Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2026

The Effects of Different Doses of Combined Exercise Training with Caloric Restriction on Levels of Endocan and Interleukin-6 in Overweight and Obese Sedentary Women

Protocol summary

Study aim
Comparison of the Effects of Different Doses of Combined Exercise Training with Caloric Restriction on Levels of Endocan and Interleukin-6 in Sedentary Overweight and Obese Women

Design
Controlled clinical trial with parallel groups, involving a sample size of 40 participants. Participants will be allocated to groups using a non-randomized, purposive assignment method. Each group will consist of 10 participants.

Settings and conduct
Obese and overweight women living in Tehran will be included in the study if they are eligible and will be assigned to the intervention and control groups using a non-random allocation method. The study is not blinded.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Body Mass Index between 27 and 35, Not taking specific medications, No history of underlying diseases such as diabetes. Exclusion Criteria: Presence of physical conditions that prevent participation in physical activity

Intervention groups
Intervention Group1:Two exercise sessions per week combined with caloric restriction (360 calories) Intervention Group2:Three exercise sessions per week combined with caloric restriction (285 calories) Intervention Group3:Four exercise sessions per week combined with caloric restriction (215 calories) Control Group: Caloric restriction (500 calories) The intervention will last for a total duration of 8 weeks. The energy consumed in each training session is equivalent to 500 calories, and in the control group, the adjusted daily diet will be 500 calories less than the participants' usual consumption. Therefore, in order to keep the calorie consumption constant in all groups, the adjusted daily diet in the three intervention groups will be 360, 285, and 215 calories less than the participants' usual consumption, respectively.

Main outcome variables
Endocan, Interleukin-6

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250505065611N1**
Registration date: **2025-07-06, 1404/04/15**
Registration timing: **retrospective**

Last update: **2025-07-06, 1404/04/15**
Update count: **0**

Registration date
2025-07-06, 1404/04/15

Registrant information

Name
Katayoun Zamani

Name of organization / entity
Tehran University

Country
Iran (Islamic Republic of)

Phone
+98 21 4612 3722

Email address
katayoun.zamani@ut.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-18, 1404/02/28

Expected recruitment end date
2025-05-26, 1404/03/05

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effects of Different Doses of Combined Exercise Training with Caloric Restriction on Levels of Endocan and Interleukin-6 in Overweight and Obese Sedentary Women

Public title
The Effect of Physical Activity and Caloric Restriction on Inflammatory Markers and Blood Glucose in Overweight and Obese Women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Body Mass Index (BMI) between 27 and 35 No use of specific medications No underlying diseases such as diabetes
Exclusion criteria:
Physical problems that prevent engagement in physical activity Under medical treatment or following a specific diet
Age
From **19 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Research Ethics Committees of Tehran University - Faculty of Sport Sciences and Health
Street address
Faculty of Physical Education and Sport Sciences, between 15th and 16th St., North Kargar st., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1439813117
Approval date
2025-05-03, 1404/02/13
Ethics committee reference number
IR.UT.SPORT.REC.1404.046

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
Endocan
Timepoint
Endocan levels are measured through blood tests one week before the intervention begins and 60 days after the intervention period ends.
Method of measurement
Endocan levels are measured through blood tests using ELISA kits

2

Description
Interleukin-6
Timepoint
Interleukin-6 levels are measured through blood tests one week before the intervention begins and 60 days after the intervention period ends.
Method of measurement
Interleukin-6 levels are measured through blood tests using ELISA kits

Secondary outcomes

1

Description
weight
Timepoint
Weight measurement is at the beginning of the study (before the start of the intervention) and 60 days after the start of the intervention.

Method of measurement
A scale is used to measure weight.

2

Description
Body Fat Percentage
Timepoint
Body Fat Percentage is at the beginning of the study (before the start of the intervention) and 60 days after the start of the intervention.
Method of measurement
Body fat percentage will be measured using a body composition analyzer (InBody 270)

3

Description
Muscle mass
Timepoint
Muscle mass is at the beginning of the study (before the start of the intervention) and 60 days after the start of the intervention.
Method of measurement
Muscles mass will be measured using a body composition analyzer (InBody 270)

4

Description
Visceral Fat Levels
Timepoint
Visceral Fat Levels is at the beginning of the study (before the start of the intervention) and 60 days after the start of the intervention.
Method of measurement
Visceral Fat Levels will be measured using a body composition analyzer (InBody 270)

Intervention groups

1

Description
Intervention Group 1: Two exercise sessions per week + caloric restriction (a daily deficit of 360 kcal). In addition, each exercise session will involve an energy expenditure of approximately 500 kcal. Participants in this group will engage in designated exercise two days a week, consuming 500 calories per exercise session, and the diet set for these individuals will be 360 calories less than their usual daily intake, so that the total calorie intake through diet and two sessions of exercise per week will be equivalent to 3,500 calories per week. A total of 8 weeks have been planned for this intervention. Exercise activity in each session includes warm-up and aerobic activity (treadmill) and resistance activity (chest press, lat pull-ups, military press, leg extension, leg press, crunches) and cool-down. The intensity of the exercises increases from 60% of one repetition maximum in the first week to 80% of one repetition maximum in the eighth week.
Category
Rehabilitation

2

Description
Intervention Group 2: Three exercise sessions per week + caloric restriction (a daily deficit of 285kcal). In addition, each exercise session will involve an energy expenditure of approximately 500 kcal. Participants in this group will engage in designated exercise three days a week, consuming 500 calories per exercise session, and the diet set for these individuals will be 285 calories less than their usual daily intake, so that the total calorie intake through diet and three sessions of exercise per week will be equivalent to 3,500 calories per week. A total of 8 weeks have been planned for this intervention. Exercise activity in each session includes warm-up and aerobic activity (treadmill) and resistance activity (chest press, lat pull-ups, military press, leg extension, leg press, crunches) and cool-down. The intensity of the exercises increases from 60% of one repetition maximum in the first week to 80% of one repetition maximum in the eighth week.
Category
Rehabilitation

3

Description
Intervention Group 3: Four exercise sessions per week + caloric restriction (a daily deficit of 215kcal). In addition, each exercise session will involve an energy expenditure of approximately 500 kcal. Participants in this group will engage in designated exercise four days a week, consuming 500 calories per exercise session, and the diet set for these individuals will be 215 calories less than their usual daily intake, so that the total calorie intake through diet and four sessions of exercise per week will be equivalent to 3,500 calories per week. A total of 8 weeks have been planned for this intervention. Exercise activity in each session includes warm-up and aerobic activity (treadmill) and resistance activity (chest press, lat pull-ups, military press, leg extension, leg press, crunches) and cool-down. The intensity of the exercises increases from 60% of one repetition maximum in the first week to 80% of one repetition maximum in the eighth week.
Category
Rehabilitation

4

Description
Control Group: Caloric restriction only (a daily dietary caloric deficit of 500 kcal). Participants in this group do not participate in any exercise activities and the diet adjusted for these people will be 500 calories less than their usual daily intake, so that the total calorie restriction through the diet is equivalent to 3500 calories per week. A total of 8 weeks are planned to conduct this intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Abadis Clinic
Full name of responsible person
Katayoun Zamani
Street address
No. 42, Koodakan-e-Ghazzeh (Pourmoshkanai) St., above Zafar St., Shariati St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1948654711
Phone
+98 21 2671 0270
Email
Abadisspine.group@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University
Full name of responsible person
Soori Rahman
Street address
between 15th and 16th St., North Kargar st., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1439813117
Phone
+98 21 8835 1730
Email
soori@ut.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University

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
Full name of responsible person
Katayoun Zamani
Position
Nutritionist
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
No. 26, Morvarid Baharestan Tower, Kermanshah St., West Hamedan, Iran
City
Tehran
Province
Tehran
Postal code
1497973590
Phone
+98 21 4612 3722
Email
Katayoun.zamani@ut.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University
Full name of responsible person
Katayoun Zamani
Position
Nutritionist
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
No. 26, Morvarid Baharestan Tower, Kermanshah St., West Hamedan, Iran
City
Tehran
Province
Tehran
Postal code
1497973590
Phone
+98 21 4612 3722
Email
Katayoun.zamani@ut.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University

Full name of responsible person
Katayoun Zamani
Position
Nutritionist
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
No. 26, Morvarid Baharestan Tower, Kermanshah St., West Hamedan, Iran
City
Tehran
Province
Tehran
Postal code
1497973590
Phone
+98 21 4612 3722
Email
Katayoun.zamani@ut.ac.ir

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