Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Bahnar 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

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Name of organization / entity

Kharazmi University

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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, Osgoodschlatter 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)

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No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran

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Tehran

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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 Bahoner University, Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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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