

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation the effect of eight weeks aerobic training and Omega3 ingestion on the levels of CTRP-9 and Adiponectin in overweight and obese women

Protocol summary

Study aim

Explaining The effect of eight weeks aerobic training and omega3 ingestion on the levels of CTRP-9 and adiponectin 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:aerobic exercise, Intervention group 2:Omega 3, Intervention group 3 : aerobic exercise + omega 3.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.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).3rd intervention group: Aerobic Exercise For eight weeks and three sessions per week and 2000 mg daily omega 3 supplement, taken in two

capsules of 1000 mg in the morning and evening.

Main outcome variables

level of CTRP-9 and adiponectin in overweight and obese women, Weight, Study the risk of inflammatory diseases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200810048359N1**

Registration date: **2020-12-24, 1399/10/04**

Registration timing: **retrospective**

Last update: **2020-12-24, 1399/10/04**

Update count: **0**

Registration date

2020-12-24, 1399/10/04

Registrant information

Name

Sahar Shoaie mekanat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4401 6641

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sahaar_sho@yahoo.com

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 weeks aerobic training and Omega3 ingestion on the levels of CTRP-9 and Adiponectin in overweight and obese women

Public title
The effect of aerobic training and Omega3 ingestion on the levels of CTRP-9 and Adiponectin

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Overweight and Obese Age range 25_40 years
Exclusion criteria:
Simultaneous participation in other sports training programs Type 2 diabetes Other chronic diseases such as Cancer History of Cardiovascular disease Physical or medical restrictions for participating in sports exercise

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

Gender
Female

Phase
3

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

Parallel

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

Science and Research Branch, Daneshgah Blvd, Daneshgah Sq, Simon Bulivar Blvd

City

Tehran

Province

Tehran

Postal code

1477893855

Approval date

2020-11-17, 1399/08/27

Ethics committee reference number

IR.IAU.SRB.REC.1399.090

Health conditions studied

1

Description of health condition studied

overweight

ICD-10 code

E66.3

ICD-10 code description

Overweight

2

Description of health condition studied

obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Serum of CTRP-9 level

Timepoint

Before the intervention/After the intervention

Method of measurement

Measurement of serum levels in participants blood samples

2

Description

Serum of adiponectin level

Timepoint

Before the intervention/After the intervention

Method of measurement

Measurement of serum levels in participants blood samples

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, 2000 mg daily, in the form of two 1000 mg capsules in the morning and evening (with or

after breakfast and dinner) oral paraffin.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic and University Science and Research Branch

Full name of responsible person

Mandana Gholami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad 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

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
Sahar Shoaie Mekanat
Position
M.S.student
Latest degree
Bachelor
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

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

The effect of eight weeks aerobic training and omega3 ingestion on the levels of CTRP-9 and adiponectin in overweight and obese women

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

Sahar shoaie mekanat E-mail address:
Sahaar_sho@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