Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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 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 ≥ 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

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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

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

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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 Mostafaee
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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