

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 74 3100 1550

##### Email address

a.saadatian@yu.ac.ir

##### 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

### City

Isfahan

### Province

Isfahan

### Postal code

8155139998

### 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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Faculty of Physical Education and Sport Sciences, Arghavanieh , Jey St, Isfahan, Iran

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

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

**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**

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**

Sport Sciences

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Yasouj university

**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**