Trials

STUDY PROTOCOL

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Effectiveness of combining a proximal strengthening exercise program and foot orthosis on pain and performance among women with patellofemoral pain syndrome and a pronated foot: study protocol for a randomized clinical trial

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Abstract

Backgrounds Patellofemoral pain syndrome (PFPS) is one of the most frequent musculoskeletal disorders. Flat-foot and weakness of the hip and core muscles have been introduced as distal and proximal factors associated with this syndrome, respectively. The aim of this study is to investigate the effectiveness of a combination of a proximal strengthening exercise (PSE) program and a foot orthosis (PSEFO) on pain and function in women with PFPS and a pronated foot (PF).

Methods In this randomized clinical trial (RCT), 117 female patients aged 18–40 years will be recruited through online announcements on cyberspace as well as those installed in rehabilitation and healthcare centers and gyms. Considering the inclusion criteria, the participants will be randomized into three groups of 39 (group I: practicing PSEs and wearing PSEFO; group II: practicing only PSEs; and group III: control group [CG]). Randomization will be conducted using the sequentially numbered, opaque, sealed envelope (SNOSE) technique. The intervention groups (groups I and II) will perform PSEs at gyms for 2 months at the rate of three sessions per week (each session lasting 45–60 min) under the guidance of a trainer. In addition to the PSE, group I participants will receive prefabricated polyurethane FOs with an 8° varus wedge. They will be asked to wear the orthosis for 2 h a day and then slowly increase their wearing time to a full day. The CG participants will follow their routine lives during this study. Pain, as the primary outcome, will be measured by the visual analog scale before and after the 8-week intervention program. Additionally, quality of life, disability, Q angle, performance, and dynamic balance will be evaluated as secondary outcomes using the 36-item Short Form Health Survey, the Kujala score, a goniometer, the step-down test, the unilateral squat test, the anteromedial lunge test, the bilateral squat test, and the Y-balance test, respectively.

Discussion In this RCT, the effectiveness of PSEs focusing on the hip and core muscles, with and without FOs, on pain and performance among women with PFPS and PF will be investigated and compared.

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Trial registration The present study was approved by the Research Ethics Committee of Guilan University of Medical Sciences, Rasht, Iran (code: IR.GUILAN.REC.1402.021) and registered on the Iranian Registry of Clinical Trials (IRCT, code: IRCT20230604058380N1) at 28 July 2023.

Keywords Anterior knee pain syndrome, Flat foot, Insole, Balance, Core, Hip, Q angle, Disability, Quality of life

Background {6a}

Patellofemoral pain syndrome (PFPS), one of the most common musculoskeletal disorders (MSDs), is typically characterized by dull pain in the front and center of the knee and behind the patella [1].

Of note, no symptoms of other knee injuries are observed in this condition. It is usually aggravated in the course of weight-bearing activities involving knee flexion, in which augmented loads are imposed on the patellofemoral joint (PFJ) [1, 2]. Currently, PFPS represents nearly 25–40% of all knee problems and 25% of the injuries diagnosed in sports medicine clinics. According to annual statistics, this syndrome now affects 23% of the general adult population, and its prevalence rate among female cases is higher than that among males [1, 3, 4].

Pain and decreased quality of life (QoL) triggered by the low participation levels in many daily activities, moderated physical activities and sports ability among the affected cases, declines in walking mechanics, varying movement patterns due to biomechanical changes and hip, knee, and ankle susceptibility, muscle imbalance, loss of muscle strength in thighs, a higher risk of anterior cruciate ligament injuries, an increased chance of joint arthritis, extreme anxiety, fear of movement or kinesiophobia, poor postural control, and unsteadiness during routine activities have been all been acknowledged as potential complications and negative consequences of PFPS [1, 5–10]. If PFPS is not effectively treated in the early stages, it may eventually convert into irreversible PFJ arthritis, and even raise the need for treatments with invasive procedures, such as surgeries and joint replacement, which will compound treatment difficulty, lengthen the cycle of treatment, and bring about significant economic losses. Therefore, early treatment using conservative methods, such as therapeutic exercises and the use of foot orthoses (FOs), is of paramount importance [11].

Although the etiology of PFPS remains unclear, previous studies have reflected on the distal, proximal, and local factors contributing to PFPS. Among the local factors typically related to the PFJ and its tissues are changes in the activity of the vastus medialis oblique (VMO) and vastus lateralis [12, 13]. Proximal factors leading to PFPS include weakness in the hip abductor and external rotator muscles and the absence of trunk stability, resulting in adduction and internal rotation of the thighs, respectively, and valgus knee and pressure due to asymmetric loading on the surfaces of the patella and femoral trochlear groove, which is a factor contributing to destructive changes in PFJ [14]. The decrease in core stability following the changing movement patterns of the muscles can thus result in excessive trunk movements in different planes and consequently influence the pelvis position and lower limb mechanics. A decline in the precontraction of trunk stabilizers may lead to excessive displacement of the trunk in the frontal plane and increased loads on the knee. Moreover, it may induce knee disruption and injury due to a lack of mass control [15].

One of the distal factors inducing PFPS is excessive pronation of the subtalar joint, which may bring about internal rotation and tibial abduction, followed by hip adduction and an increase in the Q angle and valgus knee, thereby exerting significantly more pressure on the PFJ [16, 17]. A rise in rearfoot eversion during heel contact with the ground while walking is also among the distal factors that contribute to PFPS [15]. Previous studies have considered the use of FOs to be an effective element in the treatment of patients with PFPS and pronated foot (PF) to adjust distal factors [18]. The application of FOs and assistive devices has also been recommended in previous studies, and their effectiveness has been highlighted [18, 19]. It appears that FOs can reduce PF, modify PFJ movement patterns, and effectively improve the compensatory internal rotation of the lower limb. Moreover, FOs help increase lower limb muscle activity and prevent excessive outward movement of the patella by strengthening the VMO and gluteus maximus [7]. Either by supporting the medial longitudinal arch of the foot or by raising the sole edge, FOs control foot eversion and affect PFJ movements through a chain effect [20–25].

In this regard, therapeutic exercises have been presented as an integral part of PFPS rehabilitation programs, which aid patients through biomechanical and psychological effects and are typically recommended to reduce pain and improve performance in the medium or long term [1]. As established in previous research, strengthening exercises boost performance and ease pain in PFPS patients. However, it has thus far been challenging to find which group of muscles is more effective for this purpose, thereby demanding further studies in this field [26]. It has been assumed that hip and core proximal strengthening exercises (PSEs), compared to single-joint

exercises, are much more effective in recovering patients with PFPS. Such exercises can increase hip stability and neuromuscular control in the kinetic chain [22, 23]. Moreover, hip and core PSEs relieve pain in patients with PFPS through core strengthening and stabilization [27]. Considering the effectiveness of PSEs and the use of FO in treating people with PFPS, this study aims to investigate the simultaneous effectiveness of both interventions in women with PFPS and PF, as it is likely to be more effective in improving them.

Objectives {7}

This primary study aims to explore the effects of combining a hip and core PSE program and FO (PSEFO) on pain and performance among women with PFPS and PF. Secondary objectives include evaluating changes in disability, dynamic balance, knee joint function, Q angle, and quality of life between groups after the intervention. Our hypothesis is that both interventions are effective for PFPS patients, but the effects of PSEs and FOs may be greater.

Trial design {8}

This is a prospective, single-center, single-blinded, parallel-arm, superiority randomized controlled trial with a 1:1 allocation that is currently being conducted at Arak University, Iran. In total, 117 female participants meeting the inclusion criteria will be selected and randomized into three groups of 39. Group I will practice PSEFO, group II will do only PSEs, and group III will be the control group (CG). Measurements will be taken before and after the interventions.

Materials and methods

Study setting {9}

The study will be conducted at a sport rehabilitation lab at Arak University, located in Arak, Iran. This lab will serve as the primary site for recruiting participants and implementing the clinical trial. The expected length of the study is 2 years, which includes the enrollment of participants, the implementation of the intervention, assessments, and the analysis of data.

Eligibility criteria {10}

In this study, women with PFPS will be informed about the present study through online announcements on cyberspace as well as those installed in rehabilitation and healthcare centers and gyms. Then, eligible people will be referred to the healthcare center and evaluated in line with the inclusion and exclusion criteria. Finally, the study participants will be recruited. From August 21, 2023, women with PFPS were informed about the present study through online notices in cyberspace and those posted in rehabilitation and healthcare centers and gyms. We are currently in the phase of recruiting participants according to the inclusion and exclusion criteria of the study.

The inclusion criteria are as follows:

1. Women aged 18–40 years with the following attributes:
2. Knee pain for at least 6 weeks or more before the study
3. Anterior knee pain of non-traumatic origin
4. PF with a minimum navicular drop greater than 9 mm
5. Foot posture index greater than 6
6. Severe pain during at least two activities, such as running, jumping, walking on hills or stairs, sitting for a long time, kneeling, and squatting
7. A knee pain distribution score >3 and ≤ 7 based on the visual analog scale (VAS; 0: no pain and 10: the worst imaginable pain) in the week before the onset of the study
8. Positive Clark's sign

The exclusion criteria are as follows:

1. Other forms of anterior knee pain
    a. Osgood-Schlatter disease
    b. Plica syndrome
    c. Sinding-Larsen-Johansson syndrome
2. Patellar instability
3. Knee joint effusion
4. History of injuries and spine and lower limb surgeries
5. Meniscus and knee ligament or tendon injuries
6. Foot problems that may prevent the use of FOs
7. Referred pain to the pelvis and lumbar spine
8. Miss the exercises in two consecutive or three non-consecutive sessions

Navicular drop test (NDT)

PF will be examined using NDT. The patient will first be asked to sit on a chair with no weight bearing, bare feet, and 90° hip and knee flexion. The navicular tuberosity will then be found and marked regarding the internal and external rotations of the sole, touching the most prominent bony protrusion in the inner part of the foot. Then, the distance between the protrusion of the navicular bone and the ground surface in the sitting position will be measured. Next, the patient will be placed in a standing (weight-bearing) position, and the distance between the navicular bone protrusion and the ground will be

measured once again. If the difference between the two recorded values is over 9 mm, the sole of a person's foot will be considered flat [18–24].

Foot posture index (FPI-6)

Relaxed foot posture will be assessed using the FPI-6. FPI-6 consists of six criteria: (i) palpation of the talar head, (ii) superior and inferior curvature of the lateral malleolus, (iii) inversion/abduction of the calcaneus, (iv) protrusion of the talonavicular joint area, (v) congruence of the medial longitudinal arch, and (vi) abduction/adduction of the forefoot into the hindfoot [18]. Each criterion is examined and scored on a 5-point scale from −2 to +2 and summed to classify the foot as severely pronated, pronated, normal, supinated, or severely supinated [18, 28]. The FPI-6 is a robust clinical instrument for which high intra-rater reliability has been reported [28].

Who will take informed consent? {26a}

All eligible individuals will be invited to take part in this study. Two trained research staff members will hold face-to-face sessions with potential participants, during which they will deliver detailed explanations about the study's goals, processes, potential risks, and participants' rights. They will respond to any questions from participants or representatives and ensure a full understanding of the information provided. Before enrollment, informed consent will be secured through signed written consent forms from either the participant or their authorized representative.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

It is important to note that the trial does not include the collection of biological specimens. However, the consent form asks participants to allow the continued use of their data even if they decide to withdraw from the trial. Additionally, participants are asked to give permission for the research team to share relevant data with the appropriate regulatory authorities.

Interventions

Exercise protocol {11a}

First, the participants in the intervention groups will be warmed up for 10 min and then asked to perform the PSEs. The exercise protocol will be performed in three phases for 8 weeks. The first-phase exercises will be performed for 2 weeks to enhance voluntary control of the core muscles of the body and the hip. The exercises in the second and third phases will be performed to restore contraction responses to perturbations and restore pattern-generated movement, respectively. The exercises will be done for 3 weeks for each phase. The participants will attend three sessions a week, with each session lasting 45–60 min, and perform the exercises under the guidance of a trainer. Finally, a cooldown will be done for 5 min.

Table 1 presents the exercise protocol. The progress in the dynamic exercises will be applied in each phase as follows: 10×3 reps, 15×3 reps, and 20×3 reps in the first, second, and third phases, respectively. The isometric exercises will be further employed in the first phase with 15×2 reps with a 10-s break. Progress in each phase will be determined by increasing resistance (via a Thera-Band) and the ability to maintain proper alignment during standing exercises [29, 30].

FOs {11a}

Prefabricated FOs (Medial Wedge Insole, Teb & Sanat Co., Tehran, Iran) made up of polyurethane with internal longitudinal and transverse arch support and an 8° varus wedge will be given to the group I participants practicing

Table 1 Proximal stability program for PFPS

Phase 1 (weeks 1–2)	Phase 2 (weeks 3–5)	Phase 3 (weeks 3–5)
1. Abdominal draw-in exercises 2. Bridge 3. Side-lying clamshells 4. Side-lying straight-leg raises 5. Supine arm/leg extensions 6. Quadruped arm/leg extensions 7. Isometric single-legged stance (SLS) 8. Hamstring stretch 9. Quadriceps stretch 10. Calf stretch	1. Isometric SLS with hip abduction 2. Unilateral supine bridge 3. Side lying clam with resistance 4. SLS quick kicks 5. Prone plank exercise 6. Single leg deadlift 7. Bilateral mini squat 8. Hamstring stretch 9. Quadriceps stretch 10. Calf stretch 11. Iliotibial band "pretzel" stretch	1. "Monster walks" 2. Forward lunge (progression bridge) 3. Side lunge (progression clam resistance) 4. SLS with sport-specific upper body movement (progression balance) 5. Mini squat progression (mini lunge, SLS, step down) 6. Rear cross-over lunges (progression single deadlift) 7. Hamstring stretch 8. Quadriceps stretch 9. Calf stretch 10. Iliotibial band "pretzel" stretch
Goal: improve volitional control of the hip and core muscles	Goal: restore reflex contractions to perturbations	Goal: restore pattern generated movements

PSEFO. Participants will be asked to wear the orthosis for 2 h a day and then slowly increase their wearing time to a full day [19]. Before wearing the FOs, the patients will perform an agreed-upon functional activity, such as climbing stairs. Then, a standard method will be applied to use the FOs. The participants will subsequently perform the desired activity after using the FOs. If they feel comfortable with the FOs while climbing the stairs, they will be allowed to wear them; otherwise, three attempts will be made to change the FOs and create comfort. If patients feel unsatisfied with using FOs, even after three attempts to reach comfort, they will be excluded from this study. There will be much effort to change the FOs and comfort the participants. To maximize the sense of comfort with the FOs, changes will be made in thermal molding, medial wedges to the rearfoot (2–4°) and/or forefoot (4–6°), and/or heel raise (a height of 4, 6, or 8 mm). Once the patients feel comfortable with the FOs, they will be asked to do a high-intensity activity, such as climbing the stairs. If the performance improves after the changes, the participants will be suitable for the study [18].

Control group {11a}

During the interventions, the participants in group III, i.e., the CG, will perform their routine activities and will not receive any interventions.

Patient public involvement

In this research, the team will comprise practicing experts (PhD, MSc) who will work together to guarantee that the study addresses the viewpoints of patients and community members. They will offer insights into the chosen practices.

Strategies to improve adherence to interventions {11c}

To reduce the risk of missing data, each participant will receive paper reminders that include specific dates and times for all scheduled sessions. We will also gather feedback from participants during the intervention sessions. Additionally, the investigator will make weekly phone calls to remind participants about upcoming sessions and to check on their adherence to the training schedule. Participants in the control group will also be contacted weekly to discuss their adherence to the study and their ability to maintain a daily routine.

Relevant concomitant care permitted or prohibited during the trial {11d}

Participants will be asked to avoid other exercise programs during the intervention period to prevent interference with the obtained results.

Provisions for post-trial care {30}

N/A. Due to the minimal risk associated with this study, we do not expect the need for post-trial care arrangements.

Patient participation in general practice {24}

Diagram 1. A summary of sample enrollment and retention from eligibility to 8-week follow-up interviews

This study protocol adheres to the guidelines of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [31]. The participant flow is shown in Figs. 1 and 2. All participants will be engaged in the study for 2 months. Assessments will be conducted at baseline (T1 = week 0) and post-intervention (T2 = + week 8). Allocation to intervention will occur on completion of the baseline assessment.

Sample size calculation {14, 15}

The G*Power (version 3.1) software package will be used to estimate the sample size. According to the software output for the F test and its values (test power = 0.8, significance level = 0.05, and effect size = 0.25) for three study groups and two times of measurements, the sample size is equal to 111, and each group consists of 37 participants. However, 117 people will be recruited with the possibility of sample attrition (i.e., 39 subjects in each group).

Assignment of intervention: allocation {16a, 16b}

To allocate participants to each study group, a third party who is not present in the study, sealed, numbered, and opaque envelopes will be prepared based on the number of patients. Notably, the envelope will contain a slip of paper on which the treatment will be written in coded letters (namely, ABC). Then, each participant will randomly select an envelope like a lottery and will be allocated to one of three groups (group I: PSEFO, group II: PSEs, or group III: CG) according to the code in each envelope. In this study, the outcome assessor will remain blind. That is, this person will not be informed about the study's objectives, the participants' allocation to the desired groups, and the interventions performed.

Implementation {16c}

Once the participants have been enrolled, a physician who is not part of the study will review the inclusion and exclusion criteria. After verifying the final enrollment, the randomization process will take place.

Assignment of intervention: blinding {17a, 17b}

Who will be blinded {17a}

The data analysts will not know the group assignment since they are not involved in participant allocation or intervention implementation.

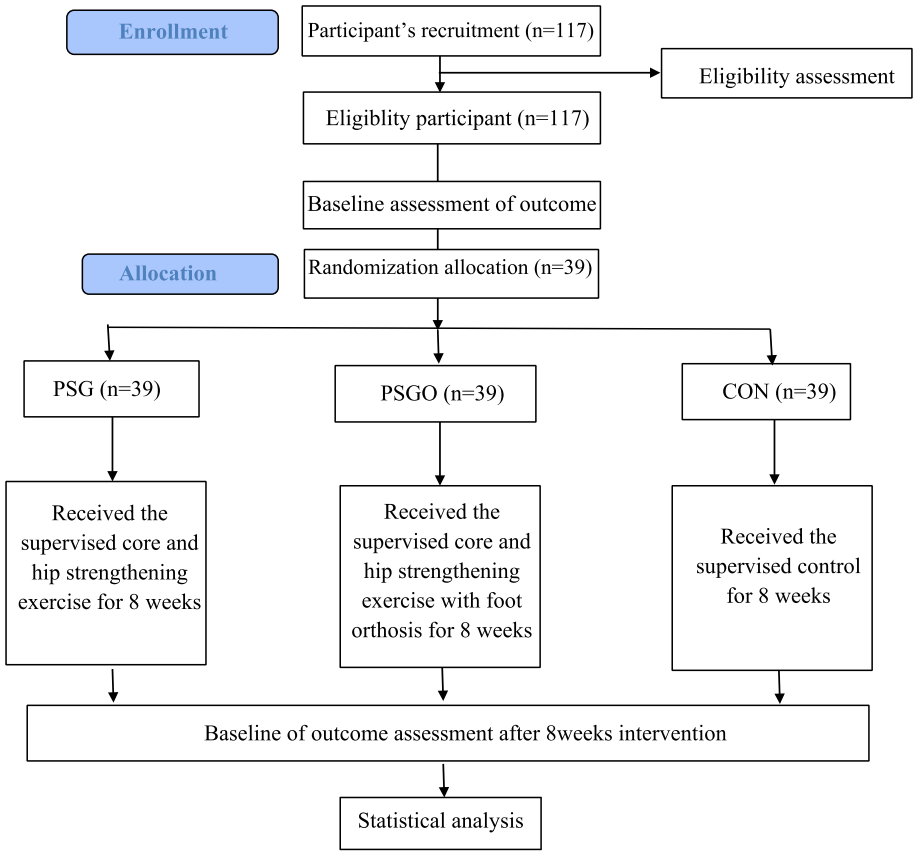

Fig. 1 SPIRIT diagram

Procedure for unblinding if needed {17b}
Not applicable to the study.

Outcome measurement {12}

The primary outcome of this study, which is pain level, will be assessed alongside secondary outcomes such as disability, dynamic balance, knee joint function, Q angle measurements, and overall quality of life. To ensure the confidentiality of personal information, participants will be assigned numerical codes instead of using their names. Both primary and secondary outcomes will be measured before and after the intervention.

Pain

The VAS will be applied to measure pain intensity in the patients before and after the interventions. The scale consists of a horizontal line that is 10 cm long, with zero on one end, meaning no pain, and ten on the other, representing the worst imaginable pain. The participants will then be asked to mark their pain intensity on this line [32]. The reliability of this scale has been reported to be 77–79% for patients with PFPS [33].

Secondary outcome measurement

Disability

The Kujala score will be employed to measure disability. It consists of 13 knee-related items that help assess six functional activities associated with PFPS, including walking, running, jumping, climbing stairs, squatting, and sitting for a long time with knees bent. Moreover, symptoms such as limping, pain, swelling, abnormal movements of the patella, and atrophy in the thighs will be questioned. The maximum score is 100, with higher scores denoting better functional activities and less pain [34]. The validity and reliability of this questionnaire have been previously declared to be 95% [34, 35].

Dynamic balance

The Y-balance test (YBT) will be utilized to evaluate dynamic balance. For this purpose, three measuring tapes will first be stuck on a smooth ground surface in a Y shape with angles of 135°, 135°, and 90° [36]. Then, the participants will be asked to stand on the PFPS-affected

		STUDY PERIOD			
	Enrolment	**Pre-Allocation**	**Allocation**	**Intervention**	**Post-Allocation**
TIMEPOINT**	$-t_1$	t_1	**0**	*Wk1-8*	t_2
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Demographic data	X				
Navicular drop	X				
Foot posture index	X				
Allocation			X		
INTERVENTIONS:					
Proximal Strengthening Exercise				← — →	
Proximal Strengthening Exercise with Foot Orthosis Control				← — →	
ASSESSMENTS:					
Pain	X	X			X
Disability		X			X
Knee joint function		X			X
Dynamic balance		X			X
Q angle		X			X
Quality of life		X			X

Schedule of enrolment, interventions, and assessments

Fig. 2 Participant timeline. Schedule of enrolment, interventions, and assessments

leg in the test center and reach in three directions with the other leg. The test will be repeated three times in each direction, and the mean reach distance will be recorded. The rest time between the repetitions will be 10 s in each direction and 20 s between each movement direction. The participants' leg lengths will be further measured from the anterior superior iliac spine to the inner ankle while lying on the bed. To remove the effect of individual differences, such as height, the reach distance will be divided by the leg length and then multiplied by 100 to express the final number as the percentage of the leg length. To minimize the learning effects and prevent bias in the outcomes, each participant will practice this test six times in three directions. Moving the weight-bearing leg and losing balance during the test or bearing weight on the reach leg are accordingly considered errors, leading to test repetitions [37–39]. The reliability of this test has been reported to be 88% [40].

Evaluation of knee joint function

In the step-down test, the participants will stand on the PFPS-affected leg on a surface with a height of 20 cm and take a controlled step forward and down. When the heel comes into contact with the ground, the knee of the

same leg will be fully opened, and after the heel hits the ground, it immediately goes back and up. These steps will be counted as one repetition, and the number of repetitions in 30 s will be recorded as the score. The validity and reliability of this test have been estimated to be 94% [41, 42].

During the unilateral squat test, the participants will stand on a smooth surface, such as on the ground, in such a way that one leg is flexed at 90° from the knee, and the thigh is at 45°. The other leg will also be placed unilaterally at 60° flexion while bearing weight. For the duration of the participants' movement, their arms, trunks, hips, thighs, knees, and legs will be checked. Instances of proper and improper movements will be recorded as 0 and 1, respectively, in an individual form. The best and worst overall scores are 0 and 10, respectively [43].

The bilateral squat test will start while the participants stand with straight knees on a smooth surface on the ground. The patients will then open their legs to the width of the pelvis, bend their knees to 90°, and return to the initial position. The repetition consists of a complete cycle, from standing straight to 90° knee flexion and back to standing and straight positions. The number of repetitions in 30 s will also be recorded. The reliability of this test has been previously reported, with an intraclass correlation coefficient (ICC) of 0.79 [42].

To perform the anteromedial lunge test, the participants will be positioned behind the starting line and then asked to take a step forward with the involved limb so that the knee of the front leg is bent by 90°. Patients should have good balance and keep their trunks straight. The maximum distance of three attempts for the anteromedial lunge will be marked and recorded. Additionally, 80% of the maximum distance will be calculated and marked with a piece of tape as the target distance for the timed throws. The participants will then be asked to do as many anteromedial lunges as possible in 30 s. The number of correct repetitions will be recorded for each individual; however, those less than 80% will not be counted. If the patients deviate from the movement patterns or take extra steps, that repetition will not be included in the count. The reliability of this test has been estimated to be ICC = 82 [42].

Q angle

A universal goniometer will be used to measure the Q angle while the participants lie on their backs. The fixed arm of the goniometer will be placed on the anterior superior iliac spine, the center of the goniometer will be positioned on the center of the patella, and the movable arm will be kept on the tibial tubercle. The obtained angle will be considered the Q angle [44].

Quality of life

The 36-item Short Form Health Survey (SF-36) contains 36 items under eight dimensions: general health, physical functioning, role limitations due to physical problems, bodily pain, vitality, social functioning, mental health, and role limitations due to emotional problems. In this questionnaire, 0 and 100 represent the worst and best scores, respectively [45].

Plans for assessment and collection of outcomes {18a}

Baseline data will be recorded, including height, weight, age, body mass index (BMI), whether symptoms are unilateral or bilateral, and the duration of symptoms. Participants will also complete a questionnaire that gathers information about their medical history, the specific body part affected by patellofemoral pain syndrome (PFPS), previous treatments received, and the positions or factors that worsen pain and crepitus.

Plans to promote participant retention and complete follow-up {18b}

To enhance participant retention and ensure a complete post-test, we will establish regular communication and engagement with participants, implement flexible scheduling for the post-test, and provide reminders through phone calls and messages.

Data management {19}

The data collected will be reviewed by two researchers and organized for statistical evaluation. To guarantee the thoroughness and precision of the data, it is crucial that every trial record is fully completed. Researchers must keep all original participant documents to ensure data remains accurate and up-to-date.

Statistical methods {20a}

After data collection, the Kolmogorov–Smirnov test will be employed to check the normality of the data distribution. If found to be normal, the repeated measures analysis of variance at a significance level of 0.05 will be used to reflect on the effect of time and group and the interaction effect of time × group. For pairwise comparisons, Bonferroni's post hoc test will be used if there is a significant difference. All statistical analyses will be performed using the SPSS Statistics (version 22) software package.

Interim analysis and method for additional analyses {20b}

No additional analysis, such as subgroup analysis, is intended for this study.

Interim analyses {21b}

Not applicable to the study. Data analysis will begin only after all participants have completed the study.

Methods of analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

The analysis will prioritize the intention-to-treat (ITT) principle. Experience shows that dropouts are infrequent. If the amount of missing data exceeds 10%, multiple imputation techniques will be utilized to ensure the robustness of our study results.

Plans to give access to the complete protocol, participant-level data, and statistical code {31c}

The datasets analyzed during the current study and statistical code are available from the corresponding author on reasonable request, as is the full protocol.

Confidentiality {27}

Information regarding participants will be gathered, communicated, and preserved with utmost confidentiality during the trial. Each participant will receive a unique identification number, which will be utilized to mark all documents and data associated with the study to maintain their anonymity. Data will be stored in secure electronic databases protected by passwords, while physical documents will be kept in locked cabinets accessible only to those authorized.

Access to data will be restricted to the research team and authorized monitors, auditors, and regulatory bodies as necessary. Any data shared will be de-identified to safeguard the identities of participants. Transfers of electronic data will be encrypted for enhanced protection.

Routine audits and data verifications will be conducted to ensure adherence to confidentiality protocols. Following the trial, personal data will be securely retained for at least 3 years. Personal information about participants will not be revealed in any publications or reports.

Monitoring

Composition of the coordinating center and trial steering committee {5d}

The coordinating center is the Department of Sport Rehabilitation at Arak University in Arak, Iran. The trial steering committee includes the principal investigator and other researchers responsible for patient recruitment, study conduction, and data entry.

Composition of the data monitoring committee and its role and reporting structure {21a}

The clinical research coordinator will carry out data monitoring. An internal inspection will take place at the Sport Rehabilitation Centre in Arak. Patient safety and data adequacy will be monitored every 2 weeks under the supervision of the principal investigator.

Adverse event reporting and harms {22}

The interventions in this study are expected to carry low risks. However, participants may experience new illnesses or worsened existing symptoms that may not necessarily be related to the exercise protocol or FOs. All adverse events, whether solicited or spontaneously reported, as well as any unintended effects from the trial interventions, will be documented from participant enrollment until the conclusion of the study. The report will include details on the causality, onset time, resolution time, severity, management provided, and relevance to the current clinical trial.

Serious adverse events (SAEs) must be reported to the ethics committee within 24 h of the researchers becoming aware of the event. Following an SAE, researchers are required to provide appropriate treatment to the participant and submit a follow-up report to the ethics committee within 14 days. This report should detail the cause of the event and the measures taken in response.

Frequency and plans for auditing trial conduct {23}

The ethics committee will conduct monthly audits of the study to ensure adherence to the protocol, ethical guidelines, and regulatory requirements. The audits will involve a thorough review of trial documentation, participant records, and data management practices.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

Any modifications will be discussed within the steering committee to reach a consensus. After reaching an agreement, amendments will be submitted for approval to the Department of Rehabilitation Research and the Guilan University's Ethics Committee. Once approved, a formal document outlining the protocol revisions will be shared with all relevant parties. Participants in the trial will be notified about any changes that could affect their involvement, and consent will be re-obtained if needed.

Dissemination plans {31a}

At the conclusion of the study, a summary of the results will be emailed to each participant. Additionally, the findings will be published in peer-reviewed journals and presented at both national and international conferences and seminars.

Discussion

As one of the most frequently encountered MSDs, PFPS causes dull pain behind the patella and in the anterior and upper surfaces of the knee. Although the etiology of this condition remains unclear, some possible reasons have been mentioned thus far [1, 15, 46]. Different therapeutic methods have been practiced for PFPS, including therapeutic exercises and FO use as active and passive procedures, respectively, for rehabilitation purposes [1]. According to previous research, hip and core PSEs are more effective in improving patients than single exercises for knee joint muscles [47, 48]. Moreover, FOs appear to be effective in bringing about improvements in patients with PFPS and PF by modifying the movement patterns of the PFJ and increasing lower limb muscle activity [7]. The success rates of FOs in those having PFPS with and without PF have been reported to be 78% and 20%, respectively [18]. Previous research has also suggested combined hip and core or knee muscle group exercises along with passive treatments (e.g., Kinesio taping, FO use, and patellar strap) for those with PFPS [1].

Given that the participants in this study have PFPS along with PF, it appears that a treatment approach addressing both issues may be more beneficial than focusing solely on PFPS. One aspect that has received less attention in previous research is the condition of the feet in PFPS patients. A key strength of this study is the simultaneous consideration of both the knee and foot, which could enhance the effectiveness of the intervention. Additionally, prior studies have indicated that combined PSEs are more effective than individual training sessions. Thus, another strength of this study lies in its use of the PSEs.

However, this study also has several limitations, including the lack of long-term data on PSEs and FOs use, which is challenging due to the research conditions and participant constraints. Furthermore, the absence of follow-up assessments is another limitation. The higher prevalence of PFPS led us to consider only female subjects, which may restrict the generalizability of the results to the overall population.

This RCT, which will recruit a sample size of 117 female patients in two intervention groups and one CG, aims to investigate the effectiveness of PSEFO on pain and performance among women with PFPS and PF.

Trial status and ethical considerations {3, 24}

The present study was approved by the Research Ethics Committee of Guilan University of Medical Sciences, Rasht, Iran (code: IR.GUILAN.REC.1402.021) and registered on the Iranian Registry of Clinical Trials (IRCT, code: IRCT20230604058380N1). From August 21, 2023, women with PFPS were informed about the present study through online cyber notices and those posted in rehabilitation and healthcare centers and gyms. We are currently recruiting participants based on the study's inclusion and exclusion criteria.

Consent for publication {32}

This manuscript does not include any personal data of individual patients. The materials related to participant information and the informed consent form can be obtained from the corresponding author upon request.

Roles and responsibilities: sponsor and funder {5c}

The sponsor played no part in the study design, collection, management, analysis, and interpretation of data, writing of the report, and the decision to submit the report for publication.

Data availability {29}

The datasets used and/or analyzed during the current study will be available from the corresponding author upon reasonable request.

Abbreviations

PFPS	Patellofemoral pain syndrome
MSDs	Musculoskeletal disorders
PFJ	Patellofemoral joint
QoL	Quality of life
FOs	Foot orthoses
VMO	Vastus medialis oblique
PF	Pronated foot
PSEs	Proximal strengthening exercises
PSEFO	PSE program and FO
RCT	Randomized clinical trial
CG	Control group
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
NDT	Navicular drop test
FPI-6	Foot posture index
ICC	Intraclass correlation coefficient

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08787-w.

Additional file 1. SPIRIT checklist.

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Authors' contributions

All authors read and approved the final manuscript.

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The datasets used and/or analyzed during the current study will be available from the corresponding author upon reasonable request.

Ethics approval and consent to participate
The study will adhere to all the protocols stipulated in the 2008 Declaration of Helsinki. It was approved by the Ethics Committee of Guilan University of Medical Sciences in Rasht, Iran (code: IR.GUILAN.REC.1402.021) and registered on the Iranian Registry of Clinical Trials (IRCT, code: IRCT20230604058380N1). All participants will receive completed information about the study and signed informed consent before their participation.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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