

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of biofeedback on pain relief and function in patients with patellofemoral syndrome

Protocol summary

Study aim

Suggest a more effective treatment method to strengthen muscles, improve function and reduce pain in patients with patellofemoral syndrome

Design

Randomized, Double-blind, clinical trial with two parallel groups (control and intervention)

Settings and conduct

Informed consent will be obtained from patients before entering the study. Demographic information of all patients including age, sex, BMI, duration of illness was first collected and goniometer tests, VAS, KUJALA and SF36 questionnaires and quadriceps muscle range of motion and thigh diameter before rehabilitation were assessed by the Physical Medicine and Rehabilitation resident. After 3 months, the rehabilitation program will re-evaluate all the tests and the level of satisfaction.

Participants/Inclusion and exclusion criteria

No evidence of other injuries inside or outside the knee joint Normal range of motion of knee No history of knee trauma, intra-articular injection or surgery Do not use non-steroidal anti-inflammatory drugs for 15 days before starting treatment Full collaboration to conduct the study

Intervention groups

Strengthen knee stabilizer muscles including quadriceps, gastrocnemius and soleus, hamstrings, knee abductors and adductors Routine isometric exercises of each muscle, in the form of quadratic isometric contraction in full extension, hamstring at 90 degrees, plantar flexors in neutral position and adductors and abductors in sitting position via biofeedback For 4 weeks three times a week with 30-minute sessions with occupational therapist supervision and sham biofeedback for the control group.

Main outcome variables

Pain intensity; Quality of Life; Satisfaction rate; Daily performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180804040685N4**

Registration date: **2022-02-09, 1400/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-09, 1400/11/20**

Update count: **0**

Registration date

2022-02-09, 1400/11/20

Registrant information

Name

Hamid Reza Fateh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2110

Email address

hr-fateh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of biofeedback on pain relief and function in patients with patellofemoral syndrome

Public title

Evaluation of the effectiveness of biofeedback in patients with patellofemoral syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of unilateral patellofemoral syndrome based on at least 5 of 7 symptoms There is no evidence of other injuries intra- and extra-articular of knee joint, which can be determined by physical examination and radiographic evaluation Normal range of motion of the knee as measured by a goniometer No history of knee trauma, intra-articular injection or surgery Do not use nonsteroidal anti-inflammatory drugs for 15 days before starting treatment Full collaboration to conduct the study

Exclusion criteria:

Having a pain score less than 3 on a numerical scale History of knee locking and patella dislocation Osteoarthritis or arthritis of the knee and any abnormal radiography of the knee Joint infection and knee ligamentous laxity History of previous knee physiotherapy, knee surgery, and knee injuries and bruises Genu valgum, Osgood-Schlatter disease, and any other pathological disease Any other treatment for patellofemoral syndrome during the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method will be used to maintain the balance between the intervention and control groups. In each block, 6 people will be in the study group as 3 people and 3 people in the control group. How to assign people in each group will be done using a table of random numbers read from top to bottom

Blinding (investigator's opinion)

Double blinded

Blinding description

According to the patients are in two groups, A and B; group A are patients who after connecting the biofeedback device are taught how to perform exercises and how the device works by changing shapes and playing games. Group B are patients who, after connecting the biofeedback device are taught only how to do exercise and do not see how the device works, and only a game is being played in front of them that they do

not know is related to exercise and muscle contraction. The device is connected to patients by a trained occupational therapist who is aware of how patients are coded according to the randomization formula. Another occupational therapist performs an initial evaluation of the table of variables in patients before and after biofeedback, knowing only the names of the patients and the patient's belonging to group (A or B). Therefore, the study is the double blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Jalal Ale-Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1417863181

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.916

Health conditions studied

1

Description of health condition studied

patellofemoral pain syndrome

ICD-10 code

M22.2X

ICD-10 code description

Patellofemoral disorders

Primary outcomes

1

Description

Pain intensity

Timepoint

Before the intervention, immediately and 3 months after the intervention

Method of measurement

Visual Analog Scale

2

Description

Satisfaction rate

Timepoint

Immediately and three months after the intervention

Method of measurement

Satisfaction rate questionnaire

3

Description

Quality of life

Timepoint

Before the intervention, immediately and 3 months after the intervention

Method of measurement

SF36 Questionnaire

4

Description

Daily performance

Timepoint

Before the intervention, immediately and 3 months after the intervention

Method of measurement

Kujala scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Informed consent will be obtained from patients before entering the study. Demographic information of all patients including age, sex, BMI, duration of the disease is first collected and goniometer tests, VAS and KUJALA and SF36 questionnaires and quadriceps muscle range of motion and thigh diameter are evaluated before rehabilitation. Then, to strengthen the stabilizer muscles of the knee, biofeedback is performed three times a week for 4 weeks with 30-minute sessions with the supervision of an occupational therapist. Immediately after 3 months of the rehabilitation program, the tests and the level of satisfaction are evaluated again. The evaluator and the patients are not informed about the groups and divisions. As a result, double-blinded randomization is performed for study.

Category

Rehabilitation

2

Description

Control group: All assessments and rehabilitation interventions are the same as the intervention group. The only difference is the use of sham-biofeedback

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Ahmad Reza Jamshidi

Street address

Jalal Ale-Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8822 5880

Email

hr-fateh@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6405 3491

Email

deanmed@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Hamid Reza Fateh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Jalal-Al-Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8940 2110

Email

hr-fateh@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Hamid Reza Fateh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Jalal Ale-Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2110

Email

hr-fateh@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Hamid Reza Fateh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Jalal Ale-Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2110

Email

hr-fateh@tums.ac.ir

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient privacy

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

Undecided - It is not yet known if there will be 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 data can be shared after patient are not going to be identified

When the data will become available and for how long

6 months after the end of the study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in related studies

From where data/document is obtainable

Corresponding Author

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

By email

Comments