

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of lower limb resistance exercises with and without blood flow restriction on muscle strength, balance, and knee proprioception, in people with patellofemoral pain syndrome

Protocol summary

Study aim

The general aim is to determine the effect of lower limb strength training with and without blood flow restriction on strength, balance and knee proprioception in people with patellofemoral pain syndrome.

Design

Simple random sampling individually into two intervention groups and a control group of 36 patients

Settings and conduct

Training place: gym and training with front leg machine and leg press. Testing place: Biomechanics laboratory of Bahonar University (Biodex machine, hand dynamometer, photogrammetry)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women suffering from femoral patellofemoral pain syndrome with an age range of 18 to 40 years pain with any activity, including running, jumping, squatting, kneeling, climbing/descending stairs, or prolonged sitting; pain with patellar pressure; touching the area around the patella; and pain in sitting position with resistance to isometric knee extension Positive patellar grind (or inhibition) test exclusion criteria: Having a concomitant injury around the knee, including patellar laxity or dislocation and other causes of anterior knee pain (bursa, fat pad) having diabetes History of knee surgery in the past year If the subject does not have the necessary cooperation to do the exercises. The subject has pain during the exercises.

Intervention groups

The first group: strength exercises with 30% of maximum strength (leg extension machine and leg press machine) with blood circulation restriction Second group: strength exercises with 70% of maximum strength (leg extension machine and leg press machine) without blood circulation restrictions Control group: no training

Main outcome variables

lower limb strength training with and without blood flow

restriction on muscle strength in knee extension movement; the balance; The proprioception of people with patellofemoral pain syndrome has a different effect.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180627040251N6**

Registration date: **2023-08-01, 1402/05/10**

Registration timing: **prospective**

Last update: **2024-06-05, 1403/03/16**

Update count: **1**

Registration date

2023-08-01, 1402/05/10

Registrant information

Name

Hassan Sadeghi

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8001

Email address

hassan.sadeghi81@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-16, 1402/05/25

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of lower limb resistance exercises with and without blood flow restriction on muscle strength, balance, and knee proprioception, in people with patellofemoral pain syndrome

Public title
Comparison the Effect of lower limb resistance exercises with and without blood flow restriction on muscle strength, balance, and knee proprioception, in people with patellofemoral pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Men and women between the ages of 18 and 40 with femoral patellofemoral pain syndrome pain with any activity, including (running, jumping, squatting, kneeling, climbing/descending stairs, or long sitting) pain with patellar pressure; Touching the area around the patella Pain in sitting position with resistance to isometric knee extension Positive Patellar grinding test
Exclusion criteria:
Having an injury around the knee, including a laxity or dislocation of the patella Knee ligament and meniscus injuries Other knee injuries such as osteoarthritis of the knee, Osgood-Schlatter syndrome or Sinding-Larsen-Johnson or tendinopathy of the muscles around the knee

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

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomized into one of three groups (Two interventions and one control) using an online randomization system (randomizer.org). A member of the research team who is not involved in the selection of samples will determine the randomization sequence using a computer program. Participants will be notified of their group allocation with a sealed envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the outcome assessor is blind to the groups' randomization and interventions receiving by participants. In this way, during the evaluation before and after the intervention protocol, they do not make

mistakes in their judgments in favor of a specific therapeutic intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Sport Sciences Research Institute (SSRI)
Street address
No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1587958711
Approval date
2023-06-21, 1402/03/31
Ethics committee reference number
IR.SSRC.REC.1402.053

Health conditions studied

1

Description of health condition studied
Knee pain

ICD-10 code
M22.2

ICD-10 code description

2

Description of health condition studied
Patellofemoral disorders

ICD-10 code
M22.2

ICD-10 code description
Patellofemoral disorders

Primary outcomes

1

Description
Muscle strength

Timepoint
Immediately before intervention; immediately after intervention

Method of measurement

Dynamometer

Secondary outcomes

1

Description

Balance

Timepoint

before intervention; immediately after intervention

Method of measurement

Biodex Balance System

2

Description

Knee proprioception

Timepoint

before intervention; immediately after intervention

Method of measurement

Goniometer

3

Description

Visual Analogue Scale

Timepoint

before intervention; immediately after intervention

Method of measurement

Score of 100 mm visual analog scale to assess pain intensity

Intervention groups

1

Description

The first intervention group: This group includes patients with anterior knee pain (patellofemoral pain syndrome) who are found to be treatable with physical therapy after initial examination. This group of patients has the ability to perform movements as determined by their doctor. The exercises of these people include strength exercises (front leg machine, machine leg press) with 30% of the maximum strength, which are performed with 60% arterial occlusion pressure, by closing a pneumatic cuff around the thigh for 8 weeks and 3 times a week. The exercises of this group are one set of 30 repetitions (or voluntary exhaustion), then three sets of 15 repetitions. Also, rest between sets is 30 seconds and between exercises is 2 minutes.

Category

Rehabilitation

2

Description

The second intervention group: This group includes patients with anterior knee pain (patellofemoral pain syndrome) who, after the initial examination, have been determined to be treatable with physiotherapy. This group of patients has the ability to perform movements

as determined by their doctor. Exercises in this group include strength training (front leg press, machine leg press) with three sets of 7 to 10 repetitions (approximately 70% of 1RM) with BFR placebo. The placebo is a 5 cm elastic cuff that is placed tightly (with enough space for two fingers between the skin and the cuff) around the proximal thigh. This does not affect the number of repetitions performed during strength training in the initial test. Rest between sets is 30 seconds and between exercises is 2 minutes.

Category

Rehabilitation

3

Description

Control group: In the control group, there is no intervention and only pre-test and post-test are taken. They are asked not to exercise during this time.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Physical Education, Shahid Bahonar University, Kerman

Full name of responsible person

Mina Bahrami

Street address

Faculty of sport sciences, Shahid Bahonar University, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

۷۶۱۶۹۱۳۳۳۹

Phone

+98 34 3132 3177

Email

minabahrami8564@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Dr Mohammad Delnavaz

Street address

Vice-Chancellor for Research and Technology. No. 43. South Mofatteh Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code
15719-14911

Phone
+98 21 2222 8001

Fax

Email
Delnavaz@khu.ac.ir

Web page address
<https://research.khu.ac.ir/en>

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
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
Kharazmi University

Full name of responsible person
Hassan Sadeghi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
Mirdamad - Shahid Hesari St. - Shahid Keshvari
Complex - Faculty of Physical Education and Sports
Sciences

City
Tehran

Province
Tehran

Postal code
33111-15447

Phone
+98 21 2222 8001

Fax

Email
hassan.sadeghi81@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person
Hassan Sadeghi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
Mirdamad - Shahid Hesari St. - Shahid Keshvari
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Sciences

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Tehran

Province
Tehran

Postal code
33111-15447

Phone
+98 21 2222 8001

Fax

Email
hassan.sadeghi81@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kharazmi University

Full name of responsible person
Hassan Sadeghi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
Mirdamad - Shahid Hesari St. - Shahid Keshvari
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Sciences

City
Tehran

Province
Tehran

Postal code
33111-15447

Phone
+98 21 2222 8001

Fax

Email
hassan.sadeghi81@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available