Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Graded Sensorimotor Imagery on pain and disability of patients with Patellofemoral Pain Syndrome – Randomized Clinical Trial

Protocol summary

Study aim

The aim of this study is to determine whether graded sensory-motor imagery has an effect on the improvement of pain and disability in patients with patellofemoral pain syndrome. And if it has an effect, is its effect clinically significant.

Design

Two arm parallel group randomized clinical trial with blinded assessor on 72 patients. Sealedenvelop.com is used for randomization.

Settings and conduct

The patients are referred by the orthopedist to the physiotherapy department of Omid Clinic and if they meet the inclusion and exclusion criteria and consent to participate in the research project, they are evaluated by a third party who does not know about the treatment received by the patients. Then, based on the group in which they are classified, they receive 18 sessions of relevant treatments. After the end of the sessions, they are re-evaluated in order to see the effect of the considered treatment.

Participants/Inclusion and exclusion criteria

People aged 18 to 45 years who experience pain in the front of the knee during movements that exert compressive force on the knee in the last 3 months, the intensity of which is at least 3.5 and a maximum of 7.4 out of 10 based on the VAS scale, and have not received physical therapy in the last 6 months. Also, they have no history of trauma to knee structures, surgery or osteoarthritis in the lower limbs, rheumatology and neurological diseases, low back pain with/without referred pain to the leg, and Cognitive and psychological imbalance.

Intervention groups

Participants in both groups receive electrotherapy, manual therapy, and therapeutic exercises. Additionally, the intervention group also receives left-right discrimination, graphesthesia, motor imagery, and mirror visual feedback.

Main outcome variables

Primary outcome measure: Pain intensity Secondary outcome measure: Disability; Tactile Acuity; Central Sensitization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240613062111N1**
Registration date: **2024-08-10, 1403/05/20**
Registration timing: **prospective**

Last update: **2024-08-10, 1403/05/20**
Update count: **0**

Registration date

2024-08-10, 1403/05/20

Registrant information

Name

Maryam Abbaszadeh-Amirdehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 4941

Email address

m.abbaszadeh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-05, 1403/06/15

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Graded Sensorimotor Imagery on pain and disability of patients with Patellofemoral Pain Syndrome – Randomized Clinical Trial

Public title
The effect of Graded Sensorimotor Imagery in Patellofemoral Pain Syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-45 years Increase in pain with at least two of the following movements: squatting, going up and down stairs, running, prolonged sitting, kneeling, jumping and landing Positive Clark's test (method: guide the patient's patella downwards. Then ask the patient to perform quadriceps contraction. The presence or exacerbation of pain is considered a positive test.) The patient has had pain in front of his knee for at least the last 3 months. The intensity of the patient's pain based on the VAS scale should be at least 3.5/10 and at most 7.4/10. They have not received physiotherapy in the past 6 months.
Exclusion criteria:
History of trauma, meniscus or ligament injury, or patellar tendinopathy Osteoarthritis in any of the lower limb joints History of Rheumatic or neurological diseases Lower back pain with/without referred pain to the leg History of surgery in any of the lower limbs Cognitive and psychological imbalance affecting the individual's functioning and perception.
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample size of this study will be 72 people, who are randomly divided into 36 participants in the intervention group and 36 participants in the control group. The block random allocation method was designed by the methodologist using website Sealedenvelop.com. The number of considered blocks is 4. The random allocation list will only be available to the first supervisor. To conceal the random allocation process, the type of intervention (intervention group or control) will be written on 74 paper cards and placed inside opaque paper envelopes. Only the first supervisor will be aware of the corresponding codes. The order of the cards will be arranged based on the randomization list in the box. When the questioner (student/executive) declares the eligibility of the sample, the first supervisor will provide them with the paper envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor is a third party who is unaware of the random allocation process and the type of intervention performed. A statistician who is separate from the study process and is unaware of all the procedures that have been carried out will be used for data analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganj afrooz Ave.
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶۴۷۷۴۵
Approval date
2024-06-10, 1403/03/21
Ethics committee reference number
IR.MUBABOL.HRI.REC.1403.029

Health conditions studied

1

Description of health condition studied
Patellofemoral Pain Syndrome
ICD-10 code
M22.4
ICD-10 code description
Chondromalacia patellae

Primary outcomes

1

Description
Pain Intensity

Timepoint
Before starting and after the end of 6 weeks of intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Disability
Timepoint
before the beginning and after the end of 6 weeks of intervention
Method of measurement
Anterior Knee Pain Questionnaire (Kujala)

2

Description
Tactile Acuity
Timepoint
before the beginning and after the end of 6 weeks of intervention
Method of measurement
caliper

3

Description
Central Sensitization
Timepoint
before the beginning and after the end of 6 weeks of intervention
Method of measurement
Central Sensitization Inventory Questionnaire

Intervention groups

1

Description
Control group: Electrotherapy: Initially, the patient receives TENS current for 20 minutes. 4 electrodes are placed around the knee at least 1 inch apart. Current settings will be 100-150 PPS pulse frequency and 50-80 microsecond pulse duration, and the current intensity will be increased to the patient's tolerance level. Manual Therapy: The therapist then applies two manual techniques: medial glide of the patella and medial tipping of the patella. Therapeutic exercise: includes stretching and strengthening exercises. a) Stretching: Stretching is performed for the hamstring, quadriceps, and gastrocnemius muscles. Stretching exercises are performed for each muscle 3 times and each time for 30 seconds. b) Strengthening: Since studies have shown that performing hip and knee exercises simultaneously have better effects compared to only knee exercises, and those hip muscles that are weakened in patients with patellofemoral pain syndrome are the abductor and extensor muscles. Exercises targeting to this group of muscles are also included in the patient's exercise program. [1- Strengthening the hip extensors and abductors (side-lying) - Strengthening the quadriceps (Quadriceps Setting – SLR – terminal knee extension) (two sets of 10-20 repetitions depending on the patient's condition)] To progress these exercises, after 2 weeks, when the patient can perform the exercises without pain and fatigue, weight-bearing exercises will continue. [2- Strengthening the hip extensor and abductor muscles (single leg on the non-involved leg) - strengthening the quadriceps muscle (standing) (three sets with 8-12 repetitions depending on the patient's condition)] these exercises are also followed for two weeks or until the patient reaches a level where they can perform these exercises correctly without pain and fatigue, we enter the next stage. 3- Lunge - Standing wall slide (three sets with 8-12 repetitions depending on the patient's condition)]. The frequency of all exercises is twice a day.
Category
Rehabilitation

2

Description
Intervention group: In addition to the treatment of the control group, patients in the intervention group also receive the following interventions. These exercises will be performed three days a week (every other day) under the supervision of a therapist. In the first two weeks, they receive left and right discrimination exercises. For this exercise, the Recognise™ Knee application is used. In this exercise, 20 images (each image lasts for five seconds) are randomly shown to the person, and they must identify whether it is the right or left knee without focusing on their knees. At first, the patient is explained about how to perform this intervention, and after making sure that they are fully justified, the intervention begins. Basic, Vanilla and Context modes of this application are used to progress the practice from simple to complex. At each level, they can enter the next level by achieving more than 80% accuracy and a response time of 1.5-2.5 seconds. This exercise will be done once a day and every other day under the supervision of a therapist. In the second two weeks, motor imagery exercises are performed. To perform this exercise, participants must imagine themselves (not someone else) in a particular position or movement. In order to do this, a video of the desired activity will be shown to the patient, they are asked to mentally review it and focus on performing the movement correctly. This exercise starts with activities that the patient feels more comfortable with and progresses towards activities that are more difficult for them. Initially, to avoid provoking pain, they are asked to imagine the non-involved limb in the said position or movement, and then perform this mental exercise for the involved side. Positions that the patient is asked to visualize include: sitting with knees bent, walking, descending stairs, ascending stairs, squatting, and running. Furthermore, these exercises begin in a quiet environment and can later be performed in a more crowded environment. Each movement is visualized 10 times in five double sets with 30 seconds of rest between each set. Additionally, in the second two weeks, we also

start Graphesthesia to improve the patient's sensory performance. Patients are asked to keep their eyes closed and use their sense of touch to recognize what is randomly written on the skin around the knee. Initially, we start with letters and single-digit numbers written in large size at a slow writing speed. The progression of this exercise involves increasing the writing speed, reducing the size of the written characters, and creating combinations of up to three letters. In the third two weeks, we use mirror for visual feedback. For this purpose, while the patient is sitting on the edge of a bed, we place a portable mirror between his legs so that the painful limb is behind the mirror and the other limb is in front of it. Then we ask the patient to lean forward to see the reflection of the leg in front of the mirror and focus on it until he feels comfortable. Then we ask him to extend both legs; the painful limb only to its point of pain and the non-painful limb to its full range. This exercise continues until the patient achieves full extension in the painful leg. Then we use weights to progress the exercise. Also, the patient performs lunge and standing wall slide exercises in front of the mirror. This exercise lasts at least 5 and at most 10 minutes.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid clinic

Full name of responsible person
Maryam Abbaszadeh Amirdehi

Street address
Omid clinic, West side of Ayatollah Rouhani hospital, Ganj Afrooz Ave.

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶۴۴۷۷۵۴

Phone
+98 11 3219 9592

Fax
+98 11 3220 7751

Email
m.abbaszadeh@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Mehdi Rajabnia

Street address
Babol University of Medical Sciences, Ganj Afrooz Ave.

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۵۴

Phone
+98 11 3219 7667

Fax
+98 11 3219 7667

Email
research@mubabol.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Maryam Abbaszadeh-Amirdehi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran

City
Babol

Province
Mazandaran

Postal code
4774547176

Phone
+98 11 3219 4941

Fax
+98 11 3219 4945

Email
m.abbaszadeh@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Maryam Abbaszadeh-Amirdehi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran

City
Babol

Province
Mazandaran

Postal code
4774547176

Phone
+98 11 3219 4941

Fax
+98 11 3219 4945

Email
m.abbaszadeh@mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Maryam Abbaszadeh-Amirdehi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran

City
Babol

Province
Mazandaran

Postal code
4774547176

Phone
+98 11 3219 4941

Fax
+98 11 3219 4945

Email
m.abbaszadeh@mubabol.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Data including main, confounder and demographic outcomes are shared while maintaining the principle of anonymity.

When the data will become available and for how long
Access to the data will begin after the results are published.

To whom data/document is available
Researchers working in the relevant field.

Under which criteria data/document could be used
Data from this study are accessible for use in systematic review articles.

From where data/document is obtainable
Requests for data should be sent to the e-mail of principal investigator, Dr. Maryam Abbaszadeh, at m.abbaszadeh@mubabol.ac.ir.

What processes are involved for a request to access data/document
After receiving a data request, his request will be reviewed by principal investigator, and if eligible, the requested information will be sent to the applicant.

Comments