Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2026

Effect of exercise volume and caloric restriction on the ADMA and LOX-1 levels in obese and overweight sedentary women

Protocol summary

Study aim
To determine the effect of exercise volume and caloric restriction on the ADMA and LOX-1 levels in obese and overweight sedentary women

Design
The clinical trial will have three experimental (intervention) groups and one control group, and will be conducted as a double-blind, randomized study on 40 participants. Randomization will be performed using the online research randomizer software (https://www.randomizer.org) to randomly select and assign 40 participants to four equal groups of 10.

Settings and conduct
The study will be conducted at the Abadiis Clinic in Tehran, Iran. Participants, exercise and diet design specialist, exercise instructor, outcomes examiner/assessor, and statistical analyst, will be blinded in this study.

Participants/Inclusion and exclusion criteria
Obese and overweight sedentary women aged 19-40 years Inclusion criteria: Body mass index between 27 and 35 kg/m2 No underlying, cardiovascular, or musculoskeletal diseases Lack of pregnancy or breastfeeding No-use of specific medication

Intervention groups
First intervention group: Exercise volume 1 (16 sessions in eight weeks, two sessions per week, calorie consumption per session 500 calories) + caloric restriction 1 (caloric restriction per day 360 calories). Second intervention group: Exercise volume 2 (24 sessions in eight weeks, three sessions per week, calorie consumption per session 500 calories) + caloric restriction 2 (caloric restriction per day 285 calories). Third intervention group: Exercise volume 3 (32 sessions in eight weeks, four sessions per week, calorie consumption per session 500 calories) + caloric restriction 2 (caloric restriction per day 215 calories). Control group: Only caloric restriction (caloric restriction for eight weeks per day 500 calories).

Main outcome variables
ADMA, LOX-1, body mass index, body composition, blood lipid profile.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260123068640N1**
Registration date: **2026-03-16, 1404/12/25**
Registration timing: **prospective**

Last update: **2026-03-16, 1404/12/25**
Update count: **0**

Registration date
2026-03-16, 1404/12/25

Registrant information

Name
Hosna Hatami

Name of organization / entity
University Of Tehran Aras International Campus

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-20, 1405/01/31

Expected recruitment end date
2026-05-05, 1405/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of exercise volume and caloric restriction on the ADMA and LOX-1 levels in obese and overweight sedentary women

Public title
Effect of physical exercise and caloric restriction on the inflammatory processes and pathogenesis of the cardiovascular system
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Body mass index between 27 and 35 kg/m2 No underlying (e.g., diabetes), cardiovascular, or musculoskeletal diseases Lack of pregnancy or breastfeeding No-use of specific medication
Exclusion criteria:
Having physical injury/problem restricting physical exercise Being under treatment or following a special diet
Age
From **19 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
A unique ordinal number will be allocated to each volunteer (starting at 1). The web-based research randomizer software (https://www.randomizer.org) will then be used to randomly select and assign 40 participants to four equal groups of 10. The input values in this software are the number of sets (group = 4), the number of numbers in each set (each group = 10), and the range of numbers (1 to the number of volunteers).
Blinding (investigator's opinion)
Double blinded
Blinding description
1. Participants will not be informed regarding the type of interventions/groups and will only be given a general explanation of the study. 2. The exercise and diet design specialist will not be informed about the outcome variables. 3. The exercise instructor will not be informed about the outcome variables. 4. The outcomes examiner/assessor at pre-test and post-test will not be informed regarding intervention/group type and the participants' belonging to a given intervention/group. 5. The statistical analyst will not be informed of the type of interventions/groups.
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 Sport Sciences and Health, Between 15th and 16 Ave., Northern Kargar St.
City
Tehran
Province
Tehran
Postal code
۱۴۱۷۹۳۵۸۴۰
Approval date
2025-05-10, 1404/02/20
Ethics committee reference number
IR.UT.SPORT.REC.1404.076

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
Concentration of Asymmetric Dimethylarginine (ADMA) in blood serum
Timepoint
Immediately before and after 8-week intervention
Method of measurement
ELISA kit based on the laboratory protocols

2

Description
Concentration of Lectin-like Oxidized Low-density

Lipoprotein Receptor-1 (LOX-1) in blood serum

Timepoint

Immediately before and after 8-week intervention

Method of measurement

ELISA kit based on the laboratory protocols

3

Description

Body mass index based on the formula (weight in kilograms divided by square of height in meters)

Timepoint

Immediately before and after 8-week intervention

Method of measurement

Weighing scale and stadiometer (SECA, Germany)

4

Description

Body composition (muscle mass, fat mass, visceral fat mass, waist-to-hip ratio)

Timepoint

Immediately before and after 8-week intervention

Method of measurement

Body composition analyzer device (InBody 270)

5

Description

Blood lipid profile using colorimetric assay

Timepoint

Immediately before and after 8-week intervention

Method of measurement

Colorimetric assay based on the laboratory protocols

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Exercise volume 1 (16 sessions in eight weeks, two sessions per week, calorie consumption per session 500 calories) + caloric restriction 1 (caloric restriction per day 360 calories). The physical exercise program will include a general warm-up (for five minutes), aerobic exercise (running on a treadmill for 25-35 minutes at 65-75% of maximum heart rate), resistance exercises (chest press, Lat pull-down, military press, leg extension, leg press, and crunches for 25-45 minutes at 60-80% of one maximum repetition) and cool-down (for five minutes). The intensity of physical exercises will gradually increase on a weekly basis over the course of eight weeks. The total calories deducted through physical exercise and the calorie restriction will be approximately 3,500 calories per week.

Category

Rehabilitation

2

Description

Second intervention group: Exercise volume 2 (24 sessions in eight weeks, three sessions per week, calorie consumption per session 500 calories) + caloric restriction 2 (caloric restriction per day 285 calories). The physical exercise program will include a general warm-up (for five minutes), aerobic exercise (running on a treadmill for 25-35 minutes at 65-75% of maximum heart rate), resistance exercises (chest press, Lat pull-down, military press, leg extension, leg press, and crunches for 25-45 minutes at 60-80% of one maximum repetition) and cool-down (for five minutes). The intensity of physical exercises will gradually increase on a weekly basis over the course of eight weeks. The total calories deducted through physical exercise and the calorie restriction will be approximately 3,500 calories per week.

Category

Rehabilitation

3

Description

Third intervention group: Exercise volume 3 (32 sessions in eight weeks, four sessions per week, calorie consumption per session 500 calories) + caloric restriction 2 (caloric restriction per day 215 calories). The physical exercise program will include a general warm-up (for five minutes), aerobic exercise (running on a treadmill for 25-35 minutes at 65-75% of maximum heart rate), resistance exercises (chest press, Lat pull-down, military press, leg extension, leg press, and crunches for 25-45 minutes at 60-80% of one maximum repetition) and cool-down (for five minutes). The intensity of physical exercises will gradually increase on a weekly basis over the course of eight weeks. The total calories deducted through physical exercise and the calorie restriction will be approximately 3,500 calories per week.

Category

Rehabilitation

4

Description

Control group: Only caloric restriction (caloric restriction for eight weeks per day 500 calories). The total calories deducted through the caloric restriction will be approximately 3,500 calories per week.

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, Pourmoshkanei St., Shariati St.,

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1948654711
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University
Full name of responsible person
Rahman Soori
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Faculty of Sport Sciences and Health, Between 15th and 16 Ave., Northern Kargar St.
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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
Hosna Hatami
Position
PhD Candidate
Latest degree
Master
Other areas of specialty/work
Sport Physiology
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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 will be available without mentioning the names of the participants.
When the data will become available and for how long
After Juanary 2027
To whom data/document is available
Students and researchers employed in academic and scientific institutions
Under which criteria data/document could be used
The data and documents from this study will be available for research and rehabilitation purposes.
From where data/document is obtainable
All requests must be sent to the E-mail resposible for public responsiveness at hatami.hosna@ut.ac.ir.
What processes are involved for a request to access data/document
1. Send the request mentioning the required documents and the purposes of its use by applicant 2. Review by the research team 3. Send the documents to the applicant
Comments