Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of the Effect of Core and Hip Muscle Strengthening Protocols Pre- and Post-Functional Movement Retraining on Pain and Function in Men with Patellofemoral Pain Syndrome

Protocol summary

Study aim

The aim of this study is to compare the effects of trunk and hip muscle strengthening protocols before and after functional movement retraining on pain and function in men with patellofemoral pain syndrome.

Design

A randomized clinical trial with three parallel groups, including two intervention groups and one control group, single-blinded, with a sample size of 45 people. After baseline assessment, participants will be randomly allocated to trunk strengthening, hip strengthening, and control groups. Allocation concealment will be performed using sequentially numbered, opaque, sealed envelopes.

Settings and conduct

This study will be conducted in Arak on men with patellofemoral pain syndrome. After screening and baseline assessment, participants will receive exercise interventions and functional movement retraining. Outcome assessor and data analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Males aged 18 to 40 years; patellofemoral pain syndrome; pain for at least 3 months; activity-related pain 3 to 7; functional movement impairment. Exclusion criteria: Other knee pain causes; patellar instability or effusion; conditions affecting function; significant foot or ankle impairment; referred pain.

Intervention groups

Intervention group 1: Participants will receive 4 weeks of trunk strengthening and core stabilization exercises (3 sessions per week), followed by 4 weeks of functional movement retraining. Intervention group 2: Participants will receive 4 weeks of hip strengthening exercises (3 sessions per week), followed by the same functional movement retraining program. Control group: Participants will continue usual activities without exercise intervention for 4 weeks, followed by functional movement retraining.

Main outcome variables

Pain intensity; knee function and functional performance

General information

Reason for update

As the trial has not yet entered the participant recruitment phase, the registered study information was reviewed to complete and align the registered outcomes with the study assessment plan. Pain intensity was retained as the primary outcome, while knee symptoms and function, functional performance, knee-related quality of life, kinesiophobia, and dynamic balance were registered as secondary outcomes. The measurement time points and methods for the relevant outcomes were also specified in the corresponding fields. All other registered information and protocol specifications remain unchanged.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210802052056N1**
Registration date: **2026-08-15, 1405/05/24**
Registration timing: **prospective**

Last update: **2026-08-17, 1405/05/26**
Update count: **1**

Registration date

2026-08-15, 1405/05/24

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-01, 1405/06/10

Expected recruitment end date

2026-11-01, 1405/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Core and Hip Muscle Strengthening Protocols Pre- and Post-Functional Movement Retraining on Pain and Function in Men with Patellofemoral Pain Syndrome

Public title

Comparison of the Effect of Core and Hip Muscle Strengthening Protocols Pre- and Post-Functional Movement Retraining on Pain and Function in Men with Patellofemoral Pain Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Males aged 18 to 40 years Diagnosis of patellofemoral pain syndrome based on the clinical criteria of the 2018 consensus statement including anterior knee pain and pain provocation during functional activities Activity-related pain intensity between 3 and 7 on the visual analog scale Presence of anterior knee pain for at least 3 months Presence of observable movement impairments during at least two movements including double-leg squat, single-leg squat, step-down, and sit-to-stand Ability to walk independently and perform double-leg squat and step-down without assistive devices No history of receiving specialized physical therapy for patellofemoral pain syndrome during the previous 3 months

Exclusion criteria:

Presence of other causes of anterior knee pain including Osgood-Schlatter disease, plica syndrome, and Sinding-Larsen-Johansson syndrome. Presence of patellar instability. Presence of knee joint effusion. History of injury or surgery to the spine or lower extremities. Presence of knee meniscal, ligament, or tendon injuries. Presence of systemic or neurological diseases affecting motor function including rheumatoid arthritis, uncontrolled diabetes, multiple sclerosis, Parkinson’s disease, stroke, or other severe musculoskeletal and neurological disorders. Presence of significant functional impairment of the ankle or foot including limited ankle dorsiflexion with more than 3 cm difference between the two sides in the Weight-Bearing Lunge Test. Inability to perform at least 20 correct single-leg heel raises or a difference of more than 5 repetitions between the two sides in the Single Leg Heel Rise Test. History of ankle injury or instability within the previous 6 months resulting in altered gait pattern or functional limitation. Presence of referred pain from the hip or lumbar spine.

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

After screening according to the eligibility criteria and completing the baseline assessment, eligible participants will be randomly allocated into three groups: the core strengthening group, the hip strengthening group, and the control group. The random allocation sequence will be prepared before the start of the intervention, and each participant will be assigned to one of the three study groups according to this predefined sequence after final enrollment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the exercise interventions, blinding of participants and the intervention provider will not be feasible because the type of exercise received will be apparent to both participants and the intervention provider. However, outcome assessments will be performed by an independent assessor who will be blinded to participants’ group allocation and the type of intervention received by each group. In addition, data analysis will be performed after coding the groups, so that the data analyst will not be aware of the relationship between the codes and the intervention and control groups. These procedures will be implemented to minimize potential bias in outcome assessment and data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of University of Guilan

Street address
University of Guilan Campus, Km 5 Tehran Road, Persian Gulf Highway, Rasht

City
Rasht

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Guilan

Postal code
4199613776

Approval date
2026-08-03, 1405/05/12

Ethics committee reference number
IR.GUILAN.REC.1405.054

Health conditions studied

1

Description of health condition studied
Patellofemoral Pain Syndrome

ICD-10 code
M22.2

ICD-10 code description
Patellofemoral disorders

Primary outcomes

1

Description
pain intensity

Timepoint
At baseline (before the intervention), after completion of the first four weeks of intervention (end of phase one), and after completion of the eight-week intervention period (end of phase two)

Method of measurement
Ten-centimeter Visual Analogue Scale

Secondary outcomes

1

Description
Knee symptom and function score related to patellofemoral pain syndrome

Timepoint
At baseline (before the intervention), after completion of the first four weeks of intervention (end of phase one), and after completion of the eight-week intervention period (end of phase two)

Method of measurement
Kujala Anterior Knee Pain Scale for assessment of knee symptoms and function related to patellofemoral pain syndrome

2

Description
Number of correct repetitions in the step-down test

Timepoint
At baseline (before the intervention), after completion of the first four weeks of intervention (end of phase one), and after completion of the eight-week intervention period (end of phase two)

Method of measurement
Step-down test from a twenty-centimeter platform with recording of the number of correct repetitions performed in thirty seconds

3

Description
Number of correct repetitions in the single-leg sit-to-stand test

Timepoint
At baseline (before the intervention), after completion of the first four weeks of intervention (end of phase one), and after completion of the eight-week intervention period (end of phase two)

Method of measurement
Single-leg sit-to-stand test with recording of the number of correct repetitions performed in thirty seconds

4

Description
Knee-related quality of life

Timepoint
At baseline (before the intervention), after completion of the first four weeks of intervention (end of phase one), and after completion of the eight-week intervention period (end of phase two)

Method of measurement
Twelve-item Knee Injury and Osteoarthritis Outcome Score, using the knee-related quality of life subscale

5

Description
Kinesiophobia

Timepoint
At baseline (before the intervention), after completion of the first four weeks of intervention (end of phase one), and after completion of the eight-week intervention period (end of phase two)

Method of measurement
Tampa Scale for Kinesiophobia

6

Description
Dynamic balance

Timepoint
At baseline (before the intervention), after completion of the first four weeks of intervention (end of phase one), and after completion of the eight-week intervention period (end of phase two)

Method of measurement

Y-Balance Test for assessment of dynamic balance

Intervention groups

1

Description
Intervention group 1: Supervised trunk muscle strengthening for four weeks, three sessions per week. After completion of the first phase, participants will receive a functional movement retraining program for four weeks, three sessions per week.
Category
Rehabilitation

2

Description
Intervention group 2: Supervised hip muscle strengthening for four weeks, three sessions per week. After completion of the first phase, participants will receive a functional movement retraining program for four weeks, three sessions per week.
Category
Rehabilitation

3

Description
Control group: No exercise or stretching intervention will be provided during the first four weeks, and participants will continue their usual daily activities. After completion of the first phase, participants will receive a functional movement retraining program for four weeks, three sessions per week.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Hygia Corrective Exercise and Hydrotherapy Center
Full name of responsible person
Mohammad Yasavoli Sharahi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Guilan
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
The University of Guilan
Full name of responsible person
Mohammad Yasavoli Sharahi
Position
Phd student in sports injuries and corrective exercises
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to considerations regarding participant confidentiality and privacy and the study's data management policy, there is no plan for public sharing of individual participant-level data, even in de-identified form.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study protocol, statistical analysis plan, and study results report: The study protocol, including the study design, objectives, methodology, eligibility criteria, interventions, outcomes, and statistical analysis plan, will be made available after trial registration and through the scientific publication process as a study protocol article and/or relevant scientific documentation. The statistical analysis plan, if published, will be made available as part of the study protocol article and/or relevant scientific documentation. The study results report will include findings related to the primary and other pre-specified outcomes, data analysis methods, and final study results. It will be disseminated after completion of the study and analysis of the data through publication of a scientific article in a relevant peer-reviewed journal.

When the data will become available and for how long

Study protocol and statistical analysis plan: Available from the time of publication following trial registration and through the scientific publication process. Study results report: Available from the time of publication of the results article following completion of the study and data analysis.

To whom data/document is available

The published study documents will be publicly accessible, and researchers, healthcare professionals, and other individuals interested in research may access them through the journal or scientific source in which they are published.

Under which criteria data/document could be used

The published documents may be used for scientific, educational, research, and clinical purposes, including related research and informing the assessment and interventions evaluated in the study, and will be subject to the terms and conditions of use established by the journal or scientific source in which they are published.

From where data/document is obtainable

For access to the published study documents, users should refer to the journal or scientific source in which

the relevant article is published.

What processes are involved for a request to access data/document

After publication, the study documents will be made available through the journal or scientific source in which they are published. Access to these documents will be subject to the access policies and terms of use of the respective journal or publication platform, and no separate request or approval process by the research team will be required.

Comments