

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparison of the effect of a course of corrective exercises with and without foot orthosis on the improvement of pain and performance of patients with patellofemoral pain syndrome.

Protocol summary

Study aim

Comparison of the effect of proximal hip-core strengthening exercises with and without foot orthosis on improving pain and performance of women with patellofemoral pain syndrome

Design

A clinical trial with the control group, with parallel groups, single-blind, randomized, on 117 patients. SNOSE will be used for randomization

Settings and conduct

The work will be done in sports clubs and orthopedic clinics. The patients will be randomly divided into three groups of 39 people using a sequentially numbered, opaque, sealed envelope (SNOSE) technique. The study will be single-blind.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1. Age range between 18 and 40 years 2. Having knee pain for at least 6 weeks or more 3. Having anterior knee pain with non-traumatic origin 4. Not having a history of injury and surgery on the spine and lower limbs 5. Exacerbation of pain with at least 2 of the following activities including running, jumping, walking on stairs, sitting for a long time, kneeling, squatting 6. Navicular drop greater than 9 mm and foot posture index greater than 6
Exclusion criteria: If they have the following, they will be excluded from the study. Knee meniscus and ligament or tendon damage, patella dislocation (patellar instability), Osgood Schlatter disease, Pelica syndrome, Larsen-Johnson syndrome, knee joint effusion.

Intervention groups

The first intervention group: Participants in this group receive hip and core proximal strengthening exercises. The second intervention group: In addition to hip and core proximal strengthening exercises, the participants of this group also will receive foot orthosis. The third intervention group: includes a group of people with

patellofemoral pain syndrome who continue their normal lifestyle and do not receive any treatment.

Main outcome variables

Pain ; Performance

General information

Reason for update

The initial number of registered participants was regardless of the amount of attrition, which is why 6 people were added to the number of participants. Also, due to the need for more time to complete the number of participants, this period was increased.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230604058380N1**

Registration date: **2023-07-28, 1402/05/06**

Registration timing: **prospective**

Last update: **2023-12-14, 1402/09/23**

Update count: **1**

Registration date

2023-07-28, 1402/05/06

Registrant information

Name

mansoureh barati ashtiani

Name of organization / entity

Gilan University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-21, 1402/05/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of a course of course of corrective exercises with and without foot orthosis on the improvement of pain and performance of patients with patellofemoral pain syndrome.

Public title

Comparison of the effect of a course of corrective exercises with and without foot orthosis on people with patellofemoral pain syndrome.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range between 18 and 40 years Having knee pain for at least 6 weeks or more Having anterior knee pain with non-traumatic origin Not having a history of injury and surgery on the spine and lower limbs Exacerbation of pain with at least 2 of the following activities including: running, jumping, walking on a hill or stairs, sitting for a long time, kneeling, squatting Clark's test is positive Navicular drop more than 9 mm A score greater than 6 from the foot posture index Pain score greater than 3 on the visual analog scale

Exclusion criteria:

Knee meniscus and ligament or tendon injury patellar dislocation (patellar instability) Osgood-Schlatter disease Celica syndrome, Larsen-Johnson syndrom knee joint effusion

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **117**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate participants to each study group by a third party who is not present in the study, sealed, numbered, and opaque envelopes will be prepared based on the number of patients. Notably, the envelope will contain a slip of paper on which the treatment will be written in coded letters (namely, ABC). Then, each participant will

randomly select an envelope like a lottery and will be allocated to one of three groups (Group I: PSEFO, Group II: PSEs, or Group III: CG) according to the code in each envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome evaluator is blind, so that he does not know how the subjects are assigned to the groups and what treatment intervention each group of subjects will receive. In this way, during the evaluation before and after the period of interventions, they do not make mistakes in their judgments in favor of a specific therapeutic intervention.

Placebo

Not used

Assignment

Parallel

Other design features

NO

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Gilan University of Medical Sciences

Street address

1st block, 13th floor, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simai Iran St., between South Flank and Zarafshan, Quds town, Tehran

City

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Province

Guilan

Postal code

1467664961

Approval date

2023-05-28, 1402/03/07

Ethics committee reference number

IR.GUILAN.REC.1402.021

Health conditions studied**1****Description of health condition studied**

Patellofemoral pain syndrome

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

pain

Timepoint

Pain measurement before and after exercises and intervention

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Disability

Timepoint

Measurement of functional before and after exercises and intervention

Method of measurement

Kujala questionnaire

2

Description

Balance

Timepoint

Measurement of functional before and after exercises and intervention

Method of measurement

Y balance test

3

Description

functional

Timepoint

Measurement of functional before and after exercises and intervention

Method of measurement

step down test at 30 second

4

Description

functional

Timepoint

Measurement of functional before and after exercises and intervention

Method of measurement

Single leg squat test

5

Description

functional

Timepoint

Measurement of functional before and after exercises and intervention

Method of measurement

bilateral squat test

6

Description

Q angle

Timepoint

Measurement of Q angle before and after exercises and intervention

Method of measurement

Measuring the angle Q with a goniometer

7

Description

Flat foot

Timepoint

Measurement before and after exercises and intervention

Method of measurement

Navicular drop

8

Description

Quality of life

Timepoint

Measurement before and after exercises and intervention

Method of measurement

Quality of life questionnaire (SF_36)

9

Description

functional

Timepoint

Measurement of functional before and after exercises and intervention

Method of measurement

anteromedial lunge test

10

Description

disability

Timepoint

Measurement disability of before and after exercises and intervention

Method of measurement

Kujala questionnaire

Intervention groups

1

Description

Intervention group: Intervention group: The first intervention group receives proximal hip and core strengthening exercises for eight weeks.

Category

Rehabilitation

2

Description

Intervention group: The second intervention group receives foot orthotics in addition to proximal strengthening hip and core exercises.

Category

Rehabilitation

3

Description

Control group: These people continue their way of life as usual.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Corrective movements center and sports clubs

Full name of responsible person

Behnaz Tabatabai

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Khoram Street, Hakim building, third floor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of guilan

Full name of responsible person

Farhad Rahmani Nia

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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

University of guilan

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

Gilan University

Full name of responsible person

mansoureh barati ashtiani

Position

Student

Latest degree

Master

Other areas of specialty/work

Corrective Exercises

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Other areas of specialty/work

Corrective Exercises

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Person responsible for updating data

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Name of organization / entity

the university of guilan

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Position

student

Latest degree

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Other areas of specialty/work

Corrective exercises

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Kilometer 5 of Qazvin Highway - Rasht, Faculty of
Physical Education and Sports, Pilan

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

No, there is no plan to publish

Study Protocol

No - There is not 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