

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of neuromuscular training by biofeedback method and conventional exercise therapy of hip abductor muscles on pain, function and electrical activity of the muscle in patients with patellofemoral pain syndrome

#### Protocol summary

##### Study aim

Determining the effect of gluteus medius muscle training with electromyography biofeedback during Functional activities and comparing it with routine therapeutic exercise of this muscle in patients with patellofemoral pain syndrome

##### Design

Clinical trial with control group, with parallel groups, single-blind, randomized on 30 patients. Coin flipping is used for randomization.

##### Settings and conduct

The study is conducted at Shahid Beheshti University of Medical Sciences. Both groups receive the usual physiotherapy. In addition, group A receives the common exercises of the gluteus medius muscle and group B receives functional exercises along with biofeedback. The evaluator does not know the group of patients and the study is single blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-40 years old; Anterior knee pain during at least 3 of following: stair ascent or descent, squatting, kneeling, jumping, running; Visual analog score ranging from 3 to 10; Positive patellar grind test; A history of at least 3 days of continuous pain in front of the knee (not caused by trauma) in the last 3 months, which is gradual; BMI 20-30 Exclusion criteria: Patella tendon pathology; Chondral damage of the knee joint; Osteoarthritis of the knee joint; Pain referred from the spine to the lower limbs; Neuromuscular, Rheumatology or Metabolic Diseases such as Diabetes and Neuropathy; Dislocation or subluxation of the patella and signs of meniscus or ligament damage; Trauma caused by injury or surgery in the lower limb in the last 12 months

##### Intervention groups

Group A receives the common strengthening exercises of the gluteus medius muscle. Group B receives functional

exercises of accent and decent stairs, walking and accent and decent stairs to the side along with biofeedback

##### Main outcome variables

Pain intensity; Function; Onset, offset and intensity of electrical muscle activity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230725058919N1**

Registration date: **2023-08-16, 1402/05/25**

Registration timing: **prospective**

Last update: **2023-08-16, 1402/05/25**

Update count: **0**

##### Registration date

2023-08-16, 1402/05/25

##### Registrant information

##### Name

Hossein Rabieifar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7756 1723

##### Email address

pt.rabieifar@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-22, 1402/05/31  
**Expected recruitment end date**  
2023-11-21, 1402/08/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

### Scientific title

Comparison of neuromuscular training by biofeedback method and conventional exercise therapy of hip abductor muscles on pain, function and electrical activity of the muscle in patients with patellofemoral pain syndrome

### Public title

Comparison of neuromuscular training and conventional exercise therapy of hip abductor muscles in patients with patellofemoral pain syndrome

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

18-40 years old Anterior knee pain during at least 3 of the following: stair ascent or descent; squatting; kneeling; jumping; running Visual analog score ranging from 3 to 10 A history of at least 3 days of continuous pain in front of the knee (not caused by trauma) in the last 3 months, which is gradual. Not receiving medical and physical treatment in the last three months BMI 20-30 Positive patellar Grind test

#### Exclusion criteria:

Patella tendon pathology Chondral damage of the knee joint Osteoarthritis of the knee joint Pain referred from the spine to the lower limbs Neuromuscular, rheumatology or metabolic diseases such as diabetes and neuropathy Dislocation or subluxation of the patella and signs of meniscus or ligament damage Trauma caused by injury or surgery in the lower limb in the last 12 months

### Age

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

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Outcome assessor

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

A simple randomization is done with Non-transparent and sealed envelope tools in such a way that the letters A and B are inserted in the envelopes and patients are asked to select an envelope that the intervention group A and the group B they will be tested.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Since the patient knows which group he is in but the evaluator dose not know so this study is one-way blind

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

#### Approval date

2023-03-05, 1401/12/14

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1401.840

## Health conditions studied

### 1

#### Description of health condition studied

Anterior knee pain syndrome (patellofemoral pain syndrome)

#### ICD-10 code

M22.2

#### ICD-10 code description

Patellofemoral disorders

## Primary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

Before the start of the intervention and after the end of the 10 intervention sessions (23 days after the start of the sessions)

#### Method of measurement

Visual Analogue Scale

## 2

### **Description**

Knee function

### **Timepoint**

Before the start of the intervention and after the end of the 10 intervention sessions (23 days after the start of the sessions)

### **Method of measurement**

KOOS questionnaire

## 3

### **Description**

Electromyographic activity of muscles

### **Timepoint**

Before the start of the intervention and after the end of the 10 intervention sessions (23 days after the start of the sessions)

### **Method of measurement**

Electromyography

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Intervention group: Functional exercise therapy group with biofeedback: participants in 10 sessions and 3 sessions per week, in addition to regular physical therapy (the same in both groups), receive functional exercises of going up and down the stairs, walking and going up and down the stairs to the side along with biofeedback. In each of the activities, the patient is asked to increase the activity of the gluteus medius muscle, to activate the muscle early and even if possible to maintain the activity of the muscle until the end of the respective activity. The activities of going up and down the stairs and going up and down the stairs to the side are done as 4 sets with 5 repetitions and a 30-second rest between sets, and the walking activity as 4 repetitions of 90 seconds and a 30-second rest between repetitions. Each session lasts approximately 180 minutes.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: Gluteus medius muscle strengthening exercise group: participants in 10 sessions and 3 sessions per week, in addition to regular physical therapy (the same in both groups), receive Gluteus medius muscle strengthening exercise group. The exercises become progressively more difficult, and when the patient can repeat the desired exercise 15 times without problems, the exercises will become more difficult and the external force will be gradually added (if 15 repetitions are done without problems, 1 pound of

external resistance will be added). The exercises in order of difficulty are: abduction and external rotation in side lying position (clamshell), full thigh abduction with straight knee, thigh abduction in quadruped position. Each session lasts approximately 180 minutes.

### **Category**

Rehabilitation

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Akhtar hospital

#### **Full name of responsible person**

Seyyed Morteza Kazemi

#### **Street address**

Akhtar Hospital., Azar Dead End., Sharifi Menesh St., in front of Qitarieh Metro., Shariati St., Tehran

#### **City**

Tehran

#### **Province**

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1964714953

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akhtarhospital@sbmu.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

#### **Full name of responsible person**

Afshin Zarghi

#### **Street address**

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

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#### **Email**

zarghi@sbmu.ac.ir

#### **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**

Hossein Rabeie Far

**Position**

Physiotherapy Master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

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

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pt.rabieifar@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hoda Niknam

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hossein Rabeie Far

**Position**

Physiotherapy Master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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**Email**

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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**