Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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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

City

Tehran

Province

Tehran

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
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Sponsors / Funding sources

1

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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
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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