Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Comparison of the effectiveness of 12 weeks of aerobic exercise, Tabata, and high-intensity interval training on adipo-myokine levels in obese men

Protocol summary

Study aim
Comparison of the effectiveness of 12 weeks of aerobic exercise, Tabata, and high-intensity interval training on adipo-myokine levels in obese men

Design
This randomized clinical trial is conducted in four groups of 11 participants each, consisting of Tabata training, high-intensity interval training, continuous aerobic training, and a control group. Random allocation of participants is performed at the individual level based on age and body mass index using specialized software.

Settings and conduct
This clinical study will be conducted on obese men in Amol. Forty-four participants will be randomly divided into four groups of 11, including Tabata, HIIT, aerobic exercise, and a control group, based on age and body mass index through social media and in-person recruitment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Inactivity among men aged 21-35 years, with general physical and mental health and a body mass index greater than 30 kg/m², is the focus of this study. Exclusion criteria: include the presence of any physical or orthopedic lesions that interfere with exercise performance or hinder the ability to perform quality exercises

Intervention groups
This study includes four groups: 1. Control (CON): No exercise, maintaining routine lifestyle. 2. Moderate-Intensity Continuous Training (MICT): 12 weeks (3 sessions/week); 10-min warm-up, 30–40 min treadmill running at 65%–75% HRmax, and 10-min cool-down. 3. High-Intensity Interval Training (HIIT): 12 weeks (3 sessions/week); 10-min warm-up, 8 × 4-min treadmill running at 85%–95% HRmax (1-min recovery at 45%–55% HRmax), and 10-min cool-down. 4. Tabata Training (TAB): 12 weeks (3 sessions/week); 10-min warm-up, 8 × 4-min sets of low-load/bodyweight Tabata exercises (20-s work at 85%–95% HRmax, 10-s rest; 1-min inter-set rest), and 10-min cool-down.

Main outcome variables
Dermatopontin, Decorin, Follistatin, Myostatin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120129008863N20**
Registration date: **2026-11-01, 1405/08/10**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-01, 1405/08/10**
Update count: **0**

Registration date
2026-11-01, 1405/08/10

Registrant information

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Name of organization / entity
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2026-12-19, 1405/09/28

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of 12 weeks of aerobic exercise, Tabata, and high-intensity interval training on adipo-myokine levels in obese men

Public title
The effect of exercise training on the profile of myokines and muscle proteins
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Inactive male, aged 21 to 35 In good general physical and mental health Body mass index greater than 30 kg/m²
Exclusion criteria:
Any physical injury or orthopedic issue that interferes with training can hinder its quality
Age
From **21 years** old to **35 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to four study groups in a 1:1:1:1 allocation ratio. Initially, eligible participants will be stratified based on two variables: age and body mass index (BMI). Predetermined categories will be created for each variable, and randomization will be performed independently within each stratum to ensure balance across age and BMI levels. Subsequently, block randomization with block sizes of 4 and 8 and an allocation ratio of 1:1:1:1 will be executed within each stratum. For this purpose, all possible balanced combinations of group assignments for block sizes of 4 and 8 will first be defined. Then, in SPSS software (version 26), using Syntax and the uniform random number generator command RV.UNIFORM (0,1), a random number between 0 and 1 will be generated for each block combination. The block combinations will be sorted in ascending order based on these random numbers, and the final group assignment sequence will be extracted from this ordering. To prevent sequence predictability, block sizes of 4 and 8 will be varied systematically/alternately. The final random allocation sequence will be generated by a biostatistician who is not involved in participant screening, enrollment, or evaluation, and will be stored as a coded allocation list. Group allocation will be concealed using sequentially numbered, opaque, sealed envelopes to ensure the allocation sequence remains hidden from both researchers and participants until the point of assignment. Consequently, the person assigning participants will open the corresponding envelope and reveal the allocated group only after the participant's baseline information has been fully recorded.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University-Ayatollah Amoli Branch
Street address
Islamic Azad University, Ayatollah Amoli Branch, Km 5, Old Amol Road
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Postal code
678
Approval date
2023-05-03, 1402/02/13
Ethics committee reference number
IR.IAU.AMOL.REC.1402.070

Health conditions studied

1

Description of health condition studied
Overweight and obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Dermatopontin
Timepoint
Before the intervention and three months following it
Method of measurement
Cusabio kit (ng/ml)

2

Description
Decorin
Timepoint
Before the intervention and three months following it
Method of measurement
zellBio kit (pg/ml)

3

Description
Follistatin
Timepoint
Before the intervention and three months following it
Method of measurement
zellBio kit (pg/ml)

4

Description
Myostatin
Timepoint
Before the intervention and three months following it
Method of measurement
zellBio kit (pg/ml)

Secondary outcomes

1

Description
Body Mass Index (BMI) Kg/m2
Timepoint
Before the intervention and three months following it
Method of measurement
The body mass (kg) divided by the square of the body height (cm)

Intervention groups

1

Description
Intervention group: The Tabata training group will consist of 12 weeks of training (three sessions per week), with each session lasting 60 minutes and comprising 10 minutes of warm-up, 40 minutes of main training, and 10 minutes of cool-down. The main exercises for this group will be executed in eight 4-minute sets, featuring 20 seconds of very high-intensity activity (85 to 95 percent of maximum heart rate) followed by 10 seconds of rest at an intensity of 45 to 55 percent of maximum heart rate.
Category
Rehabilitation

2

Description
Intervention group: The High-Intensity Interval Training (HIIT) group will also perform 12 weeks of training (three sessions per week), with a similar duration of 60 minutes per session (10 minutes of warm-up, 40 minutes of main training, and 10 minutes of cool-down). The main exercises for this group will have a structure similar to the Tabata protocol, consisting of eight 4-minute sets featuring 20 seconds of high-intensity activity (85 to 95 percent of maximum heart rate) and 10 seconds of rest (45 to 55 percent of maximum heart rate).
Category
Rehabilitation

3

Description
Intervention group: The continuous aerobic training (ET) group will consist of 12 weeks of training (three sessions per week), with a total duration of 60 minutes per session (including 10 minutes of warm-up, 40 minutes of main training, and 10 minutes of cool-down). The intensity of the main exercises for this group will be continuously set at 65 to 75 percent of the maximum heart rate.
Category
Rehabilitation

4

Description
Control group: The control group will not receive any exercise or training intervention during the 12-week period and will only participate in the pre-test and post-test assessments and measurements to serve as a baseline for comparison with the intervention groups.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University-Ayatollah Amoli Branch
Full name of responsible person
Asieh Abbassi Daloii
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Sponsors / Funding sources

1

Sponsor

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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
Islamic Azad University, Ayatollah Amoli Branch

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
Islamic Azad University-Ayatollah Amoli Branch
Full name of responsible person
Asieh Abbassi Daloii
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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

All data, including the IPD, study protocol, statistical analysis map, informed consent form, clinical study report, and data dictionary, will be published upon completion of the study. This data will be made available in a valid journal article format.

When the data will become available and for how long

Data will be accessible immediately upon project completion, likely in 1405

To whom data/document is available

This is intended for researchers at academic and scientific

Under which criteria data/document could be used

Institutions to support the development of related sciences.

From where data/document is obtainable

Refer to Islamic Azad University

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

Please submit a valid letter from the scientific centers.

Comments