Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Added Value of Diaphragm Myofascial Release in Improving Pain, Function and Balance in Females With Patellofemoral Pain A Randomized Clinical Trial

Protocol summary

Study aim
To investigate the added value of diaphragm myofascial release in improving pain, function, and balance in females with patellofemoral pain.

Design
A controlled, double group, single blinded (assessor), randomized (Randomizer site), phase 3 clinical trial on 20 patients.

Settings and conduct
The study at Shiraz's School of Rehabilitation Sciences will investigate the effect of diaphragm release on pain, intensity, balance and function of patients with patellofemoral pain. Manual techniques are applied once per week for four weeks, alongside therapeutic exercises for 2 groups. Blinding of evaluator is maintained by separating treatment and assessment roles.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Females aged 18-35 with unilateral patellofemoral pain, anterior or retropatellar pain during at least two activities of squatting, kneeling, stair ascent or descent, prolonged sitting with knee flexed, running, or jumping, tenderness at the lateral patellar facet, anterior surface of the medial or lateral femoral condyle. Pain at least 3 on the Numeric Rating Scale (NRS). The Kujala score less than 85, positive patellar apprehension test, informed consent. Exclusion criteria: History of knee surgery, trauma, pathologies, patellar dislocation, active inflammatory conditions affecting lower limb, neurological, systemic musculoskeletal and metabolic disorders, affected gait, marked structural deformity, pathological condition of back, hip, and ankle, respiratory, cardiovascular or metabolic disorders, professional athletes, received physiotherapy or structured exercises in the past ۶ months, pregnancy, menstrual phase at assessment time, body Mass Index (BMI) > ۳۰

Intervention groups
The intervention group receives myofascial diaphragmatic release therapy and exercise therapy. The control group only receives exercise therapy.

Main outcome variables
Pain, function, balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250629066291N2**
Registration date: **2026-04-25, 1405/02/05**
Registration timing: **prospective**

Last update: **2026-04-25, 1405/02/05**
Update count: **0**

Registration date
2026-04-25, 1405/02/05

Registrant information

Name
Farzaneh Haghighat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3230 5410

Email address
haghighat_fa@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-10, 1405/02/20

Expected recruitment end date
2026-10-12, 1405/07/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Added Value of Diaphragm Myofascial Release in Improving Pain, Function and Balance in Females With Patellofemoral Pain A Randomized Clinical Trial

Public title
Added Value of Diaphragm Myofascial Release in Improving Pain, Function and Balance in Females With Patellofemoral Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of unilateral PFP by a qualified physician or physiotherapist Females between ۱۸ and ۳۵ years Presence of anterior or retro patellar knee pain during at least two of the following activities: squatting, kneeling, ascending/descending stairs, prolonged sitting with flexed knee, running, jumping pain on palpation of the medial or lateral patellar facet, or the anterior aspect of the medial or lateral femoral condyle. Duration of symptoms for more than ۸ weeks Pain intensity of ≥۳ on the NRS (numerical rating scale) during the week before assessment scoring less than ۸۵ out of ۱۰۰ on the Kujala anterior knee pain scale (AKPS) positive patellar apprehension test (sensitivity: ۸۶.۷%, specificity: ۸۶.۷%) Willingness to participate and provide informed consent
Exclusion criteria:
History of knee surgery, trauma, or patellar dislocation Evidence of other knee pathologies (e.g., meniscal tear, ligament injury, or osteoarthritis) Active inflammatory conditions affecting the lower limb Neurological, systemic musculoskeletal and metabolic disorders (e.g., multiple sclerosis, rheumatoid arthritis and diabetes respectively) History of fracture, dislocation or surgery of lower limb or any condition affecting gait Marked structural deformity and known pathological condition of back, hip, and ankle Respiratory disorders that could influence diaphragm function (e.g., COPD, asthma) Cardiovascular disorders metabolic disorders Professional athlete (an individual who regularly participates in a specific sport at least three times per week for a minimum of two hours) Participation in other physiotherapy treatments or structured exercise programs in the past ۶ months Pregnancy the patient should not be in the menstrual phase at the time of assessment Body Mass Index (BMI) > ۳۰
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned into two groups using block randomization with a block size of six
Blinding (investigator's opinion)
Single blinded
Blinding description
It is important to note that the examiners will be blinded to the randomization process, which will be carried out by an independent individual. Moreover, evaluation and intervention procedures will be conducted by two separate physiotherapists to minimize bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Ethics committee, Research and Technology Vice-Chancellor, 7th floor, Central building of Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Province
Fars
Postal code
7198754361
Approval date
2025-12-17, 1404/09/26
Ethics committee reference number
IR.SUMS.REC.1404.500

Health conditions studied

1

Description of health condition studied
Patellofemoral pain
ICD-10 code
M22.2
ICD-10 code description
Patellofemoral disorders

Primary outcomes

1

Description
Pain intensity
Timepoint
Before intervention; One day after intervention period
Method of measurement
Numerical pain rating scale

2

Description
Physical function
Timepoint
Before intervention; One day after intervention period
Method of measurement
The Kujala Anterior Knee Pain Scale (KANPS)

3

Description
Dynamic balance
Timepoint
Before intervention; One day after intervention period
Method of measurement
Modified star excursion test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Diaphragmatic Myofascial Release and Exercise Therapy. Participants in the intervention group received diaphragmatic myofascial release combined with therapeutic exercises. For diaphragmatic release, the patient was positioned in supine. The therapist stood at the head of the table and placed bilateral manual contact beneath the lower costal cartilages (ribs 5–10) using the hypothenar eminence and the last three fingers of both hands. During inspiration, gentle traction was applied in a cephalad and slightly lateral direction while simultaneously facilitating rib elevation. During expiration, the therapist gradually deepened the manual contact toward the inner costal margins, following tissue relaxation. Each session of diaphragmatic release lasted approximately 5 minutes.
Category
Treatment - Other

2

Description
Control Group: Therapeutic Exercise. Participants in the control group received therapeutic exercises only.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Rehabilitaion School, Shiraz University of Medical Sciences
Full name of responsible person
Farzaneh Haghighat
Street address
Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard
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Shiraz
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7194815644
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Research and Technology Vice-Chancellor, 7th floor, Central building of Shiraz University of Medical Sciences, Zand Street
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Shiraz
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7134814336
Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
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

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Haghighat

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information collection form including primary and secondary outcomes, informed consent form and SPSS file

When the data will become available and for how long

After publication the results of the study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only for recording information in scientific databases

From where data/document is obtainable

Correspondence with the project manager by email. Haghighat_fa@yahoo.com

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

Maximum one month after sending the request by email

Comments