

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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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

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No. 42, Koodakan-e-Ghazze (Pourmoshkanai) St.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

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

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Person responsible for scientific inquiries

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Position

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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