

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects addition of patient education to hip and knee exercise compared to hip and knee exercise only on the pain of patient with patellofemoral pain syndrome: A randomized clinical trial

#### Protocol summary

##### Study aim

A review of the additional effects of patient-specific training along with knee and hip exercises compared to knee and hip exercises alone.

##### Design

A clinical trial with a control group, an intervention group, without blinding, randomized by block method using sealed envelopes, including three evaluations before the start of the treatment, immediately after the end of the treatment (4 weeks), 2 months after the end of the treatment on 30 patients. For randomization, the table of random numbers from [www.randomization.com](http://www.randomization.com) was used.

##### Settings and conduct

The assessment and treatment of the control group and the intervention group will be carried out in a private center.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 - 45 years old Self-reported anterior knee pain when performing at least two of the following activities: prolonged sitting, squatting, kneeling, running, ascending and descending stairs, jumping and landing Self-reported anterior knee pain with insidious onset lasting at least 3 months VAS  $\geq$  3 Exclusion criteria: Trauma on the knee Patellar dislocation or subluxation Meniscal injury, ligament instability or patellar tendinopathy Osteoarthritis in any lower limb joint History of surgery on any lower limb joint Rheumatic or neurologic disease Physiotherapy treatment for PFP during the preceding 6 months History of current or past psychosis

##### Intervention groups

In the control group, patients receive physical therapy including therapeutic exercise of hip and knee muscles in 10 sessions and each session lasts 30 to 35 minutes by the therapist. In the intervention group, after receiving physiotherapy including hip and knee muscle training in

10 sessions for 30-35 minutes in each session, the patients will receive specific training by the therapist for 4-6 minutes in each session, for 8 sessions.

##### Main outcome variables

pain measurement using Visual Analog Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240713062427N1**

Registration date: **2024-08-14, 1403/05/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-08-14, 1403/05/24**

Update count: **0**

##### Registration date

2024-08-14, 1403/05/24

##### Registrant information

##### Name

Fahime Ghorbani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2024-07-19, 1403/04/29

##### Expected recruitment end date

2026-07-20, 1405/04/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects addition of patient education to hip and knee exercise compared to hip and knee exercise only on the pain of patient with patellofemoral pain syndrome: A randomized clinical trial

**Public title**

Effects addition of patient education to hip and knee exercise on the pain of patient with patellofemoral pain syndrome

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients between 18 and 45 years old. Self-reported anterior knee pain (unilateral or bilateral) when performing at least two of the following activities: prolonged sitting, squatting, kneeling, running, ascending and descending stairs, jumping and landing. Self-reported anterior knee pain with insidious onset lasting at least 3 months. Self-reported pain in the previous month should be at least 30 mm on a VAS scale of 100 mm.

**Exclusion criteria:**

Report of anterior knee pain caused by knee injury. History report of patellar dislocation. History of surgery in any lower limb joint. Report any history of meniscus damage, ligament instability or patellar tendinopathy. History of osteoarthritis in any lower limb joint. Rheumatic or neurological disease reported by the patient. Physiotherapy treatment for patellofemoral pain during the previous 6 months. History of current or past psychosis, major depressive episode, attempted suicide, post-traumatic stress disorder, bipolar disorder, manic episode, or substance dependence.

**Age**From **18 years** old to **45 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were divided into two groups of knee and hip muscle therapeutic exercise alone and knee and hip muscle therapeutic exercise combined with specific training by a block randomization method, using a closed envelope method by a person who is not involved in any of the intervention and evaluation stages. are divided The block random allocation method will be used with a

volume of 4. All possible permutations of 4 will be listed in two groups. Permutations 1 to 6 are as follows, where A is the intervention group and B is the control group: 1- AABB 2-ABAB 3-BAAB 4-BABA 5-BBAA 6- ABBA Then, from the table of random numbers with a random starting point, 6 numbers between 1 and 6 will be randomly selected (or by using the software or sitecom (randomize.. for example, if the 6 random numbers obtained are 3 5 4 3 4 6 , it will mean that the first four people will be assigned the same as block 3, the second four people will be assigned the same as block 5, etc. In this study, blinding includes a physiotherapist colleague who performs the evaluation before and after the treatment, in addition to the person who is in charge of data analysis. Before the intervention, immediately after the end of the intervention (4 weeks) and 8 weeks (two months) after the end of the physiotherapy sessions, another physiotherapist who will not know about the way of grouping and conducting the study will evaluate the patients in terms of the desired parameters.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In addition to the hip and knee treatment program (control group), patients receive 8 training sessions in person by a physiotherapist. Each training session is provided one-on-one and exclusively between the patient and the physiotherapist, each training session takes about 4-6 minutes. The first session is conducted using the history and physical examination form with the aim of collecting some information about the patient's pain, location of pain, the most painful daily activity, pain during active movements of the knee (Flexion and Extension), understanding the reason for knee pain and treatment expectations. . Based on this information, special training sessions are designed according to the characteristics of each patient. For example, fear of movement and fear of pain are important psychological factors in analgesia patients, the aim is to investigate these factors during intervention sessions. The content is included in the training sessions using explanation, display of images and text. Progress will be made in each session if the therapist ensures the patient's understanding of the material discussed. The content of the training includes: 1. The cause and causes of patellar pain (for example, the active and passive structures of the knee joint, the importance of the alignment of the hip joint and its muscles) 2. Pain management strategies (for example, how to move better during activity daily exercises, prevention of knee valgus while standing, walking, going up and down the stairs, changing from sitting to standing, riding a bicycle, etc.) 3. How to modify physical activity using strategies Speed and load management, for example, reducing the load or physical activities if necessary (feeling pain above 5 out of 10). 4. Answers to each patient's questions. The training content is prepared using previous studies and presented to the

patient.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of School of Paramedical Sciences and Health School

##### Street address

School of Paramedical Sciences and Health School

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948964

#### Approval date

2024-04-27, 1403/02/08

#### Ethics committee reference number

IR.MUMS.FHMPM.REC.1403.035

## Health conditions studied

### 1

#### Description of health condition studied

patellofemoral pain syndrome

#### ICD-10 code

M22.2

#### ICD-10 code description

Patellofemoral disorders

## Primary outcomes

### 1

#### Description

Visual Analog Scale (VAS)

#### Timepoint

They will be measured at the beginning of the study (before the intervention), immediately after the end of the treatment sessions (4 weeks) and two months after the end of the sessions.

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

The Pain Catastrophizing Scale (PCS)

#### Timepoint

They will be measured at the beginning of the study (before the intervention), immediately after the end of

the treatment sessions (4 weeks) and two months after the end of the sessions.

#### Method of measurement

13-item questionnaire of fear of pain (Pain Catastrophizing Scale)

### 2

#### Description

The Tampa scale for kinesiophobia (TSK)

#### Timepoint

They will be measured at the beginning of the study (before the intervention), immediately after the end of the treatment sessions (4 weeks) and two months after the end of the sessions.

#### Method of measurement

17-item questionnaire of fear of movement (The Tampa scale for kinesiophobia)

### 3

#### Description

The result of measurement of knee functional limitation by the patient

#### Timepoint

They will be measured at the beginning of the study (before the intervention), immediately after the end of the treatment sessions (4 weeks) and two months after the end of the sessions.

#### Method of measurement

13-item questionnaire of Kujala Patellofemoral Scale

### 4

#### Description

Outcome of treatment effectiveness

#### Timepoint

They will be measured immediately after the end of the treatment sessions (4 weeks) and two months after the end of the sessions.

#### Method of measurement

The 7-point Likert global rating of change scale (GROC)

## Intervention groups

### 1

#### Description

Intervention group: In addition to hip and knee exercise program (control group), patients receive 8 training sessions in person by a physiotherapist. Each training session is provided one-on-one and exclusively between the patient and the physiotherapist, each training session takes about 4 to 6 minutes. The first session is conducted using the history and physical examination form with the aim of collecting some information about the patient's pain, location of pain, the most painful daily activity, pain during active movements of the knee (Flexion and Extension), understanding the reason for knee pain and treatment expectations. Based on this information, special training sessions are designed according to the characteristics of each patient. For example, fear of movement and fear of pain are

important psychological factors in analgesia patients, the aim is to investigate these factors during intervention sessions. The content is included in the training sessions using explanation, display of images and text. Progress will be made in each session if the therapist ensures the patient's understanding of the material discussed. The content of the training includes: 1. The cause and causes of patellar pain (for example, the active and passive structures of the knee joint, the importance of the alignment of the hip joint and its muscles) 2. Pain management strategies (for example, how to move better during activity (daily activities, prevention of knee valgus while standing, walking, going up and down the stairs, changing from sitting to standing, cycling, etc.) 3. How to modify physical activity using strategies speed and load management, for example, load reduction or physical activities if necessary (pain feeling above 5 out of 10) 4. Answering the questions of each patient. The content of the training is prepared using previous studies and presented to the patient.

#### **Category**

Treatment - Other

## **2**

#### **Description**

Control group: Four weeks of hip and knee exercises with specific goals are divided into 3 parts: in the first week, the emphasis is on improving the control of knee and hip joint muscle movements, followed by the goal of increasing hip and knee muscle strength in the next 2 weeks, and so on. It will improve motor control. Finally, in the fourth week, strength will increase and the exercises will become more difficult using weight bearing exercises. In addition, patients will be told how to prevent lower limb abnormalities during exercise and how to perform exercises correctly by receiving feedback and performing exercises in front of a mirror. Exercises will emphasize stretching and strengthening the muscles of the knee structure (such as the quadriceps muscle, etc.) and the muscles of the hip structure (such as the muscles: Abductor Hip, Lateral rotator Hip, Extensor Hip). Force during exercise is standardized at sixty to seventy percent of RM-1, which is defined as the maximum force a person can use to complete one repetition of the exercise without pain. Maximum strength is assessed during the first treatment session and reviewed weekly for needed changes. Weight bearing exercises start with weights and based on the patient's tolerance, progress is gradually made on a weekly basis according to the patient's ability (for example: intensity, type of exercise, repetition or technique, etc.). These criteria are based on It is the protocol of previous studies. Although exercises using elastic resistance will be standardized based on the maximum resistance that each patient can use and complete 10 repetitions of the exercise, the resistance will be rechecked weekly for adequacy. Hamstring, iliotibial band and gastrocnemius are performed. Stretching Hamstrings and plantar flexors ([9] SLR in arch position), Quadriceps and Iliotibial band in side lying position) includes 30 seconds of stretching with the help of a therapist for each structure. During the training, positive and encouraging feedback is given by the

therapist to encourage the participant to finish the session with as much effort as possible. The intensity of the exercises will be controlled and progressed individually by the physiotherapist. Emphasizing that the patient does not do the exercise at home should be considered.

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Private clinic

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

Fahime Ghorbani

##### **Street address**

Fahim Physiotherapy, No. 649, 3rd floor, between 41 and 43 Fallahi St., Qasim Abad

##### **City**

Mashhad

##### **Province**

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Mashhad University of Medical Sciences

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

Mohsen Tafaghodi

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Mashhad, University St., next to Hoveize Cinema, Qurashi Building, Research and Technology Vice-Chancellor

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#### **Grant name**

#### **Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

80

**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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Neda Mostafaei

**Position**

Associate Professor, Department of Physiotherapy,  
Mashhad University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Master's student

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**Other areas of specialty/work**

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

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**Latest degree**

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**Other areas of specialty/work**

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

Undecided - It is not yet known if there will be 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**

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

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

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