

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The efficacy of biofeedback exercises of hip abductors and external rotators muscles on pain and muscle electromyographic activity in people with patellofemoral pain syndrome

Protocol summary

Study aim

The efficacy of biofeedback exercises of hip abductors and external rotators muscles on pain and muscle electromyographic activity in people with patellofemoral pain syndrome

Design

Clinical trial with an intervention group and a control group, with parallel groups, double blinded, randomly constructed, on 20 people in each group

Settings and conduct

Setting: School of Rehabilitation., Shahid Beheshti University of Medical Sciences, Tehran. In this study, eligible people will be included among the patients with patellofemoral pain syndrome and will be randomly divided into two intervention and control groups. Treatment interventions for each group will be carried out in eight weeks. Outcome assessment and data analysis will be performed by another colleague who is blinded to group assignment. Also, the patients will be blinded to the treatments of each group. Data collection tools will include visual analog scale, dynamometer and surface electromyography devices.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with patellofemoral pain syndrome with pain at least 3 on the visual analog scale. Exclusion criteria: history of patella dislocation and knee surgery.

Intervention groups

Intervention group: biofeedback exercises of hip abductors and external rotators muscles with routine physiotherapy treatments (stretching exercises, gluteal and quadriceps isometric exercises, electrotherapy including conventional tens). Control group: only routine physiotherapy treatments (stretching exercises, gluteal and quadriceps isometric exercises, electrotherapy including conventional tens). In both groups, the interventions will be conducted for eight weeks and three

sessions per week.

Main outcome variables

Pain intensity; maximum muscle isometric contraction force; Muscle electromyographic activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221214056819N1**

Registration date: **2023-11-01, 1402/08/10**

Registration timing: **prospective**

Last update: **2023-11-01, 1402/08/10**

Update count: **0**

Registration date

2023-11-01, 1402/08/10

Registrant information

Name

mehdi Banan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of biofeedback exercises of hip abductors and external rotators muscles on pain and muscle electromyographic activity in people with patellofemoral pain syndrome

Public title
The effect of biofeedback exercises on anterior knee pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with patellofemoral pain syndrome with pain at least 3 on the visual analog scale Knee pain when running, jumping, sitting and standing up
Exclusion criteria:
History of patella dislocation History of knee surgery

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized method: balanced randomized blocks.
Random concealment: sealed envelope. Randomization method: code of the intervention group: A code of the control group: B. Due to having two groups, the determined blocks are of four, so that the total number of possible permutations of four is 6, including: ABAB, ABBA, BAAB, BABA, AABB, BBAA. To create a random sequence, we will number the possible blocks (6 blocks) from 1 to 6, we will select the block numbers from the random number table, and based on these numbers, we will determine the sequence of blocks in each group. Each of these codes representing the treatment group of each patient is placed in a sealed envelope, then patients will be assigned to one of the envelopes in order of number. In this study, the unit of randomization is the individual.

Blinding (investigator's opinion)
Double blinded

Blinding description
The main researcher is blinded to the selection and randomization of participants, and assigning groups will be done by another colleague. Treatment for the

intervention group will be done on even days of the week and treatment for the control group will be done on odd days of the week, so the participants will be blinded to their treatment and group assignment. Data collection and analysis after the completion of the interventions will be done by another colleague who is blind to group assignment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committees of Vice Chancellor in Research Affairs Shahid Beheshti University of Medic

Street address

Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak

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Postal code

1983963113

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1117

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

Measurement of pain intensity at the beginning of the study (before the intervention), at the end of the study (8 weeks after the intervention)

Method of measurement

Visual Analog Scale

2

Description

Maximum muscle isometric contraction force

Timepoint

Measurement of maximum muscle isometric contraction force at the beginning of the study (before the intervention) and at the end of the study (8 weeks after the intervention)

Method of measurement

Hand dynamo-meter

3

Description

Muscle electromyographic activity

Timepoint

Measurement of muscle electromyographic activity at the beginning of the study (before the intervention) and at the end of the study (8 weeks after the intervention)

Method of measurement

Surface electromyography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: biofeedback exercises of hip abductors and external rotators muscles with routine physiotherapy treatments (stretching exercises, gluteal and quadriceps isometric exercises, electrotherapy including conventional tens). The interventions will be conducted for eight weeks and three sessions per week.

Category

Rehabilitation

2

Description

Control group: Routine physiotherapy treatments (stretching exercises, gluteal and quadriceps isometric exercises, electrotherapy including conventional tens). The interventions will be conducted for eight weeks and three sessions per week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation., Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Mohsen Roostayi

Street address

School of Rehabilitation., Shahid Beheshti University of Medical Sciences., Damavand St., Emam Hossein Sq

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehdi Banan

Position

PhD candidate Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Khalkhali Zavieh

Position

Associate professor of Physiotherapy

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

PhD candidate Physiotherapy

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All above will be published in the article.

When the data will become available and for how long

After the article publication

To whom data/document is available

Researchers and students in academic centers

Under which criteria data/document could be used

Other researchers and therapists in the rehabilitation and medical field can use this use the data of this study after the article publication.

From where data/document is obtainable

After the article publication, people can find the article by searching in internet and access the data.

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

After the article publication, people can find the article by searching in internet and access the data.

Comments