP DN of the knee musculature for knee osteoarthritis[19] or after knee replacement[28]; however, no study has previously investigated the effect of TrP DN in patients with PFP. Therefore, the objective of this study was to compare the effects of adding TrP DN to a manual therapy and exercise program on pain, function, and disability in people with PFP. We hypothesized that individuals receiving TrP DN combined with manual therapy and exercises would exhibit greater improvements in pain, function, and disability than those receiving only manual therapy and exercises.

METHODS

Study Design

This randomized, parallel-group clinical trial compared 2 treatment protocols for the management of PFP: manual therapy and exercise versus manual therapy and exercise plus TrP DN. The primary outcome was knee pain intensity, assessed with the Knee injury and Osteoarthritis Outcome Score (KOOS) pain subscale, and the secondary outcomes were function, disability, and symptom severity, assessed with the KOOS, the Knee Society Score (KSS), and the International Knee Documentation Committee Subjective Knee Evaluation Form (IKDC), respectively. The current clinical trial was conducted following the CONSORT extension for pragmatic clinical trials.[43] The study was approved by the Institutional Ethical Committee Board of the University of Valencia (Spain) (H1419939990178), and the trial was prospectively registered (www.clinicaltrials.gov; NCT02514005). It should be noted that small changes were made after registration. These are described in detail below. These changes mainly affect the description of inclusion and exclusion criteria, clarification of the inclusion of strengthening exercises in both groups, and the inclusion of knee pain intensity as a secondary outcome.

Participants

Consecutive individuals with knee pain from a local regional hospital (Valencia, Spain) were screened for eligibility criteria. Participants were invited to participate in the trial during a routine medical visit. To be included in the trial, potential participants had to have anterior knee or retropatellar pain of insidious onset for at least 6 months, provoked or associated with at least 2 of the following: prolonged sitting, prolonged kneeling, squatting, running, hopping, or stair walking. In addition, they also had to (1) be between 19 and 60 years of age, (2) have a positive sign on the patellofemoral gliding test, (3) have a negative McMurray test, and (4) have full knee range of motion. They were excluded if they exhibited (1) radiological findings suggesting knee osteoarthritis; (2) a history of knee injury, including ligament sprain or meniscus tear; (3) a history of knee fracture; (4) a history of patellar dislocation; (5) lower extremity surgery; (6) knee joint effusion;

or (7) use of physical therapy for treating knee pain within the previous year. As a modification of the trial registration, because 20% to 25% of subjects attending general medical practice may have a fear of needles,[42] patients with a fear of needles or a coagulation disorder were excluded to avoid potential risk in the needling group. All participants signed an informed-consent form prior to their participation in the study.

Randomization and Blinding

Patients were randomly assigned to receive manual therapy and exercise alone or in combination with TrP DN. Concealed allocation was conducted using a computer-generated randomized table of numbers, created by a statistician who was not otherwise involved in the trial and who did not participate in analysis or interpretation of the results. Individual and sequentially numbered index cards with the random assignment were prepared. The index cards were folded and placed in sealed opaque envelopes. A different researcher opened the envelope and proceeded with treatment allocation. Outcomes were assessed by a clinician blinded to the treatment allocation group.

Interventions

All participants received 3 sessions, once per week, during the treatment period of the study (3 weeks). Each session lasted approximately 30 to 40 minutes (15 to 20 minutes for manual therapy, 10 to 15 minutes for exercises, and 2 to 5 minutes for TrP DN).

Both groups received the same manual therapy and strengthening exercise program from a manual physical therapist who had 15 years of experience in manual therapy interventions and was blinded to the treatment allocation. Because there is a relationship between the biomechanics of the lower extremity and PFP,[31,41] the manual therapy component consisted of a comprehensive thrust and nonthrust manipulation protocol, including lumbopelvic, hip, knee, and ankle manual therapy techniques. All patients received the following interventions at all treatment sessions: lumbopelvic thrust manipulation, anterior-to-posterior nonthrust manipulation of the hip, lateral-to-medial nonthrust manipulation of the knee, proximal tibiofibular joint posterior-to-anterior nonthrust manipulation, and rearfoot distraction thrust manipulation. For each thrust manipulation technique, a maximum of 2 attempts was permitted to achieve cavitation or the audible pop, as perceived by the therapist and/or the patient. In addition, soft tissue interventions included 3 repetitions of 30 seconds of stretching of the hip external rotator muscles, and 5 minutes of fascial manipulation on the patellofemoral region.[30] These techniques are described in detail in **APPENDIX A** (available at www.jospt.org).

There is no consensus on what exercises should be prescribed to patients with PFP; however, strengthening of the quadriceps, hamstrings, and gluteus medius muscles is indicated.[5,24] Therefore, the exercise program consisted of the 4 following exercises: mini-squats, seated knee extensions, lunges, and lateral steps. Each exercise was conducted in 3 sets of 15 repetitions.[23] Each repetition began with the concentric phase and was followed by the eccentric phase of the exercise. The exercise program was taught to the patient by an experienced physical therapist in the first treatment session and monitored in the subsequent 2 sessions (once a week) during the treatment period (3 weeks). Specific details regarding the exercise program are provided in **APPENDIX B** (available at www.jospt.org). Patients were asked to perform the exercise program on an individual basis twice per day for the 3-week duration of the treatment program. No specific progression in exercise load was established.

Patients allocated to the needling group also received TrP DN to active TrPs in the quadriceps muscle, whose referred pain reproduced pain symptoms, from a second physical therapist with 10 years of clinical experience in this therapeutic approach. Patients allocated to this group received the same manual therapy interventions and exercise program instruction in the first session, and TrP DN during the 3 treatment sessions. They also performed the exercise program and were monitored by the clinician. As the vastus medialis and vastus lateralis are the most relevant muscles for neuromuscular control of the knee, TrP DN was applied to these muscles using a pragmatic approach. If multiple active TrPs were found in the same muscle, the clinician selected the most painful for applying the TrP DN procedure. The TrP DN intervention was performed with 0.32 × 40-mm disposable stainless-steel needles (Novasan, SA, Madrid, Spain) inserted into the skin over the TrP. In the current trial, the fast-in and fast-out technique described by Hong[15] was applied. Once the active TrP was located, the overlying skin was cleaned with alcohol. The needle was inserted into the skin at the TrP area until the first local twitch response was obtained. The depth of the needle depended on the muscle and ranged from 15 to 20 mm for the vastus medialis to 30 to 35 mm for the vastus lateralis muscle (**APPENDIX A**). Once the first local twitch response was obtained, the needle was moved up and down (3- to 5-mm vertical motions with no rotations) at approximately 1 Hz until no more local twitch responses were elicited.

Outcome Measures

Clinical records of all participants included questions regarding the location of the symptoms, aggravating and relieving factors, intensity, duration, and previous treatments. Outcomes were assessed at baseline, 15 days (postintervention), and 3 months after the end of therapy (follow-up) by assessors blinded to the treatment allocation of the subjects.

The primary outcome of the current trial was pain severity, as assessed with the pain subscale of the KOOS.[34] Secondary outcomes, including disability and symptoms associated with knee pain, were assessed with the most com-

mon questionnaires used in the literature.[6] The KOOS is a 42-item self-report questionnaire that assesses patients' opinions about their knee and associated problems.[34] All items are rated on a 5-point Likert scale (0-4), and their scores are transformed to a 0-to-100 scale (0, extreme knee problems; 100, no knee problems). The following domains are included in the KOOS: (1) pain frequency and severity during functional activities (9 items); (2) symptoms such as the severity of knee stiffness and the presence of swelling, grinding/clicking, catching, and range-of-motion restriction (7 items); (3) difficulty experienced during daily life activity (17 items); (4) difficulty experienced with sport and/or recreational activities (5 items); and (5) knee-related quality of life (4 items). Each dimension is scored separately as the sum of all corresponding items. A recent meta-analysis found that the KOOS exhibits adequate content validity, internal consistency, test-retest reliability, construct validity, and responsiveness for all subscales.[7] Minimum important change (MIC) values for the KOOS subscales have been reported: pain, 16.7; symptoms, 10.7; function in daily living, 18.4; function in sport and recreation, 12.5; and knee-related quality of life, 15.6 points, respectively.[7]

The KSS evaluates pain and related function in 2 sections: pain and function scores.[17] The pain score uses pain, stability, and range of motion as the main parameters, whereas the functional score utilizes walking distance and stair climbing as the main parameters. Each score is graded from 0 to 100 points, where higher values represent better function or lower pain.[17] The KSS has demonstrated substantial reliability.[25,27] There are no available data related to the MIC of the KSS.

The IKDC is a self-questionnaire designed to detect changes in symptoms, function, and sports activities due to knee pain.[18] It includes 3 domains: (1) symptoms, including pain, stiffness, swelling, locking/catching, and giving way (7 items); (2) sports (1 item) and daily activities (9 items); and (3) current knee function (1 item). The response to each item (which will differ slightly, depending on the item) is scored and summed to give a total score ranging from 0 to 100, where higher scores represent better function, that is, less limitation in daily or sporting activities and the absence of symptoms.[18] The IKDC has shown excellent reliability and validity, with a minimal detectable change of 8.8 to 15.6 points in subjects with knee problems.[14] A more recent study has reported that the IKDC presents excellent test-retest reliability and a minimal detectable change of 8.5% in individuals with PFP.[10]

As a modification of the trial registration, we included the intensity of knee pain as a secondary outcome. Therefore, an 11-point numeric pain-rating scale[21] (0, no pain; 10, maximum pain) was used to assess the patient's current level of knee pain during daily life activities. As no MIC has yet been established for knee-related pain, a change of 2 points or a 30% decrease in pain from baseline can be considered the MIC in individuals with chronic musculoskeletal pain.[11,37]

Treatment Side Effects

Patients were asked to report any adverse event that they experienced during any part of the study. In the current study, an adverse event was defined as sequelae of 1 week in duration with any symptom perceived as distressing and unacceptable to the patient and that required further treatment.[4] Particular attention was given to the presence of post-DN soreness within the group receiving TrP DN. Patients were advised to report any increase in their symptoms after any session.

Sample-Size Determination

The sample-size calculations were based on detecting treatment differences of 16.7 units on the KOOS pain subscale,[7,34] assuming a standard deviation of 17.5, a 2-tailed test, an alpha level of .05, and a desired power (beta) of 90%. The estimated desired sample size was calculated to be at least 25 subjects per group. A dropout percentage of 15% was expected, so 30 patients were included in each group.

Statistical Analysis

Statistical analysis was performed using SPSS software (Version 21.0; IBM Corporation, Armonk, NY) and was conducted according to intention-to-treat analysis for patients in the group to which they were allocated. When any data were missing, the multiple-imputation method was used.[36] The mean, standard deviation, and 95% confidence interval were calculated for each variable. The Kolmogorov-Smirnov test revealed a normal distribution of the variables ($P>.05$). Baseline demographic and clinical variables were compared between both groups using independent Student *t* tests for continuous data and chi-square tests of independence for categorical data. Data analysis included 3-by-2 repeated-measures analyses of covariance, with time (baseline, 15 days postintervention, 3 months postintervention) as the within-subject factor, group (manual therapy and exercise versus manual therapy and exercise plus TrP DN) as the between-subject factor, and adjusted for baseline data for evaluating between-group differences in the outcomes. The main hypothesis of interest was the group-by-time interaction, with a Bonferroni-corrected alpha of .017 (3 time points). To enable comparison of between-group effect sizes, standardized mean differences were calculated by dividing mean score differences between groups by the pooled standard deviation.

RESULTS

Between July 2015 and March 2016, 80 consecutive patients with knee pain were screened for eligibility. Sixty (75%) satisfied the inclusion criteria, agreed to participate, and were randomly allocated into the manual therapy and exercise group (n = 30) or the manual therapy and exercise-plus-TrP DN group (n = 30). Randomization

resulted in similar baseline characteristics for all variables (**TABLE 1**). One patient was lost at 3-month follow-up in each group for personal reasons. The reasons for ineligibility are found in **FIGURE 1**, which provides a flow diagram of patient recruitment and retention. None of the participants in either group reported receiving other interventions during the study, excluding the use of nonsteroidal anti-inflammatory drugs on an as-needed but sporadic basis. Twelve patients assigned to the manual therapy and exercise-plus-TrP DN group (40%) experienced muscle soreness after TrP DN, which resolved spontaneously within 36 to 48 hours. No other adverse events were reported by the participants.

Adjusting for baseline outcomes, the mixed-model analysis of covariance did not reveal significant group-by-time interactions for the primary outcome (KOOS pain subscale: F = 0.253, *P* = .555) or any of the secondary outcomes (knee pain: F = 0.284, *P* = .596; IKDC: F = 0.616, *P* = .436; KOOS symptoms subscale: F = 0.049, *P* = .825; KOOS function in daily living subscale: F = 0.585, *P* = .448; KOOS function in sport and recreation subscale: F = 0.218, *P* = .642; KOOS knee-related quality of life subscale: F = 0.748, *P* = .391; KSS pain subscale: F = 0.217, *P* = .805; KSS function subscale: F = 0.526, *P* = .592). There was a main effect for time for all outcomes (all, *P*<.001), showing that both groups exhibited similar changes in pain intensity (**FIGURE 2**), function, and disability at all follow-up periods (**TABLES 2** and **3**). Both groups exhibited moderate-to-large within-group effect sizes at both follow-up periods (standardized mean differences from 0.6 to 1.1), but the KOOS function in sport and recreation subscale was the only primary or secondary outcome measure to exceed the predetermined MIC.

TABLE 1 Participant Characteristics at Baseline by Treatment Assignment*

	Manual Therapy (n = 30)	Manual Therapy Plus TrP DN (n = 30)
Sex, n		
Male	15	16
Female	15	14
Age, y	29.7 ± 9.5	29.2 ± 10.5
Weight, kg	68.9 ± 13.2	72.5 ± 14.3
Height, m	1.7 ± 0.1	1.7 ± 0.1
Time with pain, y	9.5 ± 5.8	8.5 ± 6.3
Side of knee pain, n (%)		
Right knee	16 (53)	15 (50)
Left knee	14 (47)	15 (50)
Mean intensity of knee pain (NPRS, 0-10)	5.2 ± 2.7	5.2 ± 2.2
IKDC (0-100)	66.7 ± 13.4	64.2 ± 16.7
KOOS subscales		
Pain (0-100)	72.3± 10.9	71.4 ± 12.9
Symptoms (0-100)	78.6 ± 9.7	77.5 ± 16.0
Function in daily living (0-100)	80.6 ± 11.4	79.8 ± 15.1
Function in sport and recreation (0-100)	63.4 ± 19.6	61.2 ± 18.2
Knee-related quality of life (0-100)	61.4 ± 18.2	62.7 ± 18.6
KSS subscales		
Pain (0-100)	66.3 ± 12.7	64.6 ± 10.8
Function (0-100)	89.0 ± 12.1	88.0 ± 12.1

Abbreviations: DN, dry needling; IKDC, International Knee Documentation Committee Subjective Knee Evaluation Form; KOOS, Knee injury and Osteoarthritis Outcome Score; KSS, Knee Society Score; NPRS, numeric pain-rating scale; TrP, trigger point.
**Values are mean ± SD unless otherwise indicated.*

DISCUSSION

This randomized clinical trial found that the inclusion of TrP DN in a multimodal manual therapy and strengthening exercise program did not result in improved outcomes in individuals with PFP immediately after treatment and at 3-month follow-up. While both groups achieved similar and significant improvements from baseline to both follow-up periods, we cannot confirm the clinical relevance of these results because changes in the main outcome, pain severity (KOOS pain subscale), and the remaining secondary outcomes did not exceed their respective MIC values. Further, we cannot be certain whether changes were the result of the interventions or simply due to the passage of time, because we did not include a control group, although this would have been unlikely due to the chronicity of the symptoms.

Current evidence and clinical guidelines recommend the use of multimodal intervention programs consisting of strengthening exercises, patient education, and activity modification for the management of PFP.[2,5,23,24,40] Those recommendations do not identify manual therapy and/or TrP DN as potentially effective interventions, not because there is scientific evidence against these approaches, but because there is a lack of studies performed examining these 2 interventions. The current trial is the first to integrate manual therapy interventions and a strengthening exercise program in people with PFP. The results demonstrated that both groups, regardless of the application of TrP DN, exhibited positive outcomes in pain and function, which supports the notion that the combination of manual therapy and strengthening exercises may be effective for this population. Nevertheless, we should recognize that the standardized manual therapy protocol used in

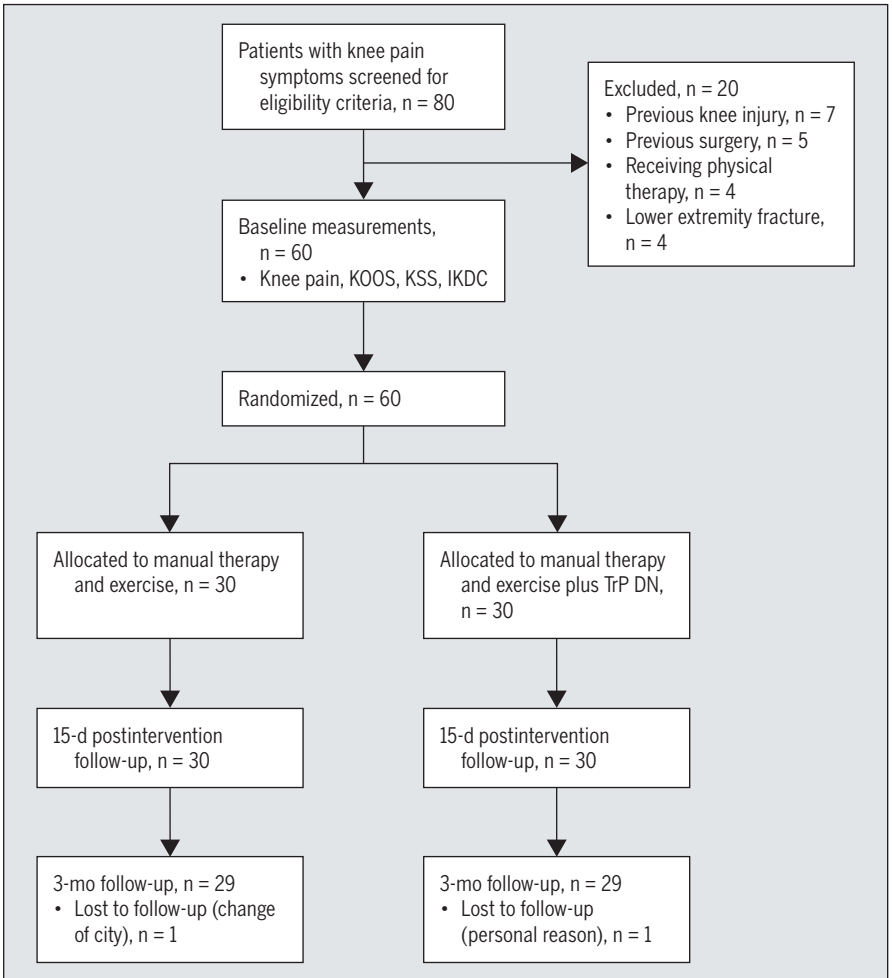

FIGURE 1. Flow diagram of patients throughout the course of the study. Abbreviations: DN, dry needling; IKDC, International Knee Documentation Committee Subjective Knee Evaluation Form; KOOS, Knee injury and Osteoarthritis Outcome Score; KSS, Knee Society Score; TrP, trigger point.

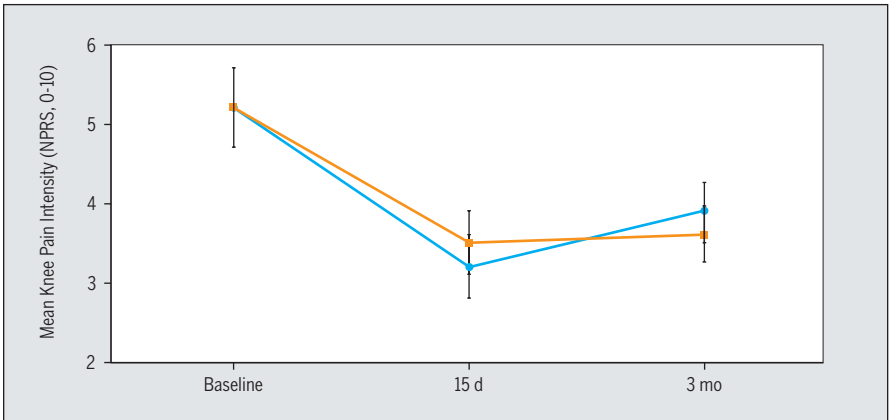

FIGURE 2. Evolution of knee pain intensity throughout the course of the study, stratified by randomized treatment assignment. The blue line represents manual therapy and exercises, and the orange line represents manual therapy and exercise plus trigger point dry needling. Data are means and standard errors. Abbreviation: NPRS, numeric pain-rating scale.

the present study was not associated with the presence or absence of impairments in the lumbopelvic, hip, knee, or ankle areas in all patients. As patients with PFP represent a heterogeneous population, future studies should consider the application of manual therapy interventions after a clinical examination of the patients.

Clinical reasoning for the application of TrP DN in PFP is based on the hypothesis that TrPs induce motor control disturbances,[26] accelerated muscle fatigability,[12] and increased motor activation[16] in the affected and related muscles. As mechanical (ie, disruption of the contraction knot or increase of sarcomere length) and neurophysiological (ie, decrease of peripheral inputs and activation of central pain pathways) mechanisms are receptive to TrP DN,[3,11] we hypothesized that the mechanical stimulus exerted by the needle into the knee musculature would be able to increase the effectiveness of the strengthening exercise program and that, therefore, patients would potentially achieve better pain and functional outcomes. However, the results of this clinical trial did not confirm that hypothesis. One possible explanation for this may be that subjects allocated to the TrP DN group received 3 sessions, based on the authors' clinical experience, as no current scientific data exist on the adequate frequency and dose of needling. We do not know if a greater number of TrP DN sessions would have resulted in between-group differences. Further, TrP DN was only applied on active TrPs in the vastus medialis and lateralis muscles; it is possible that other muscles, such as the rectus femoris, hamstring, or gastrocnemius, could also exhibit active TrPs and, therefore, should potentially also be treated with TrP DN.

The results of this trial should be considered according to some potential limitations. First, we recruited patients from a single hospital, which may decrease the generalization of our results. Multicenter studies controlling for site and clinician effects (cluster effects) might enhance the generalizability of the results. Second,

TABLE 2 KOOS Scores at Baseline and at 15 Days and 3 Months After Treatment, as Well as Within-Group and Between-Group Mean Change Scores, by Randomized Treatment Assignment*

Outcome/Time	Manual Therapy	Manual Therapy Plus TrP DN	Between-Group Change Score
KOOS pain (0-100)			
Baseline	72.3 ± 10.9 (67.8, 76.9)	71.4 ± 12.9 (67.0, 75.8)	
15 d	87.5 ± 8.4 (83.7, 91.3)	83.7 ± 11.1 (80.0, 87.4)	
Within-group change: baseline to 15 d	15.2 (10.1, 20.3)	12.3 (6.7, 17.9)	−2.9 (−5.8, 0.0)
3 mo	85.8 ± 11.0 (80.4, 91.2)	82.7 ± 16.8 (77.4, 88.0)	
Within-group change: baseline to 3 mo	13.5 (6.8, 20.2)	11.3 (5.4, 17.2)	−2.1 (−4.6, 0.4)
KOOS symptoms (0-100)			
Baseline	78.6 ± 9.7 (73.6, 83.6)	77.5 ± 16.0 (72.5, 82.5)	
15 d	88.3 ± 8.3 (84.0, 92.6)	86.5 ± 13.3 (82.3, 90.7)	
Within-group change: baseline to 15 d	9.7 (5.4, 14.0)	9.0 (4.3, 13.7)	−0.7 (−2.4, 1.0)
3 mo	88.7 ± 10.6 (83.6, 93.8)	86.8 ± 15.5 (81.9, 91.7)	
Within-group change: baseline to 3 mo	10.1 (5.0, 15.2)	9.3 (4.3, 14.3)	−0.8 (−1.9, 0.3)
KOOS function in daily living (0-100)			
Baseline	80.6 ± 11.4 (75.6, 85.6)	79.8 ± 15.1 (74.8, 84.8)	
15 d	91.5 ± 7.0 (88.3, 94.7)	89.8 ± 9.6 (86.6, 93.1)	
Within-group change: baseline to 15 d	10.9 (7.1, 14.7)	10.0 (5.5, 14.5)	−0.9 (−1.8, 0.0)
3 mo	92.6 ± 6.9 (88.9, 96.3)	89.0 ± 12.0 (85.4, 92.6)	
Within-group change: baseline to 3 mo	12.0 (7.5, 16.5)	9.2 (4.0, 14.4)	−2.8 (−5.7, 0.1)
KOOS function in sport and recreation (0-100)			
Baseline	63.4 ± 19.6 (56.7, 71.2)	61.2 ± 18.2 (54.2, 68.2)	
15 d	79.8 ± 17.2 (72.9, 86.7)	77.8 ± 25.9 (70.9, 84.7)	
Within-group change: baseline to 15 d	16.4 (10.5, 22.3)	16.6 (8.7, 24.5)	0.2 (−1.0, 1.4)
3 mo	80.2 ± 13.6 (72.3, 88.1)	74.8 ± 3.9 (67.1, 82.5)	
Within-group change: baseline to 3 mo	16.8 (9.0, 24.6)	13.6 (7.1, 20.1)	−3.2 (−6.4, 0.0)
KOOS knee-related quality of life (0-100)			
Baseline	61.4 ± 18.2 (54.7, 68.1)	62.7 ± 17.6 (56.0, 69.4)	
15 d	70.5 ± 22.3 (62.1, 78.9)	72.8 ± 22.3 (64.5, 81.1)	
Within-group change: baseline to 15 d	9.1 (3.8, 14.4)	10.1 (2.6, 17.6)	1.2 (−1.0, 3.4)
3 mo	72.8 ± 19.4 (65.3, 80.3)	77.6 ± 20.1 (70.2, 85.1)	
Within-group change: baseline to 3 mo	11.4 (5.6, 17.2)	14.9 (8.7, 21.1)	3.5 (−0.5, 7.5)

Abbreviations: DN, dry needling; KOOS, Knee injury and Osteoarthritis Outcome Score; TrP, trigger point.
**Outcome values at each time point are mean ± SD (95% confidence interval) and values for change scores are mean (95% confidence interval).*

we only included a follow-up period of 3 months, so we do not know whether long-term evolution of the patients would exhibit the same results. Third, because we did not include a no-intervention control group, we cannot be sure that the observed improvements are due to the natural history of the condition, although this is unlikely. Fourth, we applied a treatment period of 3 weeks. It is possible that more sessions of manual therapy and exercise would lead to better outcomes. Additionally, it should be considered that the exercise program did not progress in load or repetitions during the treatment period. Similarly, adherence to the exercise program was not strictly tracked. These factors may have limited the benefits of the exercise program in the current trial. In fact, the limited clinical effect considered in this clinical trial was based on published pooled data[7]; it is possible that the specific MIC for patients with PFP would be smaller than the MIC considered in our trial, but no available data exist for this specific population. Fifth, we did not include a sham needling technique, so blinding patients was not possible. Finally, it is possible that subgroups of individuals with PFP who will benefit from TrP DN exist and should be identified.[20]

CONCLUSION

The current study indicates that the inclusion of TrP DN in a multimodal manual therapy and strengthening exercises program did not result in better outcomes for pain and

TABLE 3 Knee Pain Intensity, the KSS, and the IKDC at Baseline and at 15 Days and 3 Months After Treatment, as Well as Within-Group and Between-Group Mean Change Scores, by Randomized Treatment Assignment*

Outcome/Time	Manual Therapy	Manual Therapy Plus TrP DN	Between-Group Change Score
Knee pain intensity (NPRS, 0-10)			
Baseline	5.2 ± 2.7 (4.3, 6.1)	5.2 ± 2.2 (4.4, 6.0)	
15 d	3.2 ± 2.0 (2.4, 4.0)	3.5 ± 2.2 (2.7, 4.3)	
Within-group change: baseline to 15 d	−2.0 (−3.2, −0.8)	−1.7 (−3.0, −0.4)	−0.3 (−0.9, 0.3)
3 mo	3.9 ± 2.3 (3.0, 4.8)	3.6 ± 2.0 (2.7, 4.5)	
Within-group change: baseline to 3 mo	−1.3 (−2.3, −0.3)	−1.6 (−3.0, −0.2)	0.3 (−0.2, 0.8)
IKDC (0-100)			
Baseline	66.7 ± 13.4 (61.5, 72.9)	64.2 ± 16.7 (58.6, 69.9)	
15 d	78.2 ± 11.9 (73.0, 83.4)	78.6 ± 15.5 (73.4, 83.8)	
Within-group change: baseline to 15 d	11.5 (6.3, 16.7)	14.4 (8.5, 20.3)	2.9 (0.0, 5.8)
3 mo	79.2 ± 12.4 (73.7, 84.7)	79.0 ± 16.2 (73.6, 84.4)	
Within-group change: baseline to 3 mo	12.5 (7.0, 18.0)	14.8 (10.1, 19.5)	2.3 (−0.1, 4.7)
KSS pain subscale (0-100)			
Baseline	66.3 ± 12.7 (61.6, 70.5)	64.6 ± 10.8 (60.2, 67.0)	
15 d	72.4 ± 8.1 (69.4, 75.4)	72.6 ± 8.0 (69.6, 75.6)	
Within-group change: baseline to 15 d	6.1 (2.0, 10.2)	8.0 (4.2, 11.8)	1.9 (−2.0, 5.8)
3 mo	74.5 ± 4.4 (71.8, 77.2)	73.0 ± 8.9 (70.4, 75.6)	
Within-group change: baseline to 3 mo	8.2 (3.5, 12.9)	8.4 (4.1, 12.7)	0.2 (−0.1, 0.5)
KSS function subscale (0-100)			
Baseline	89.0 ± 12.1 (84.7, 93.3)	88.0 ± 12.1 (83.4, 92.6)	
15 d	95.0 ± 7.9 (90.2, 99.8)	91.7 ± 15.8 (87.0, 96.4)	
Within-group change: baseline to 15 d	6.0 (1.0, 11.0)	3.7 (2.9, 4.5)	−2.3 (−6.0, 1.4)
3 mo	92.9 ± 9.8 (89.2, 96.6)	93.4 ± 9.4 (89.9, 96.9)	
Within-group change: baseline to 3 mo	3.9 (2.7, 5.1)	5.4 (3.6, 7.2)	1.5 (0.0, 3.0)

Abbreviations: DN, dry needling; IKDC, International Knee Documentation Committee Subjective Knee Evaluation Form; KSS, Knee Society Score; NPRS, numeric pain-rating scale; TrP, trigger point.
**Outcome values at each time point are mean ± SD (95% confidence interval) and values for change scores are mean (95% confidence interval).*

disability in individuals with PFP immediately after treatment and at 3-month follow-up. Both groups achieved similar improvements in pain and function, suggesting that the application of manual therapy and strengthening exercises may be effective for individuals with PFP, but this requires further investigation. ◉

KEY POINTS

FINDINGS: The addition of trigger point (TrP) dry needling (DN) to a manual therapy and exercise program for patients with patellofemoral pain did not provide additional benefits compared with manual therapy and exercise alone.

IMPLICATIONS: This study provides evidence that 3 sessions of TrP DN directed at the vastus medialis and lateralis muscles, in addition to manual therapy and exercise, did not result in superior outcomes over manual therapy and exercise alone. Changes were observed in all primary and secondary outcomes; however, only 1 secondary outcome (Knee injury and Osteoarthritis Outcome Score function in sport and recreation subscale) exceeded the minimal important change. It is not known whether additional sessions or targeting other knee muscles would have changed the outcome. Future studies are warranted to investigate this.

CAUTION: The generalizability of the results may be limited, as we only recruited patients from a single hospital, only 3 (30-40 minutes) intervention sessions were provided, and the follow-up period was only 3 months. Additionally, there was no control group, so we cannot be certain whether the within-group changes were the result of the treatments delivered or simply the passage of time.

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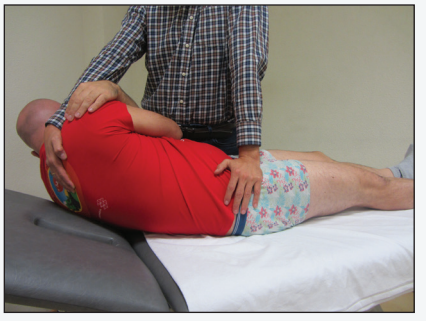
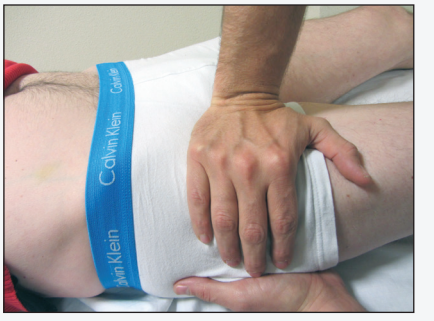
APPENDIX A

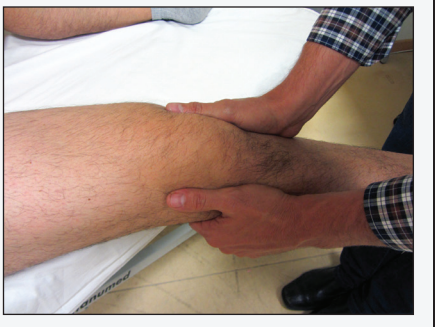
DESCRIPTION OF MANUAL THERAPY INTERVENTIONS



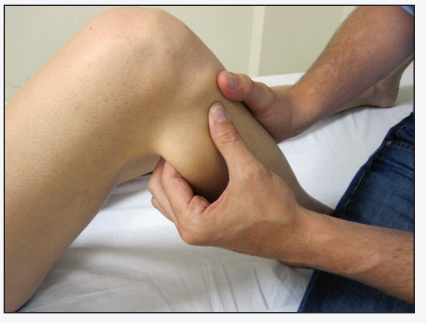
Technique: lumbopelvic thrust manipulation applied on the right side
Description: the technique is performed with the patient supine. The therapist stands on the side opposite of that to be manipulated. The patient is passively moved into side bending toward the side to be manipulated. The patient crosses his or her arms over the chest. The therapist passively rotates the patient, and then delivers a high-velocity, low-amplitude thrust to the anterior superior iliac spine in a posterior and inferior direction



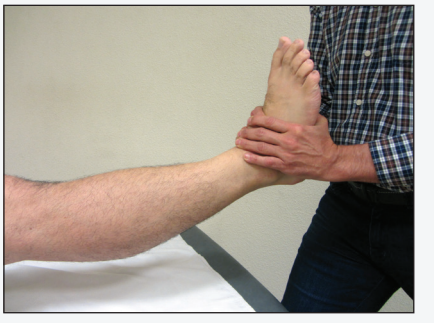
Technique: anterior-to-posterior nonthrust manipulation of the hip
Description: the technique is performed with the patient supine. The therapist stands on the same side as that to be mobilized. The therapist holds the anterior and posterior parts of the hip and then performs an anterior-to-posterior mobilization of the femur on the acetabulum



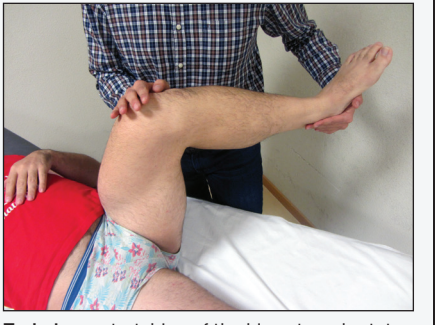
Technique: lateral-to-medial nonthrust manipulation of the knee
Description: the patient is supine, near the edge of the table, with the leg to be treated off the edge of the table. The clinician places the patient's leg between the knees and holds the treated knee at the joint line with both hands in slight flexion (around 10°). Lateral-to-medial glides (varus-to-valgus force) are added



Technique: proximal tibiofibular joint posterior-to-anterior nonthrust manipulation
Description: the patient is supine with the knee flexed at 90° and the feet over the table. The clinician grasps the patient's fibular head and uses the opposite hand to stabilize the contra-lateral side of the knee. Posterior-to-anterior forces are applied over the fibular head

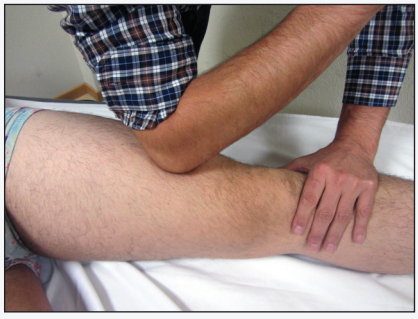


Technique: rearfoot distraction thrust manipulation
Description: the patient is supine, with the ankle off the treatment table. The clinician grasps the patient's ankle/foot, with the fingers interlaced around the dorsum of the foot and thumbs on the plantar aspect. The clinician induces pronation and slight dorsiflexion of the foot, induces a "slack" in a caudal/distraction direction, and applies a high-velocity, low-amplitude force in a caudal direction

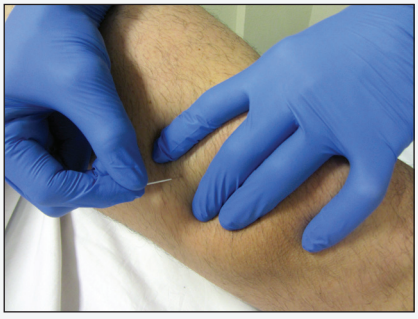


Technique: stretching of the hip external rotator muscles
Description: the patient is supine, with the hip and knee flexed to 90° and neutral abduction/adduction. The cephalic hand of the clinician is placed on the lateral part of the knee, whereas the caudal hand grasps the ankle. The hip is placed in internal rotation until the barrier is reached. This position is maintained for 30 seconds

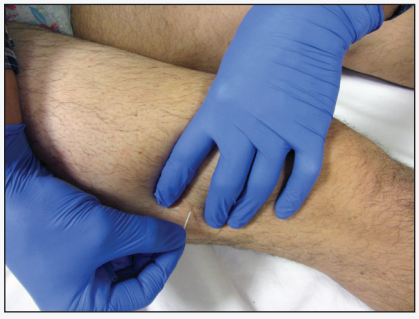
APPENDIX A



Technique: fascial manipulation on the patellofemoral region
Description: the patient lies supine, with the lower extremity over the table. The therapist places the elbow over the anterior distal part of the rectus femoris and applies a longitudinal stroke distally to the knee. A total of 8 to 10 strokes are applied for 5 minutes



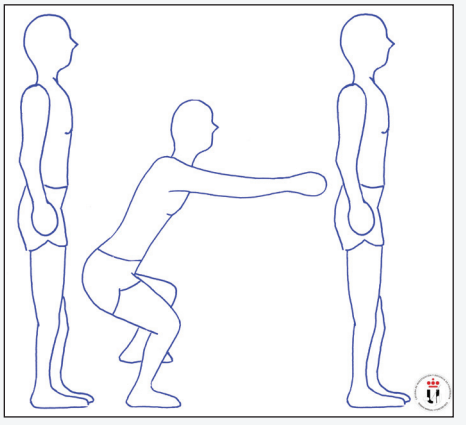
Technique: dry needling on active trigger points in the vastus medialis muscle
Description: with the patient supine, the needle is inserted perpendicular to the muscle surface directly into the trigger point, as identified by flat palpation



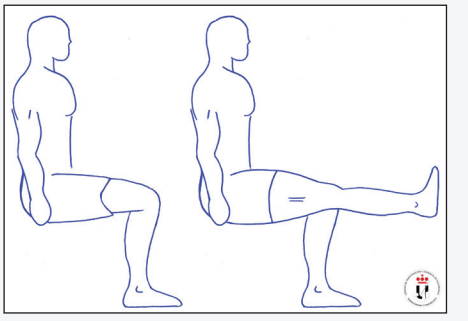
Technique: dry needling on active trigger points in the vastus lateralis muscle
Description: with the patient supine, the needle is inserted perpendicular to the muscle surface directly into the trigger point, as identified by flat palpation

APPENDIX B

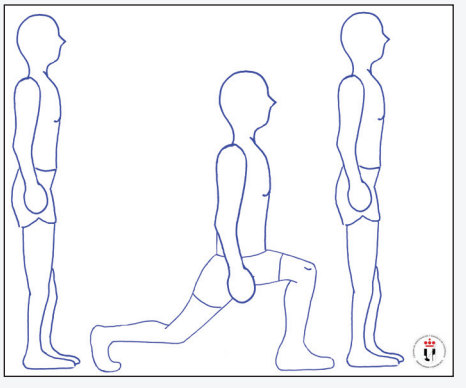
GUIDELINE FOR STRENGTHENING EXERCISES



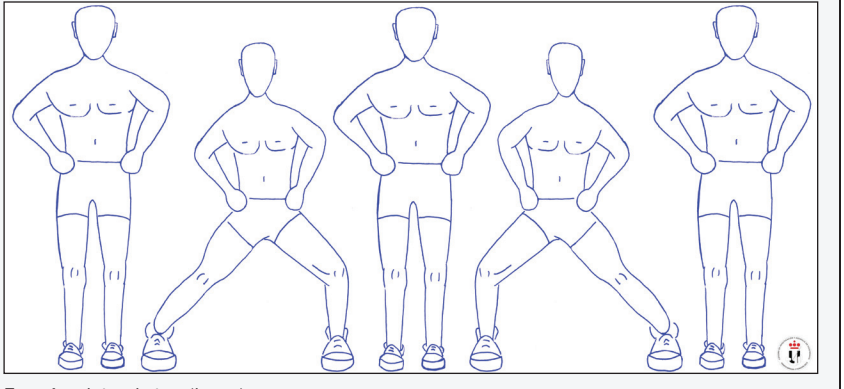
Exercise: mini-squats
Description: the patient stands in an upright position. From that position, he or she performs a squat to approximately 90° of knee flexion while maintaining the knee behind the toes, and then returns to the initial upright position



Exercise: seated knee extension
Description: from a seated position, the patient performs a long-arc quad from 90° of knee flexion to complete extension



Exercise: front lunges
Description: from an upright standing position, the patient performs a lunge, leading with the involved lower extremity while maintaining the knee behind the toes



Exercise: lateral step (lunge)
Description: from an upright standing position, the patient performs a lateral lunge, leading with the involved lower extremity while maintaining the knee behind the toes, and then returns to the initial upright position. The exercise is repeated to both sides