

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effects of hip and knee strengthening with internal and external instruction exercises on pain and performance in patients with patellofemoral pain syndrome

Protocol summary

Study aim

Comparison of the effects of hip and knee strengthening with internal and external instruction exercises on pain and performance in patients with patellofemoral pain syndrome

Design

Randomized control trial , with parallel groups, Double blinded, Randomized

Settings and conduct

Seventy five patients with patellofemoral pain syndrome who met the inclusion criteria will be allocated randomly into three intervention groups .Treatment in all three groups will be three times a week for 6 weeks totally In each group, the patients will warmed up for 10 minutes and then will practiced for 30 minutes. Finally, 5 minutes cool down will be applied.

Participants/Inclusion and exclusion criteria

Inclusion criteria:1-they had anterior knee pain for at least 3 months 2-reported increase pain for 2 or more activities These activities included ascending and descending stairs, squatting, kneeling, long periods of sitting 3- pain on palpation of the medial and/or lateral facet of the patella.4- positive Clarc Test Exclusion criteria: neurological disorder; injury to the hip, ankle, or lumbosacral region; rheumatoid arthritis; heart condition; previous surgery involving the lower extremities; or if they were pregnant. other knee pathologies, such as patellar instability, patellofemoral dysplasia, meniscal or ligament tears, osteoarthritis, or tendinopathies,those who exhibited a leg length difference of more than 1 cm when measured in supine, from the anterior superior iliac spine to the medial malleolus.

Intervention groups

1- Hip and Knee strengthening with internal instruction exercise 2-Hip and Knee strengthening with external instruction exercise 3- Hip and Knee strengthening exercise alone

Main outcome variables

pain, Function, muscle strength of the Hip abductors and external rotators, dynamic knee valgus angle, lower limb kinematics during walking

General information

Reason for update

-

Acronym

PFPS

IRCT registration information

IRCT registration number: **IRCT20150503022068N3**

Registration date: **2020-01-05, 1398/10/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-25, 1399/03/05**

Update count: **1**

Registration date

2020-01-05, 1398/10/15

Registrant information

Name

amir letafatkar

Name of organization / entity

kharazmi university

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 8084

Email address

amir.letafatkar@khu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-03-03, 1398/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of hip and knee strengthening with internal and external instruction exercises on pain and performance in patients with patellofemoral pain syndrome

Public title

Comparison of the effects of hip and knee strengthening with internal and external instruction exercises on pain and performance in patients with patellofemoral pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

they had anterior knee pain for at least 3 months reported increase pain for 2 or more activities These activities included ascending and descending stairs, squatting, kneeling, long periods of sitting pain on palpation of the medial and/or lateral facet of the patella. positive Clarc Test

Exclusion criteria:

neurological disorder injury to the hip, ankle, or lumbosacral region heart condition previous surgery involving the lower extremities if theywere pregnant other knee pathologies, such as patellar instability,patellofemoral dysplasia, meniscal or ligament tears those who exhibited a leg length difference of more than 1 cm when measured in supine, from the anterior superior iliac spine to the medial malleolus. osteoarthritis, or tendinopathies

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are selected according to the criteria for entering the research and are randomly divided into three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome evaluator, Participants, Researcher and data analyzer are kept blind. The assessor was blinded to the group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

None

Secondary Ids

empty

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

Ethics committee of Kharazmi University

Street address

Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street ,Keshvari Sport complex Tehran, Iran

City

Tehran

Province

Tehran

Postal code

-

Approval date

2019-12-15, 1398/09/24

Ethics committee reference number

IR.KHU.REC.1398.034

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

Patellofemoral pain syndrome

ICD-10 code

M22.2X

ICD-10 code description

Patellofemoral disorders

Primary outcomes**1****Description**

Pain

Timepoint

Before and after the intervention

Method of measurement

VAS

2**Description**

Function
Timepoint
Before and after the intervention
Method of measurement
Kujala questionnaire

3

Description
Muscle strength of the Hip abductors and external rotators
Timepoint
Before and after the intervention
Method of measurement
handheld dynamometer

4

Description
dynamic knee valgus angle
Timepoint
Before and after the intervention
Method of measurement
using two-dimensional motion analysis systems

5

Description
lower limb kinematics during walking
Timepoint
Before and after the intervention
Method of measurement
using two-dimensional motion analysis systems

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Thirty minutes of hip and knee strengthening each session
Category
Rehabilitation

2

Description
Intervention group: Thirty minutes of hip and knee strengthening with internal instruction exercises each session
Category
Rehabilitation

3

Description
Intervention group: Thirty minutes of hip and knee strengthening with external instruction exercises each session

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Kharazmi University Health and Wellness Center
Full name of responsible person
Fatemeh Aghakeshizadeh
Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street, Keshvari Sport complex Tehran, Iran
City
Tehran
Province
Tehran
Postal code
-
Phone
+98 21 2222 8001
Email
std_aghakeshizadefateme@khu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi University
Full name of responsible person
Amir Letafatkar
Street address
-
City
Tehran
Province
Tehran
Postal code
-
Phone
+98 21 4471 8356
Email
letafatkaramir@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kharazmi University
Proportion provided by this source
20
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

Center for Human Movement Sciences Kharazmi University

Full name of responsible person

Fatemeh Aghakeshizadeh

Position

Master student of Corrective exercise and sport injury prevention

Latest degree

Master

Other areas of specialty/work

Corrective exercise and sport injury prevention

Street address

Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street ,Keshvari Sport complex Tehran, Iran

City

Tehran

Province

Tehran

Postal code

-

Phone

+98 21 2222 8001

Fax

Email

std_aghakeshizadefateme@khu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Center for Human Movement Sciences Kharazmi University

Full name of responsible person

Fatemeh Aghakeshizadeh

Position

Master student of Corrective exercise and sport injury prevention

Latest degree

Master

Other areas of specialty/work

Corrective exercise and sport injury prevention

Street address

Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street ,Keshvari Sport complex Tehran, Iran

City

Tehran

Province

Tehran

Postal code

-

Phone

+98 21 2222 8001

Fax

Email

std_aghakeshizadefateme@khu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Center for Human Movement Sciences Kharazmi University

Full name of responsible person

Fatemeh Aghakeshizadeh

Position

Master student of Corrective exercise and sport injury prevention

Latest degree

Master

Other areas of specialty/work

Corrective exercise and sport injury prevention

Street address

Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street ,Keshvari Sport complex Tehran, Iran

City

Tehran

Province

Tehran

Postal code

-

Phone

-

Fax

Email

std_aghakeshizadefateme@khu.ac.ir

Web page address

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

Only part of the data, such as dependent variables, The average of all samples, can be shared in scientific articles.

When the data will become available and for how long

The date of access is April 2020.

To whom data/document is available

Personal information is confidential and General outcomes in paper form Available to everyone.

Under which criteria data/document could be used

Information is not available to anyone. General outcomes in paper form Available to everyone.

From where data/document is obtainable

Fatemeh Aghakeshizadeh Phone: 09142366537 Email: std_aghakeshizadefateme@khu.ac.ir

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

-

Comments

-