Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of two types of resistance training with and without blood flow restriction on some pro-inflammatory cytokines in overweight men

Protocol summary

Study aim

The Effect of Two Types of Resistance Training With and Without Blood Flow Restriction on Selected Pro-inflammatory Cytokines in Overweight Men

Design

This clinical trial is a controlled, parallel-group study with single-blind design. A total of 50 participants were randomly allocated into five groups: Resistance Training 1 (RT1) group (n=10), Resistance Training 2 (RT2) group (n=10), Resistance Training 1 with Blood Flow Restriction (RT1+BFR) group (n=10), Resistance Training 2 with Blood Flow Restriction (RT2+BFR) group (n=10), and a Control group (n=10).

Settings and conduct

The statistical population of this quasi-experimental study consisted of overweight men aged 20 to 30 years old, with no prior history of regular physical activity, residing in the city of Ardabil. The intervention period lasted six weeks. Following the pre-test phase and the commencement of the training program, participants were assigned to separate groups and performed two different types of resistance exercise protocols. The resistance exercises were conducted both with and without blood flow restriction. After completion of the training period, all measurements related to the outcome variables were repeated under the same conditions during a post-test session. Outcome assessors were blinded to group allocation to minimize measurement bias.

Participants/Inclusion and exclusion criteria

Age between 20 and 30 years, being overweight, having no history of chronic diseases, and not using medications or tobacco products.

Intervention groups

Resistance Training 1 (RT1), Resistance Training 2 (RT2), Resistance Training 1 with Blood Flow Restriction (RT1+BFR), Resistance Training 2 with Blood Flow Restriction (RT2+BFR), Control group.

Main outcome variables

TNF-a، IL-1b، (IL-6)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044649N2**
Registration date: **2025-09-20, 1404/06/29**
Registration timing: **retrospective**

Last update: **2025-09-20, 1404/06/29**
Update count: **0**

Registration date

2025-09-20, 1404/06/29

Registrant information

Name
Ali Barzegari
Name of organization / entity
Payame noor university
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Iran (Islamic Republic of)
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+98 11 3225 0048
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-08-06, 1404/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of two types of resistance training with and without blood flow restriction on some pro-inflammatory cytokines in overweight men

Public title
The effect of two types of training with and without blood flow restriction on some cytokines in men

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
The subjects' age should be between 20 and 30 years old. Subjects are overweight. Subjects should not have a history of any specific illness. Not using drugs and tobacco

Exclusion criteria:
Age outside the defined range of 20 to 30 years. Body Mass Index (BMI) outside the defined overweight range or severe obesity (BMI ≥ 35 kg/m²). History of uncontrolled cardiovascular, respiratory, renal, hepatic, or metabolic diseases Use of medications known to significantly affect metabolism, inflammation, or immune function Regular structured physical activity or exercise training within the past 3 months. Tobacco smoking or alcohol consumption within the past 6 months.

Age
From **20 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants (n=50), who were screened based on the inclusion and exclusion criteria, were randomly assigned to one of the five study groups. To ensure genuine random allocation, a standard randomization procedure, such as using a random number table, was employed. This process was conducted in a manner that prevented the researchers from predicting which group a subsequent participant would be assigned to, thereby minimizing selection bias. To guarantee an equal number of participants across all groups (10 per group), a blocked randomization method was utilized. In this technique, a fixed block size (e.g., 5 or 10) was defined, and the sequence of assignments within each block was generated randomly. This approach ensures that at the end of the recruitment period, the number of participants in all groups is precisely balanced.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the intervention (resistance exercise training), implementation of double blinding was not feasible in this study. Participants were explicitly aware of their assigned group (resistance training with or without blood flow restriction), and trainers as well as researchers were necessarily informed about the type of intervention being administered. However, to enhance methodological rigor and minimize potential bias: Independent assessors , responsible for measuring outcome variables such as BMI and other anthropometric indices, were blinded to participants' group allocations (single blinding). Statistical analyses were conducted by data analysts who remained unaware of the group assignments throughout the analytical process.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Payam Noor University

Street address
Tehran, Mini City, Artesh Blvd., 1st Oil City, Nakhl St., Central Organization of Payam Noor University

City
Tehran

Province
Tehran

Postal code
19395-4697

Approval date
2022-09-19, 1401/06/28

Ethics committee reference number
IR.PNU.REC.1401.285

Health conditions studied

1

Description of health condition studied
overweight

ICD-10 code
E66.9

ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
TNF-a
Timepoint
two stages: pre-test and post-test
Method of measurement
Sandwich ELISA kit

2

Description
IL-1b
Timepoint
two stages: pre-test and post-test
Method of measurement
Sandwich ELISA kit

3

Description
IL-6
Timepoint
two stages: pre-test and post-test
Method of measurement
Sandwich ELISA kit

Secondary outcomes

1

Description
Descriptive Indice: Height
Timepoint
pre-test
Method of measurement
Height was measured using a wall-mounted stadiometer (Model: Seca 213, Germany) with a measurement unit of centimeters (cm) and an instrument precision of 0.1 cm.

2

Description
Weight
Timepoint
In two stages: pre-test and post-test
Method of measurement
Body weight was measured using a calibrated digital scale (Model: Seca 813, Germany) with a precision of 0.1 kg.

3

Description
Body Mass Index (BMI)
Timepoint
In two stages: pre-test and post-test
Method of measurement
Body Mass Index (BMI) is a derived anthropometric measure calculated from direct measurements of body weight and height.

Intervention groups

1

Description
Group 1: Resistance Training with Elastic BandsParticipants in this group performed a resistance training program using TheraBand elastic bands for 6 weeks, with 3 sessions per week (total of 18 sessions). Each session consisted of 10 minutes of warm-up, 25–35 minutes of main exercise, and 5 minutes of cool-down. The training protocol began with 2 sets of 8 repetitions at ~60% of 1RM and progressively increased to 3 sets of 10 repetitions at ~75% of 1RM by the sixth week. The exercises included 6 movements (3 upper-body and 3 lower-body). Active rest periods of 60 seconds were implemented between sets.
Category
Other

2

Description
Group 2: Resistance Training with DumbbellsThis group performed a resistance training program using adjustable dumbbells for 6 weeks, with 3 sessions per week. The session structure was identical to that of Group 1. The protocol included 12 exercises (6 upper-body and 6 lower-body) performed on alternating days. Training intensity started at 2 sets of 8 repetitions at 60% of 1RM and progressed to 3 sets of 10 repetitions at 75% of 1RM by the sixth week. Active rest intervals of 60 seconds were maintained between sets.
Category
Other

3

Description
Group 3: Resistance Training with Elastic Bands + Blood Flow Restriction (BFR)The training protocol for this group was identical to that of Group 1 but was combined with blood flow restriction (BFR). Specialized rubber tourniquets (width: 3–5 cm) were applied to the proximal portion of the limbs. The tourniquet pressure was calibrated using Doppler ultrasonography to ensure complete arterial occlusion. The tourniquets remained inflated throughout the entire session (including rest intervals) and were deflated only after the session concluded. The procedure was supervised by a medical professional to ensure safety.
Category
Other

4

Description
Group 4: Resistance Training with Dumbbells + Blood Flow Restriction (BFR)The training protocol for this group was identical to that of Group 2 but was combined with blood flow restriction (BFR). The BFR application protocol (tourniquet type, pressure, and supervision) was identical to that used in Group 3. Participants performed

dumbbell exercises at the same volume and intensity as Group 2, with simultaneous application of BFR.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Ardabil University

Full name of responsible person
Ali Barzegari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Payame Noor University

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
Payame Noor University

Proportion provided by this source
50

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
Payame Noor University

Full name of responsible person
Ali Barzegari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information about the main outcome

When the data will become available and for how long
6 months after results are published

To whom data/document is available
حققین شاغل در موسسات دانشگاهی و علمی

Under which criteria data/document could be used
مقایسه با تحقیقات محققین دیگر

From where data/document is obtainable
آدرس پست الکترونیک

What processes are involved for a request to access data/document
پاسخ به درخواست حداکثر یک هفته پس از ایمیل تقاضاکننده قابل وصول است

Comments