Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Sep 2026

Comparison of the effects of traditional resistance training and high-intensity functional training on toll-like receptor 4, matrix metalloproteinase 9, interleukin 4, interferon-gamma, lipid profile, muscular strength, and aerobic capacity in overweight men

Protocol summary

Study aim

Comparison of the effects of eight weeks of traditional resistance training and high-intensity functional training on body composition, functional capacity, inflammatory markers (toll-like receptor 4, matrix metalloproteinase 9, interferon-gamma, interleukin-4), lipid profile, and fasting blood sugar in overweight men.

Design

Randomized controlled clinical trial with a parallel-group design, single-blind, phase 2, including 34 overweight male participants. Subjects were randomly allocated (using the RAND function in Excel) into three groups: Traditional Resistance Training (RT), High-Intensity Functional Training (HIFT), and control.

Settings and conduct

Study location: HealthLand Gym and Immunology Lab, School of Medicine, Isfahan University of Medical Sciences; Study population: 34 overweight men; Blinding type: Single-blind; Blinding method: Assessor and analyst were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy males; aged between 25 and 35 years; body mass index (BMI) between 25.0 and 29.9 kg/m²; no engagement in regular exercise during the past 6 months. Exclusion criteria: Use of specific medications or supplements within the past 6 months; history of cardiovascular disease; smoking within the past 6 months; weight gain of more than 2 kg during the past 6 months.

Intervention groups

Intervention group: High-Intensity Functional Training (HIFT) 3 weekly sessions for 8 weeks, functional high-intensity moves with 30s max effort and short rests. Intervention group: Traditional Resistance Training (RT) 3 weekly sessions for 8 weeks, 3 sets of 12 reps at 75% 1RM per session. Control group: No training, no intervention; only pre- and post-tests performed.

Main outcome variables

Toll-like receptor 4 (TLR4); matrix metalloproteinase-9 (MMP-9); interferon gamma (IFN-γ); interleukin-4 (IL-4); fasting blood sugar; total cholesterol; HDL; LDL; body composition; functional capacity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170724035269N2**
Registration date: **2025-05-27, 1404/03/06**
Registration timing: **retrospective**

Last update: **2025-05-27, 1404/03/06**
Update count: **0**

Registration date

2025-05-27, 1404/03/06

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6111 8878

Email address

shabkhiz@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-05, 1401/05/14

Expected recruitment end date
2022-09-05, 1401/06/14
Actual recruitment start date
2022-08-05, 1401/05/14
Actual recruitment end date
2022-09-05, 1401/06/14
Trial completion date
2022-09-20, 1401/06/29

Scientific title
Comparison of the effects of traditional resistance training and high-intensity functional training on toll-like receptor 4, matrix metalloproteinase 9, interleukin 4, interferon-gamma, lipid profile, muscular strength, and aerobic capacity in overweight men

Public title
Effect of training on inflammatory markers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 25 and 35 years. Healthy overweight men (BMI between 25 and 29.9 kg/m²). No participation in regular and organized exercise programs in the last six months. Completion of informed consent form and medical health questionnaire.
Exclusion criteria:
Smoking during the past 6 months. Weight gain of more than 2 kg in the last 6 months. Participation in a weight loss program during the past 6 months. Engagement in heavy resistance training aimed at increasing muscle mass and strength during the past 6 months. Presence of chronic metabolic or endocrine diseases. Family history of early cardiac mortality. Inability to complete the exercise protocol (identified during the pilot phase). Use of any specific medication or supplement in the past six months History of cardiovascular diseases
Age
From **25 years** old to **35 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **39**
Actual sample size reached: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method and description: This study utilized simple randomization. Eligible participants were randomly assigned to one of the three groups: traditional resistance training (RT), high-intensity functional training (HIFT), or control (CON). Unit of randomization: The unit of randomization was at the individual level. Stratified randomization layers: No stratified randomization was used. Randomization tool: The randomization sequence was generated using a random number table and G-Power statistical software. How the random sequence was created: The random allocation sequence was created by a researcher who was not involved in the intervention, using a random number table, and the participants were assigned accordingly. Allocation concealment: To prevent selection bias, allocation codes were sealed in opaque, sealed envelopes. The intervention supervisor was blinded to group assignments until the moment of allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, due to the nature of the interventions, participants were blinded to their group assignment and the primary aim of the intervention. Additionally, to minimize bias during data collection and analysis, biological sample collectors, laboratory analysts, and the data statistician were blinded to group allocations. Detailed description: Participants: Blinded to group assignment and the primary study hypothesis. Principal investigator and intervention supervisors: Aware of group allocations to manage the exercise sessions. Healthcare/sports personnel (trainers/supervisors): Not blinded. Sample collectors and laboratory staff: Blinded to group assignments. Data analyst/statistician: Analyzed coded data without knowledge of group allocation. Manuscript authors: Informed of group assignments only after the completion of data collection. Accordingly, the study is classified as a Single-blind study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of the Faculty of Physical Education and Sport Sciences, University of Teh
Street address
Faculty of Physical Education and Sport Sciences, University of Tehran, Opposite of Tehran University Dormitory, Between 15th and 16th Streets, North Kargar Street, Above Jalal Al-Ahmad Crossroad, Tehran, Iran
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1417935840
Approval date

2022-07-16, 1401/04/25

Ethics committee reference number

IR.UT.SPORT.REC.1401.025

Health conditions studied

1

Description of health condition studied

Overweight

ICD-10 code

E66.3

ICD-10 code description

Overweight

2

Description of health condition studied

Dyslipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidemia, unspecified

3

Description of health condition studied

Low-grade systemic inflammation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood level of toll-like receptor 4 (TLR4)

Timepoint

At baseline (before the start of the intervention) and After completing the 8-week intervention period

Method of measurement

Measured by enzyme-linked immunosorbent assay using a human-specific commercial kit

2

Description

Blood level of matrix metalloproteinase 9 (MMP-9)

Timepoint

At baseline (before the start of the intervention) and After completing the 8-week intervention period

Method of measurement

Measured by enzyme-linked immunosorbent assay using a human-specific commercial kit

3

Description

Blood level of interferon-gamma (IFN-γ)

Timepoint

At baseline (before the start of the intervention) and After completing the 8-week intervention period

Method of measurement

Measured by enzyme-linked immunosorbent assay using a human-specific commercial kit

4

Description

Blood level of interleukin-4 (IL-4)

Timepoint

At baseline (before the start of the intervention) and After completing the 8-week intervention period

Method of measurement

Measured by enzyme-linked immunosorbent assay using a human-specific commercial kit

5

Description

Fasting blood sugar (FBS)

Timepoint

At baseline (before the start of the intervention) and After completing the 8-week intervention period

Method of measurement

Measured by enzymatic method using an automatic biochemistry analyzer

6

Description

Total cholesterol (CHOL)

Timepoint

At baseline (before the start of the intervention) and After completing the 8-week intervention period

Method of measurement

Measured by enzymatic method using an automatic biochemistry analyzer

7

Description

High-density lipoprotein cholesterol (HDL)

Timepoint

At baseline (before the start of the intervention) and After completing the 8-week intervention period

Method of measurement

Measured by enzymatic method using an automatic biochemistry analyzer

8

Description

Low-density lipoprotein cholesterol (LDL)

Timepoint

At baseline (before the start of the intervention) and After completing the 8-week intervention period

Method of measurement

Measured by enzymatic method using an automatic biochemistry analyzer

9

Description

Triglycerides

Timepoint
At baseline (before the start of the intervention) and After completing the 8-week intervention period
Method of measurement
Measured by enzymatic method using an automatic biochemistry analyzer

10

Description
Change in body composition (body fat percentage and lean mass)
Timepoint
At baseline (before the start of the intervention) and After completing the 8-week intervention period
Method of measurement
Measured by bioelectrical impedance analysis using InBody 270 device

11

Description
Change in functional capacity (based on functional performance tests)
Timepoint
At baseline (before the start of the intervention) and After completing the 8-week intervention period
Method of measurement
Measured by one-repetition maximum test in bench press exercise and indirect estimation of maximal oxygen consumption (VO2max) using a treadmill test.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (High-Intensity Functional Training):Three sessions per week for 8 weeks. Each session included 4 bouts of functional exercises (squat, deadlift, shoulder press, bench press, and row) performed for 30 seconds at maximum effort using a barbell. Rest intervals were 30 seconds between exercises and 2.5 minutes between bouts. Training was supervised by an exercise physiologist at HealthLand Gym.
Category
Lifestyle

2

Description
Intervention group 2 (Traditional Resistance Training):Three sessions per week for 8 weeks. Each session involved traditional resistance exercises (squat, deadlift, bench press, shoulder press, and row) using weight machines and barbells. Participants performed 3 sets of 12 repetitions at 75% of 1RM. Sessions were conducted at HealthLand Gym under supervision.
Category
Lifestyle

3

Description
Control group:No intervention during the 8-week period; only participated in pre- and post-tests.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Land Gym, Isfahan
Full name of responsible person
Shervin Abedi
Street address
HealthLand Sports Complex, Shahidan Sharqi St., Khoram St., Jomhouri Square, Isfahan, Iran
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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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Faculty of Physical Education and Sport Sciences, University of Tehran, Opposite Tehran University Dormitory, Between 15th and 16th Streets, North Kargar Street, Above Jalal Al-Ahmad Crossroad, Tehran
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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 Physical Education and Sport Sciences, University of Tehran
Proportion provided by this source
100
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
Faculty of Physical Education and Sport Sciences, University of Tehran
Full name of responsible person
Fatemeh Shabkhiz
Position
Associate professor
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Other areas of specialty/work
Exercise physiology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Faculty of Physical Education and Sport Sciences, University of Tehran
Full name of responsible person
Fatemeh Shabkhiz
Position
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Latest degree
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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

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

Data related to toll-like receptor 4 (TLR4), matrix metalloproteinase 9 (MMP-9), interferon-gamma (IFN-γ), interleukin 4 (IL-4), fasting blood sugar (FBS), lipid profile (cholesterol, HDL, LDL), and body composition of participants. Details: The individual data includes laboratory results and physical measurements (using standard devices). All data will be shared after de-identifying the participants (removal of names and identifying information). Data related to primary outcomes (inflammatory markers and lipid profile) will be available for sharing. Only personal identifiable data or confidential information will be excluded from sharing.

When the data will become available and for how long

Access to the data will start six months after the publication of the study results. The access period will continue for three years after the starting date.

To whom data/document is available

The data will be available only to researchers affiliated with academic and research institutions who submit an official request. Individuals working in industry or private companies will not have access to the data.

Under which criteria data/document could be used

The data may only be used for scientific and research analyses. Commercial use or publication without prior written permission is prohibited. Applicants must submit an official request including a description of the research purpose and the intended analyses. A confidentiality agreement must be signed by the applicants. Access will be granted only after approval by the research committee.

From where data/document is obtainable

Applicants must contact Dr. Fatemeh Shabkhiz exclusively to request access to the data. All requests must be formally submitted via email to: fatemeh.shabkhiz@ut.ac.ir For postal correspondence, requests should be sent to: Faculty of Physical Education and Sport Sciences, University of Tehran, North Kargar Street, above Jalal Al-Ahmad intersection, between 15th and 16th Streets, opposite the University of Tehran dormitory, Tehran, Postal Code: 1417466191.

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

After submitting a formal request to Dr. Fatemeh Shabkhiz, the request will be reviewed within 10 working days. If approved by the research committee, the applicant must sign a data confidentiality agreement. After signing the agreement, the data will be provided to the applicant within a maximum of 15 working days. If the request is rejected, the reason for rejection will be formally communicated to the applicant.

Comments