

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation the effect of eight week aerobic training and Omega 3 ingestion on the levels of Adipsin and insulin resistance in overweight and obese women

Protocol summary

Study aim

The effect of eight week aerobic training and Omega 3 ingestion on the levels of Adipsin and insulin resistance in overweight and obese women

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 40 patients

Settings and conduct

Study place: Faculty of Humanities, Islamic Azad University, Science and Research Branch. Type of blinding: double blind. How to blind: Before sampling, the packages containing supplements and placebos were numbered and then the package that matched each person's number according to the list was given to them

Participants/Inclusion and exclusion criteria

Inclusion criteria: women between the ages of 25 and 40 years old; Not participating in regular exercise at least during last year. Non-inclusion criteria: cardiovascular disease, type 2 diabetes, hypertension, malignant diseases such as various types of cancer, taking nutritional supplements for at least six months before the study

Intervention groups

Control group: placebo, Intervention group 1 : Omega 3, Intervention group 2 : aerobic exercise, Intervention group 3 : aerobic exercise + omega 3.

Main outcome variables

Adipsin levels; Insulin resistance; Weight

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200811048360N1**

Registration date: **2020-12-16, 1399/09/26**

Registration timing: **retrospective**

Last update: **2020-12-16, 1399/09/26**

Update count: **0**

Registration date

2020-12-16, 1399/09/26

Registrant information

Name

Saleheh Ahmadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-15, 1399/05/25

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of eight week aerobic training and Omega 3 ingestion on the levels of Adipsin and insulin resistance in overweight and obese women

Public title

The effect of aerobic training and Omega 3 ingestion on the levels of Adipsin and insulin resistance

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
 overweight and obese Women in the age range of 25 to 40 years Not participating in regular exercise at least last year

Exclusion criteria:
 Simultaneous participation in other sports training programs Cardiovascular disease Type 2 diabetes High blood pressure Malignant diseases such as cancer Take nutritional supplements at least six months before the study

Age
 From **25 years** old to **40 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **40**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple randomization is performed. Once the participants were identified, their names were randomly written into a list, identifying each person with a number. Then, we randomly selected a number by moving the mouse. From that number to the tenth number were located in the placebo group, the eleventh to the twentieth in the supplement group, the twenty-first to the thirtieth in the aerobic exercise group and the remaining ten people in the supplement and aerobic exercise group.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Participants are blind to being in the intervention or control group. The researcher is also blind to the participants being in the supplement or placebo group. Orientation sessions are held separately for the two groups receiving aerobic exercise. All participants are asked not to exercise outside the program during the research period

Placebo
 Used

Assignment
 Factorial

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics Committee of Azad University, Science and Research Branch

Street address
 Azad University Science and Research Branch, Daneshgah boulevard, Daneshgah square, Simon Bulivar boulevard

City
 Tehran

Province
 Tehran

Postal code
 1477893855

Approval date
 2020-11-18, 1399/08/28

Ethics committee reference number
 IR.IAU.SRB.REC.1399.088

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
 levels of Adipsin

Timepoint
 Before the intervention, after the intervention

Method of measurement
 Measurement of serum levels in participants' blood samples

2

Description
 Insulin resistance

Timepoint
 Before the intervention, after the intervention

Method of measurement
 Measurement of serum levels in participants' blood samples

3

Description
 Weight

Timepoint
 Before the intervention, after the intervention

Method of measurement
 seca scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Aerobic Exercise For eight weeks and three sessions per week, Exercise intensity is 50-55% in the first two weeks, 55-60% in the second two weeks, 60-65% in the third two weeks, and 65-70% in the fourth two weeks. The duration of each exercise session is about 25 minutes. 10 minutes of warm-up and eight minutes of cooling are performed before and after each exercise session, respectively.

Category

Prevention

2

Description

2nd intervention group: omega-3 supplement, 2000 mg daily, taken in two capsules of 1000 mg in the morning and evening (with or after breakfast and dinner). Omega 3 purchased from Karen Company.

Category

Prevention

3

Description

3rd intervention group: Aerobic exercise and omega 3 supplement. Aerobic Exercise For eight weeks and three sessions per week, Exercise intensity is 50-55% in the first two weeks, 55-60% in the second two weeks, 60-65% in the third two weeks, and 65-70% in the fourth two weeks. The duration of each exercise session is about 25 minutes. 10 minutes of warm-up and eight minutes of cooling are performed before and after each exercise session, respectively. And 2000 mg daily omega 3 supplement, taken in two capsules of 1000 mg in the morning and evening (with or after breakfast and dinner). Omega 3 purchased from Karen Company.

Category

Prevention

4

Description

Control group: placebo (oral paraffin), 2000 mg daily, in the form of two 1000 mg capsules in the morning and evening (with or after breakfast and dinner).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University Science and Research Branch

Full name of responsible person

Mandana GHolami

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Science and Research Branch, Daneshgah Blvd,
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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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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad 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

Islamic Azad University

Full name of responsible person

Saleheh Ahmadzadeh

Position

M.S. student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Mandana Gholami

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

After the required time, the file containing patient information and research results will be provided only for research purposes to the research institutes or researchers who wish to research in this field

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in scientific and academic institutions

Under which criteria data/document could be used

It can be used for review and use in other research projects

From where data/document is obtainable

Saleheh Ahmadzadeh E-mail address:
s_ahmadzadeh6612@yahoo.com

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

Send a summary of the research project The relationship between the research project and the research should be announced

Comments