Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 notion 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-arthicular 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