

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effects of a Strengthening Exercise Program with EMG Biofeedback to Correct Patellar Alignment and Reduces Knee Pain in Women with Patella femoral Pain Syndrome

#### Protocol summary

##### Summary

1. Objective: The objective of this study was to investigate the effects of a strengthening exercise program with electromyographical (EMG) biofeedback on the alignment corrections of the patella and the knee pain in patients with patella\_femoral pain syndrome (PFPS). 2. Design: This study was a clinical trial. The populations of this study were women with patella femoral pain syndrome. 3. Setting and Conduct: The participants of this study were 22 females with PFPS. They are randomly divided into two groups: Group 1, including 11, underwent an exercise therapy with biofeedback program and Group 2, including 11, was provided with exercise therapy without biofeedback. The knee pain was quantified by using VAS questionnaire. Radiography technique was also applied to evaluate the knee alignment including sulcus, congruence, tilt angles, and Q angles assessed by clinical tests. 4. Inclusion criteria included 1. Being female 2. Having pain at least in two activities of activities like: going up the stairs, going down the stairs, and squatting. Exclusion criteria included 1. Having a history of knee pathology except PFPS. 2. Having a previous knee injury or surgery 3. Using anti-inflammatory drugs 5. Intervention: Receiving visual feedback to strengthen the muscles during exercise 6. Primary Outcome Variables: The results showed that congruence and Q angle were significantly reduced in both groups. However, the patellar tilt was significantly reduced only in strengthening exercise program with biofeedback group. Secondary Outcome Variable: strengthening exercise program with electromyographical biofeedback displayed a better treatment outcome.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017011732008N1**

Registration date: **2017-07-11, 1396/04/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-11, 1396/04/20

##### Registrant information

###### Name

Banafsheh Mohammadi

###### Name of organization / entity

BU-Ali Sina

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3829 2616

###### Email address

bmohammadi90@basu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Vice President, Bu-Ali Sina University, Hamedan

##### Expected recruitment start date

2015-01-01, 1393/10/11

##### Expected recruitment end date

2016-01-21, 1394/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effects of a Strengthening Exercise Program with EMG Biofeedback to Correct Patellar Alignment and Reduces Knee Pain in Women with Patella femoral Pain Syndrome

**Public title**

Training Effect with EMG Biofeedback on Patella femoral Pain Syndrome

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

Inclusion Criteria 1. Being female 2. Having the age range from 18 to 30 3. Having a history of chronic pain in the anterior region of the right knee for more than three months 4. Getting a minimum score of three based on the VAS questionnaire 5. Having pain in at least two activities such as going up the stairs, going down the stairs, squatting, sitting on knees, bending the knee more than 90 degrees for a long time, running, and jumping Exclusion Criteria 1. Having a history of knee pathology except PFP 2. Having a previous knee injury or surgery 3. Using anti-inflammatory drugs 4. Participating in Physical therapy sessions for lower limbs in the last three months 5. Having neuromuscular disorders which affect the individual's movement 6. Being pregnancy

**Age**

From 18 years old to 30 years old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 22

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Hamedan University of Medical Sciences and Health Services

**Street address**

University of Medical Sciences and Health Services,

Sahid Fahmideh St., Hamedan

**City**

Hamedan

**Postal code**

65178

**Approval date**

2014-11-23, 1393/09/02

**Ethics committee reference number**

p/16/35/9/5838

**Health conditions studied****1****Description of health condition studied**

Patello femoral disorders

**ICD-10 code**

M22.2

**ICD-10 code description**

Patello femoral disorders

**Primary outcomes****1****Description**

Q angle

**Timepoint**

Before intervention and 6 weeks after intervention

**Method of measurement**

Clinical evaluation

**2****Description**

Congruance angle

**Timepoint**

Before intervention and 6 weeks after intervention

**Method of measurement**

X-Ray

**3****Description**

Tilt angle

**Timepoint**

Before intervention and 6 weeks after intervention

**Method of measurement**

X-Ray

**Secondary outcomes****1****Description**

Pain

**Timepoint**

Before intervention and 6 weeks after intervention

**Method of measurement**

VAS questionnaire

## Intervention groups

### 1

#### Description

Intervention group 1: Strengthening Exercises for knee extensors These exercises were performed in both experimental groups (I and II) equally. The control group remained sedentary. The aim of these exercises were to increase the strength of the vastus medialis more than that of the vastus lateralis. Exercises were performed within 18 session with 3 sessions (1.5 hours each session) per week, lasting for 6 weeks. In the first week, each session were including 3 sets of 10 repetitions (10 seconds each repetition) and the intensity of exercises were increased so that it reached to 5 sets of 30 repetitions at the last week.

#### Category

Other

### 2

#### Description

Intervention group 2: Biofeedback. During the exercises, individuals in one of the experimental groups (Experimental I) received biofeedback about the electrical activity of vastus medialis and lateralis. The second experimental group, as well as the control group did not receive any biofeedback. This biofeedback was including an online figure about the peak electromyography signals of the vastus medialis and lateralis muscles online during the exercise and the subject was advised to change her foot position so that the peak value of electrical activity of the target muscle (Vastus medialis) had the largest possible difference with the other muscle.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahrekord University

##### Full name of responsible person

Mohammad Faramarzi, Research Vice President, Associate Professor of Physical Education

##### Street address

Shahrekord University, Rahbar Blvd., Shahrekord

##### City

Shahrekord

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bu\_Ali Sina University

##### Full name of responsible person

Hassan Khotanlou, Research Vice President, Bu\_Ali Sina University

##### Street address

Faculty of Physical Education and Sport Sciences, Bu\_Ali Sina University, Hamedan

##### City

Hamedan

##### Grant name

-

##### Grant code / Reference number

-

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Bu\_Ali Sina University

##### Proportion provided by this source

100

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Bu-Ali Sina University

##### Full name of responsible person

Banafsheh Mohammadi

##### Position

Ph.D. student

##### Other areas of specialty/work

##### Street address

No 2, Mojahedan St, Mo'allem Blvd, Shahrekord, Iran

##### City

Shahrekord

##### Postal code

8814871511

##### Phone

+98 38 3334 8182

##### Fax

+98 38 3232 0361

##### Email

banafsheh.mohammadi@yahoo.com

##### Web page address

-

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Bu\_Ali Sina University

##### Full name of responsible person

Nader Farahpour

##### Position

Professor

**Other areas of specialty/work**

**Street address**

Faculty of Physical Education and Sport Sciences,  
Bu\_Ali Sina University, Hamedan

**City**

Hamedan

**Postal code**

65178-38695

**Phone**

+98 8108138292616

**Fax**

+98 81 3838 1422

**Email**

naderfarahpour1@gmail.com

**Web page address**

www.basu.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Bu\_Ali sina

**Full name of responsible person**

Banafsheh Mohammadi

**Position**

Ph.D. student

**Other areas of specialty/work**

**Street address**

No 2, Mojahedan St, Mo'allem Blvd, Shahrekord, Iran

**City**

Shahrekord

**Postal code**

8814871511

**Phone**

+98 38 3334 8182

**Fax**

+98 38 3232 0361

**Email**

banafsheh.mohammadi@yahoo.com

**Web page address**

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**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*