

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

To compare the effects of low-load resistance training with and without blood flow restriction on thickness, strength and pain of shoulder girdle muscles in individuals with shoulder impingement syndrome

Protocol summary

Study aim

Investigating the effects of low-load resistance training combined with blood flow restriction on the thickness and strength of the supraspinatus, infraspinatus, middle trapezius, and biceps muscles and its pain-reducing effects in individuals with shoulder impingement syndrome

Design

a pragmatic, parallel-group, single-blind (with blinded outcome assessment), randomized controlled trial (RCT)

Settings and conduct

This single-blind trial at Amir Alam Hospital randomly allocates patients with shoulder impingement to receive 12 sessions of low-load resistance training, either with real BFR or with a sham BFR cuff. Participants and outcome assessors are blinded to the allocation, while the treating therapist is not. All patients also receive standard passive physiotherapy in each session consisting of TENS, US and hotpack.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age range of 40 to 60 years Literacy in Persian Shoulder pain with a maximum duration of 3 months since onset Nighttime shoulder pain or pain during overhead activities with a VAS score ≥ 3 Positive Painful arc test and at least three of the following tests: • Neer • Hawkins-Kennedy • Empty can • Infraspinatus
Exclusion Criteria Contraindications to the use of BFR Simultaneous pain in both shoulders Diagnosis of frozen shoulder Positive drop arm test indicating a complete rotator cuff tear History of surgery, fracture, or dislocation in the shoulder region Use of anti-inflammatory drugs during the daytime while undergoing the physiotherapy course

Intervention groups

Group 1: Low-load resistance training (at 20-40% of 1RM) with BFR (LLRT+BFR group) Group 2: Low-load resistance training (at 20-40% of 1RM) without BFR (LLRT group)

Main outcome variables

muscles thickness muscles strength pain (NRPS) pain pressure threshold SPADI questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251202068202N1**

Registration date: **2025-12-10, 1404/09/19**

Registration timing: **prospective**

Last update: **2025-12-10, 1404/09/19**

Update count: **0**

Registration date

2025-12-10, 1404/09/19

Registrant information

Name

Bahram Tabatabaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-03-01, 1404/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare the effects of low-load resistance training with and without blood flow restriction on thickness, strength and pain of shoulder girdle muscles in individuals with shoulder impingement syndrome

Public title

Comparing the effects of low-load resistance training with and without BFR in shoulder impingement syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 40 to 60 years Literacy in Persian experiencing shoulder pain for a maximum of 3 months Shoulder pain at night or during overhead activities greater than or equal to 3 based on VAS scale Positive Painful arc test and at least three of the following tests: Neer- Hawkins-kennedy- Empty can- infraspinatus

Exclusion criteria:

Contraindications for the use of BFR, including:• History of blood clots (DVT)• Blood pressure higher than 180 mmHg• Acute infection, peripheral vascular problems, varicose veins, or cancer. • History of hemorrhagic or thrombotic strokes. • History of arterial fibrillation Simultaneous pain in both shoulders Suffering from frozen shoulder Positive drop arm test indicating a complete rotator cuff tear History of surgery, fracture, or dislocation in the shoulder area Use of anti-inflammatory drugs during the day while undergoing the physiotherapy course

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

The method used is balanced block randomization with a block size of 4. The unit of randomization is the individual participant. The study did not employ stratified randomization, meaning no specific stratification variables (such as age or disease severity) were used to create subgroups before randomization. The primary tool for implementing randomization was sequentially numbered, sealed, opaque envelopes. The random sequence was built by an independent researcher prior to the study's commencement. This was done by listing all possible combinations that would result in 2

allocations to Group A (LLRT) and 2 allocations to Group B (LLRT+BFR) within each block of 4 participants. This sequence was transcribed and placed into the sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This trial implements a structured blinding protocol where participants are blinded to their group assignment through allocation concealment using sequentially numbered, sealed, opaque envelopes, coupled with a sham procedure for the control group to mimic the sensory experience of the BFR cuff. The treating physiotherapist administering the interventions cannot be blinded due to the necessary application of the BFR technique. The principal investigator overseeing the trial remains blinded to group allocation during active data collection and analysis to prevent bias. Crucially, all outcome assessors are blinded: a clinical assessor, separate from the treating therapist, conducts all physical and questionnaire-based evaluations without knowledge of the assignment, and a radiologist performs all ultrasound measurements independently with no information on the participant's group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Amir A'lam Hospital Complex

Street address

Amiralam Hospital- Beginning of Saadi Street- Enghelab Street (Dorvaze Dolat)-Tehran

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Tehran

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1145765111

Approval date

2025-05-20, 1404/02/30

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1404.008

Health conditions studied**1****Description of health condition studied**

shoulder impingement syndrome

ICD-10 code

M75.4

ICD-10 code description

Impingement syndrome of shoulder

Primary outcomes**1****Description**

isometric muscle strength of the rotator cuff muscles (supraspinatus)

Timepoint

pre and post intervention

Method of measurement

hand-held, fixed dynamometer

Secondary outcomes**1****Description**

Thickness of supraspinatus, infraspinatus, middle trapezius, and biceps muscles at rest

Timepoint

pre and post intervention

Method of measurement

B-mode ultrasonography (model: Supersonic MACH30)

2**Description**

night pain and pain while elevating the shoulder

Timepoint

pre and post intervention

Method of measurement

Numeric pain rating scale

3**Description**

Pain pressure threshold on 2 points (end of supraspinatus muscle and thenar area of the affected side)

Timepoint

pre and post intervention

Method of measurement

digital algometer

4**Description**

functional pain and disability

Timepoint

pre and post intervention

Method of measurement

Shoulder Pain and Disability Index questionnaire

Intervention groups**1****Description**

Intervention group: Low-load resistance training (LLRT) with Blood Flow Restriction (BFR). Participants in this group will perform exercises at 20-40% of 1RM. An active BFR cuff will be applied to the proximal arm and inflated to a pressure set at 50% of the individual's pre-determined Limb Occlusion Pressure (LOP) to partially restrict arterial inflow and venous return during exercise. This group will also receive standard passive physiotherapy (hot pack, TENS, ultrasound).

Category

Treatment - Other

2**Description**

Control group: Low-load resistance training (LLRT) with sham Blood Flow Restriction (BFR). Participants in this group will perform exercises at 20-40% of 1RM. A sham BFR cuff will be applied to the proximal arm; it will be inflated to a minimal, non-therapeutic pressure to provide the sensory experience without creating meaningful blood flow restriction. This group will also receive standard passive physiotherapy (hot pack, TENS, ultrasound).

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir A'lam Hospital

Full name of responsible person

Dr. Mostafa Rahimi

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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

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Bahram Tabatabaei

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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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