Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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.

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 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 Exit 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)

Phone
+98 918 698 9204

Email address
manbarati1377@gmail.com

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) Osgoodschlatter 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
Rasht
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
anteromidial 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 toproximal 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
Street address
Khoram Street, Hakim building, third floor
City
Arak
Province
Markazi
Postal code
3814813685
Phone
+98 903 499 0769
Email
manbarati1377@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of guilan
Full name of responsible person
Farhad Rahmani Nia
Street address
Kilometer 5, Grand University, Qazvin-Rasht road
City
Rasht
Province
Guilan
Postal code
4199613776
Phone
+98 13 3369 0274
Email
pr@guilan.ac.ir
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
Street address
Kilometer 5 of Qazvin Highway - Rasht, Faculty of Physical Education and Sports, Pilan
City
rasht
Province
Guilan
Postal code
4199613776
Phone
+98 903 499 0769
Fax
+98 13 3369 0451
Email
manbarati1377@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Gilan
Full name of responsible person
Hasan Daneshmandi
Position
full Profesor
Latest degree
Ph.D.
Other areas of specialty/work
Corrective Exercises
Street address
Kilometer 5, Bezgarah, Qazvin, Rasht, Faculty of

Sports Sciences and Physical Education, Gilan

City
Rasht

Province
Guilan

Postal code
guilan.central.lab@g

Phone
0133369027

Email
daneshmandi_ph@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
the university of guilan

Full name of responsible person
mansoureh barati ashtiani

Position
student

Latest degree
Master

Other areas of specialty/work
Corrective exercises

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

City
rasht

Province
Guilan

Postal code
4199613776

Phone
+98 903 499 0769

Email
guilan.central.lab@gmail.com

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