Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

The effect of proximal and distal exercises along with movement pattern retraining on kinematic and kinetic variables of patients with patellofemoral pain

Protocol summary

Study aim
The Effect of Proximal and Distal Exercises Along with Movement Pattern Retraining on Kinematic and Kinetic Variables of Patients With Patellofemoral Pain

Design
Clinical trial with a control group, with parallel groups, single blind, randomized, phase 2 on 45 patients. Random Number Generator software will be used for randomization.

Settings and conduct
All tests and exercises in sports rehabilitation laboratory Bu Ali Sina University Hamedan will be performed by laboratory's official and experts, who will not be aware research process. groups will be divided in such a way that first group includes resistance exercises with proximal movement pattern retraining, second group includes resistance exercises with distal movement pattern retraining, third group will not receive any rehabilitation exercises during this period. It should be noted that evaluators will not know the purpose study and allocation groups, so our study will be one-sided blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. 20 to 60 years 2. Pain in the anterior and posterior part of the patella 3. Pain intensity 3 out of 10 on visual analog scale 4. Dynamic Valgus angle of more than 10 degrees 5. The positiveness of the step down test and Clark Exclusion criteria: 1. Having a history of injury in the last year in the lower limb area

Intervention groups
Proximal strengthening exercises with motor retraining are specific to the first group and distal strengthening exercises with motor retraining are specific to the second group. The third group, which is the control group, will not perform any rehabilitation exercises during this period.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230425057991N1**
Registration date: **2023-06-08, 1402/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-08, 1402/03/18**
Update count: **0**

Registration date
2023-06-08, 1402/03/18

Registrant information

Name
Fatemeh Ahadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 4240 4019

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of proximal and distal exercises along with movement pattern retraining on kinematic and kinetic variables of patients with patellofemoral pain

Public title
Investigating the effect of resistance training along with movement pattern retraining in femoral patellofemoral pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
20 to 60 years Pain in the anterior and posterior part of the patella for more than 6 weeks Pain intensity 3 out of 10 on the visual analog scale Dynamic valgus angle of more than 10 degrees The positiveness of the stairs descent test and Clark No injuries in the hip and ankle joints No history of surgery or neurological disease Not having a history of participating in physical therapy in the past years

Exclusion criteria:
Deformity of Upper and Lower Limbs History of Surgery or Neurological Disease Injuries Other Than Patellofemoral Pain Knee Joint Instability Use of Painkillers Participation in Physiotherapy Sessions Participation in Sports Activities

Age
From **20 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
We used Random Allocation Software for randomization. Random codes were generated in blocks 4 and 6. We used sequentially numbered sealed opaque envelopes to conceal the allocation. The third researcher, who had no role in data collection and was not aware of the study process, opened the envelopes containing the random codes and handed them to the patients. As a result, patients were randomly assigned to experimental and control groups with a rate of 1:1.

Blinding (investigator's opinion)
Single blinded

Blinding description
The second researcher who was not involved in the data collection, opened the envelopes containing random codes and delivers to the subjects. The laboratory technicians were not aware of the purpose of the present study and the groups allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
National Ethics Committee in Biomedical Research

Street address
No. 12, Motahari St. 5, Shkoufeh Alley

City
Saveh

Province
Markazi

Postal code
3914658335

Approval date
2023-04-11, 1402/01/22

Ethics committee reference number
IR.BASU.REC.1402.012

Health conditions studied

1

Description of health condition studied
Patellofemoral Pain

ICD-10 code
M99.06

ICD-10 code description
Segmental and somatic dysfunction of lower extremity

Primary outcomes

1

Description
Pain

Timepoint
The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement
The For Evaluate be Will Use Visual Analogue Scale For Pain.

Secondary outcomes

1

Description
Dynamic Knee Valgus

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Camera Will be Used to Evaluate the Dynamic Knee Valgus.

2

Description

Strength of Hip Abductor Muscles

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Manual Dynamometer will be Used to Evaluate the Strength of Hip Abductor Muscles.

3

Description

Plantar Pressure Distribution

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Foot Pressure Device Will be Used to Evaluate The Plantar Pressure Distribution.

4

Description

Pain Catastrophic

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

Catastrophic Questionnaire Will be Used to Evaluate Catastrophic.

5

Description

Static and Dynamic Balance

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

Biodex Device Will be Used to Evaluate Static and Dynamic Balance.

6

Description

Knee Flexion

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Camera Will be Used to Evaluate the Knee Flexion.

7

Description

Pelvic Drop

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Camera Will be Used to Evaluate the Pelvic Drop.

8

Description

Rear-Foot Eversion

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Camera Will be Used to Evaluate the Rear-Foot Eversion.

9

Description

Dorsiflexion

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Camera Will be Used to Evaluate the Dorsiflexion.

10

Description

Strength of Hip External Rotators Muscles

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Manual Dynamometer will be Used to Evaluate the Strength of Hip External Rotators Muscles.

11

Description

Strength of Hip Extensors Muscles

Timepoint

The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.

Method of measurement

A Manual Dynamometer will be Used to Evaluate the Strength of Hip Extensors Muscles.

12

Description
Strength of Ankle Dorsiflexors Muscles
Timepoint
The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.
Method of measurement
A Manual Dynamometer will be Used to Evaluate the Strength of Ankle Dorsiflexors Muscles.

13

Description
Strength of Foot Invertors Muscles
Timepoint
The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.
Method of measurement
A Manual Dynamometer will be Used to Evaluate the Strength of Foot Invertors Muscles.

14

Description
Kinesiophobia
Timepoint
The Timing of The Outcome Measure Will be Performed Before The Intervention and 8 Weeks After The Intervention.
Method of measurement
Tampa Questionnaire Will be Used to Evaluate Kinesiophobia.

Intervention groups

1

Description
The first intervention group: Resistance training of the thigh muscles will be done in eight weeks, three sessions a week and each session will last about 60 minutes with the presence of 50 people and under the supervision of the researcher. Training sessions will include about 10 minutes of general warm-up, 40 minutes of mentioned resistance exercises and movement retraining, and 10 minutes of cooling down in the form of stretching exercises. The resistance training program is based on the Fukuda 2010 training program and the motor retraining training program is based on the B Noehren training program.
Category
Rehabilitation

2

Description
The second intervention group: Resistance exercises for the ankle muscles will be performed in eight weeks, three sessions a week and each session will last about 60 minutes with the presence of 50 people and under the supervision of the researcher. Training sessions will include about 10 minutes of general warm-up, 40 minutes of mentioned resistance exercises and movement retraining, and 10 minutes of cooling down in the form of stretching exercises. The resistance training program is based on the training program of Carsten M. Mølgaard 2017 and the motor retraining training program is based on the training program of Roper 2016.
Category
Rehabilitation

3

Description
Control group: No Intervention
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthopedic Clinics of Hamadan Province
Full name of responsible person
Fatemeh Ahadi
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No. 12, Motahari St. 5, Shkoufeh Alley
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3914658335
Phone
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bu ali Sina University, Hamedan
Full name of responsible person
Dr. Ali Yalfani
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Phone
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Email
f.ahadi@phe.basu.ac.ir
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
There is no source of financial support.

Proportion provided by this source
1

Public or private sector
Private

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
دانشگاه بوعلی سینا همدان

Full name of responsible person
Dr. Ali Yalfani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

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Hamedan, Shahid Mostafa Ahmadi Roshan Blvd., Bu Ali Sina University, Faculty of Physical Education and Sports Sciences

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Sharing plan

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

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data and documents can be shared, but with the non-identification of people and the preservation of private information of subjects

When the data will become available and for how

long

The Results of This Study Will Be Available In Journals 3 Months After Publication.

To whom data/document is available

The Results of The Studies Will Be Accessible to All Individuals in The Community Without Any Restrictions.

Under which criteria data/document could be used

The presented documentation can be used for the treatment of patellofemoral pain. These interventions are applicable if they are prescribed and supervised by a physiotherapist.

From where data/document is obtainable

E-mail Fatemeh Ahadi f.ahadi@phe.basu.ac.ir

What processes are involved for a request to access data/document

When the applicant provides documents for her field of work related to the subject of the thesis and in case of a reasonable request and a commitment not to misuse the data of this research, the data will be sent to her for 1 working week.

Comments