

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of knee stabilization exercises with blood flow restriction on patellofemoral pain syndrome in bodybuilding athletes

Protocol summary

Study aim

The aim of this study is to examine the combination of knee stabilizing exercises with blood flow restriction on pain, balance, proprioception, strength, and knee kinematics in bodybuilder athletes with patellofemoral pain.

Design

The number of samples is 36 qualified subjects who are selected based on the criteria for Inclusion and exclusion criteria the research. The samples are divided into three training groups.

Settings and conduct

This is a semi-experimental and interventional research with three groups and pre- and post-test. The participants were randomly allocated into three different groups: Group 1 (control group, n=12), Group 2 (knee stabilization exercises, n=12), and Group 3 (knee stabilization exercises with BFR, n=12). The study is one-sided blind, so that the subjects will not be aware of the intervention of other groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Male participants aged between 18 to 28 years. 2. Experience of non-traumatic pain around or behind the patella for at least 4 weeks, with a minimum intensity of 3 centimeters on the Visual Analog Scale (VAS). 3. To induce pain, at least two functional activities including squatting, kneeling, prolonged sitting, stair climbing, jumping, or running must be repeated. Exclusion Criteria: 1. History or presence of meniscal, ligamentous, or other knee injuries and/or knee surgery. 2. Injuries such as knee osteoarthritis, Osgood-Schlatter disease, Sinding-Larsen-Johansson syndrome, or tendinopathy of the muscles around the knee.

Intervention groups

Group 1 (control group, n=12), Group 2 (knee stabilization exercises, n=12), and Group 3 (knee stabilization exercises with BFR, n=12)

Main outcome variables

Balance, Pain, Proprioception, Strength, Knee Kinematic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240603061996N1**

Registration date: **2024-07-10, 1403/04/20**

Registration timing: **retrospective**

Last update: **2024-07-10, 1403/04/20**

Update count: **0**

Registration date

2024-07-10, 1403/04/20

Registrant information

Name

abouzar saadatian

Name of organization / entity

Yasouj university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-17, 1400/08/26

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

2022-05-15, 1401/02/25

Actual recruitment end date

2022-06-20, 1401/03/30

Trial completion date

empty

Scientific title

Effect of knee stabilization exercises with blood flow restriction on patellofemoral pain syndrome in bodybuilding athletes

Public title

Effect of knee stabilization exercises with blood flow restriction on patellofemoral pain syndrome in bodybuilding athletes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Bodybuilding athletes with patellofemoral pain syndrome in rang age 18-28 years

Exclusion criteria:

History or current presence of meniscus, Ligament, or other knee injuries and/or knee surgery

Age

From **18 years** old to **28 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method will be used to assign participants to three groups. Random allocation software will be used to create random sequences. The central randomization method will also be used to hide the allocation concealment.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The subjects will be randomly assigned to one of the three study groups . The subjects will not be aware of the type of intervention of other groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Isfahan (Khorasgan) Branch

Street address

Faculty oof Nursing, Arghavanieh, Jey St, Isfahan, Iran

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Approval date

2022-11-06, 1401/08/15

Ethics committee reference number

IR.IAU.KHUISF.REC.1401.22

Health conditions studied

1

Description of health condition studied

Patellofemoral Pain Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

The primary outcome measurement time points will be conducted before the intervention and 8 weeks after the intervention.

Method of measurement

Pain will be assessed using the Visual Analog Scale (VAS).

Secondary outcomes

1

Description

Balance, Proprioception, Strength, and Knee kinematics

Timepoint

The secondary outcome measurement time points will be conducted before the intervention and 8 weeks after the intervention.

Method of measurement

For assessment, the Y Balance Test will be used for dynamic balance, the Stork Test for static balance, a goniometer for proprioception, automated video analysis for dynamic systems to assess kinematics, and a handheld dynamometer for muscle strength.

Intervention groups

1

Description

Intervention group: The exercises include hip external

rotation while lying on the side, hip external rotation while sitting on the table, step down, knee extension between 0 and 30 degrees, and isometric contraction with a ball(subjects hold a ball between their knee), they perform all exercises with 30% of 1RM. This training performed 6 weeks and 3 sessions per week (1 hour per session)

Category

Rehabilitation

2

Description

Control group: The traditional exercises include hip strengthening exercises and quadriceps strengthening exercises. The intensity of their exercise is in a comfortable and painless condition. This training performed 6 weeks and 3 sessions per week (1 hour per session)

Category

Rehabilitation

3

Description

Intervention group: The training programs with blood flow restriction (BFR) as described before were used in conjunction with blood flow occlusion during exercises. The Katsu device was used for blood flow occlusion. Arterial occlusion pressure was measured by placing a pneumatic cuff on the proximal thigh in a standing position. The cuff pressure was set to 120 mmHg at the beginning of the exercises (this pressure was chosen based on previous research results and the capability of the present study's participants, and the training load was adjusted accordingly). The cuff was removed 30 seconds after the last set of each exercise and reapplied before the first set of the next exercise. Note: Approximately 10% of the participants reported a pain level of 7 or 8. For these individuals, the training pressure was reduced according to the physician's advice, and the exercises were performed with lower pressure. Additionally, since all exercises were performed in the last 30 degrees of knee extension, the reaction force between the patella and femur was minimized, resulting in significantly less pain compared to daily activities. This training performed 6 weeks and 3 sessions per week (1 hour per session)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratory of the Faculty of Sport Sciences, Islamic Azad University, Isfahan (Khorasgan) Branch, Is

Full name of responsible person

Erfan Ebad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

faculty of Sport Sciences, Islamic Azad University,Khorasgan Branch, Isfahan, Iran

Proportion provided by this source

20

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

Yasouj university

Full name of responsible person

Abouzar saadatian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Contact**Name of organization / entity**

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Full name of responsible person

Abouzar Saadatian

Position

Assistant Professor

Latest degree

Ph.D.

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

After Completion of Interventions And Final Evaluation, The Data Will Be Shared Through The Articles To Provide a Comprehensive Treatment Process.

When the data will become available and for how long

The Results of This Study Will Be Available In Journals 6 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 Documentation Provided Can Be Applicable to Many Musculoskeletal Pain Syndromes as a Comprehensive Treatment Intervention That Considers Several Factors. These Interventions Are Applicable If Prescribed And Monitored By Physicists .

From where data/document is obtainable

Individuals Can Refer to The Islamic Azad University(khorasgan branch) Bookstore And Scientific Research Journals For Gaining Results.

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

The Refer To The Islamic Azad University (khorasgan branch) Bookstore

Comments