

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 6 months, pregnancy, menstrual phase at assessment time, body Mass Index (BMI) > 30.

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)

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+98 71 3230 5410

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Recruitment status

recruiting

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 18 and 35 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 4 weeks Pain intensity of ≥ 3 on the NRS (numerical rating scale) during the week before assessment scoring less than 40 out of 100 on the Kujala anterior knee pain scale (AKPS) positive patellar apprehension test (sensitivity: 86.7%, specificity: 86.7%) 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 6 months Pregnancy the patient should not be in the menstrual phase at the time of assessment Body Mass Index (BMI) > 30

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 Rehabilitation School, Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Haghighat

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Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Research and Technology Vice-Chancellor, 7th floor, Central building of Shiraz University of Medical Sciences, Zand Street

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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

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
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Person responsible for updating data

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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