

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Effect of Hip Abductor and External Rotator Muscles Strengthening on Patellofemoral Pain Symptoms, Hip muscles Strength, and Lower Extremity Kinematics in Patients with Patellofemoral Pain Syndrome: A Randomized Controlled Trial

Protocol summary

Study aim

Investigating the effect of hip abductor and external rotator muscle strengthening on patellofemoral pain syndrome symptoms, hip muscles strength, and lower extremity kinematics.

Design

Randomized controlled trial with blinded outcome assessment, with a sample size of 35, restricted randomization with concealed randomization sequence

Settings and conduct

The experimental group completed hip abductor and external rotator muscles strengthening exercises for 12 weeks with thera-band, in physical therapy unit of Shahid Dastgheyb Hospital in Shiraz, Iran, for three times per week and 30 minutes per session. Every three weeks the exercise was progressed by increasing the repetitions or changing the thera-band with a more resistant one.

Participants/Inclusion and exclusion criteria

Patients with patellofemoral pain syndrome; 18-45 years old; history of having pain for at least 3 months and 3 of 10 in VAS system in daily activities; without lower extremity surgery, meniscal or ligamentus injuries, and participating in sport activities.

Intervention groups

The intervention group did hip abductor and external rotator muscles strengthening exercises by thera-band, while control group received no exercises.

Main outcome variables

pain; health status; hip abductor and external rotator muscles; lower extremity kinematics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190816044538N1**

Registration date: **2019-12-06, 1398/09/15**

Registration timing: **retrospective**

Last update: **2019-12-06, 1398/09/15**

Update count: **0**

Registration date

2019-12-06, 1398/09/15

Registrant information

Name

Narjes Jamali

Name of organization / entity

Isfahan University

Country

Iran (Islamic Republic of)

Phone

+98 71 3228 8064

Email address

narjes.jamali84@spr.ui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-01, 1398/04/10

Expected recruitment end date

2019-10-02, 1398/07/10

Actual recruitment start date

2019-07-06, 1398/04/15

Actual recruitment end date

2019-10-12, 1398/07/20

Trial completion date

2019-10-17, 1398/07/25

Scientific title

Effect of Hip Abductor and External Rotator Muscles

Strengthening on Patellofemoral Pain Symptoms, Hip muscles Strength, and Lower Extremity Kinematics in Patients with Patellofemoral Pain Syndrome: A Randomized Controlled Trial

Public title

Effect of Hip Muscles Strengthening Exercises on Anterior Knee Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with patellofemoral pain syndrome Having pain of 3 in VAS system during following activities: stair descending/ascending, prolonged sitting, running, jumping and squatting Having pain in knee joint for at least 3 months

Exclusion criteria:

Having pain less than 3 months History of lower extremity surgery Participating in exercise program Meniscal or ligamentus injury without any surgery Flat foot Prior patella dislocation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study "restricted randomization", the type of "random allocation rule", was used. With a sample size of 35 persons, 18 papers of experimental group and 18 papers of control group were put in an opaque bag and then randomly assigned to the participants without substitution, and the sequence was registered. The participants and the researcher were unaware of random sequence (Allocation concealment).

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study an expert physiotherapist, who was blind to group assignment, was invited to evaluate the variables in pre and post test stages.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University

Street address

No. 63, Shahid Gitiforouz Alley, Shahid Etemadi Ave., Sarbaz Blvd

City

Shiraz

Province

Fars

Postal code

7174834364

Approval date

2019-06-30, 1398/04/09

Ethics committee reference number

IR.UI.REC.1398.021

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 intensity during daily activities

Timepoint

Pre-intervention and after 12 weeks

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Health status

Timepoint

Pre-intervention and after 12 weeks

Method of measurement

The Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

3

Description

Hip joint muscles strength

Timepoint

Pre-intervention and after 12 weeks

Method of measurement

Hand-held dynamo meter

4

Description

Lower extremity kinematics

Timepoint

Pre-intervention and after 12 weeks

Method of measurement

2-dimensional motion analyze

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Doing hip abductor and external rotator muscles strengthening exercises with thera-band during 12 weeks, three times per week and 30 minutes per session under supervision of an expert physiotherapist

Category

Rehabilitation

2

Description

Control group: without any exercise intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dastgheyb hospital

Full name of responsible person

Narjes Jamali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University

Full name of responsible person

Dr. Rasoul Roknizadeh

Street address

Hezar Jarib Ave., Azadi Square

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7344181746

Phone

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rokni@sci.ui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University

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

Isfahan University

Full name of responsible person

Narjes Jamali

Position

Phd candidate

Latest degree

Master

Other areas of specialty/work

Physical education and sport science

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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

Not applicable

Title and more details about the data/document

All data can be shared after making the participants
unrecognizable.

When the data will become available and for how long

Start of access period, 6 months after publishing the
results

To whom data/document is available

Data will be available only to researchers working in
academic and scientific institutions.

Under which criteria data/document could be used

Data will not be accessible to other people.

From where data/document is obtainable

People can write to the following mail address to receive
the data they want: jamalinarjes84@gmail.com

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

After correspondence with the appended mail address
and confirmation of the applicant's scientific position, the
data will be made available to him/her as soon as
possible.

Comments