

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effects of aerobic training and omega-3 supplementation on the levels of Paraoxonase, myeloperoxidase and some inflammatory and oxidative markers in overweight and obese women's

Protocol summary

Study aim

The effects of aerobic training and omega-3 supplementation on the levels of Paraoxonase, myeloperoxidase and some inflammatory and oxidative markers in overweight and obese women's

Design

The study is a randomized by lottery, factorial clinical trial, double-blind. The target population includes 40 obese women in Kerman. Individuals are divided into four groups of 10, Phase 3. The intervention and control groups receive 2,000 mg of omega-3 supplement or placebo daily for 8 weeks. The aerobic training program runs for 8 weeks, 3 sessions per week, for 25 minutes and an intensity of 50 to 70% of the maximum heart rate.

Settings and conduct

.Because the placebo and omega-3 supplement are placed inside the capsule in exactly the same way, participants and researchers are not aware of the type of supplement they receive. Exercises are performed in Valiasr Sports Club in Kerman. Blood sampling is performed by the blood sampling manager of Razi Laboratory.

Participants/Inclusion and exclusion criteria

Obese women 25 to 40 years old who are physically healthy (no history of any cardiovascular disease, no history of specific disease or neuropsychiatric illness), no allergies to drugs and medications, no dietary supplements, medication or diet in the last 3 months, not doing regular exercise in the last 6 month.

Intervention groups

Subjects after filling informed consent form to participate in the research, are divided in a simple random way (based on a table of random numbers) into four groups of 10 people: 1. Placebo group 2. Omega 3 supplement group 3. Aerobic training group 4. Aerobic training group + omega 3 supplement

Main outcome variables

Paraoxonase 1, Myeloperoxidase, Apolipoprotein A1, Apolipoprotein B, C-reactive protein, Insulin resistance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200722048167N1**

Registration date: **2020-08-08, 1399/05/18**

Registration timing: **retrospective**

Last update: **2020-08-08, 1399/05/18**

Update count: **0**

Registration date

2020-08-08, 1399/05/18

Registrant information

Name

Shila Montazer

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3245 3916

Email address

sh.montazer@srbiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of aerobic training and omega-3 supplementation on the levels of Paraoxonase, myeloperoxidase and some inflammatory and oxidative markers in overweight and obese women's

Public title

Effect of aerobic training and omega-3 exercise on oxidative and inflammatory elements in obese women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 25 to 40 years; Physical health; Subjects' body mass index more than 25 kg / m² and less than 35 kg / m²; Ability to participate in aerobic exercise program; Not participating in regular exercise for the past year; No diagnosed diseases such as diabetes, cardiovascular, cancer, gastrointestinal diseases, liver, kidney, autoimmune diseases, inflammation, thyroid, polycystic ovary syndrome; Do not take antihypertensive drugs or lipid-lowering drugs; Do not take nutritional supplements for at least six months before the study.

Exclusion criteria:

No signing informed consent Smoking or drinking alcohol at least once a week Use of contraceptives and nonsteroidal anti-inflammatory drugs (NSAIDs) in the last 3 months Pregnancy and lactation

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the lottery method, the names of the subjects on a piece of paper It is written separately and placed inside a container then the names of the subjects are removed and is placed in the intervention group or placebo. The first 30 names are placed in the intervention group and the rest in the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo and supplement Omega 3 are placed inside the similar capsules. Patients and researchers are not aware of the type of supplement received.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University - University Scientific Unit

Street address

Tehran - End of Shahid Sattari Highway - University Square - Hesarak Martyrs Boulevard

City

Kerman

Province

Kerman

Postal code

1477893855

Approval date

2020-06-24, 1399/04/04

Ethics committee reference number

IR.IAU.SRB.REC.1399.010

Health conditions studied**1****Description of health condition studied**

Overweight and obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes**1****Description**

Paraoxonase 1

Timepoint

First, the end of the study

Method of measurement

ELISA Kit

2**Description**

Myeloperoxidase

Timepoint

First, the end of the study

Method of measurement

ELISA Kit

3

Description

Apolipoprotein A1

Timepoint

First, the end of the study

Method of measurement

ELISA Kit

4

Description

Apolipoprotein B

Timepoint

First, the end of the study

Method of measurement

ELISA Kit

5

Description

C-Reactive Protein

Timepoint

First, the end of the study

Method of measurement

Bionic Kit

Secondary outcomes

1

Description

Blood Sugar

Timepoint

First, the end of the study

Method of measurement

Glucose Test Kit

2

Description

Insulin

Timepoint

First, the end of the study

Method of measurement

Insulin ELISA Kit

3

Description

VO2 max

Timepoint

First, the end of the study

Method of measurement

Rockport test and formula method

4

Description

Body Mass Index

Timepoint

First, the end of the study

Method of measurement

Twice the height / weight

Intervention groups

1

Description

Intervention group: Omega 3 supplement group (taking omega 3 supplement, not participating in aerobic exercise program):for 8 weeks and daily 2000 mg of omega 3 fatty acid supplement in the form of two 1000 mg capsules containing 360 mg of Eicosa pentanoic acid and 240 mg of Docosa hexaenoic acid (morning and night) made by Karen)and do the activities of daily living

Category

Prevention

2

Description

Intervention group: Aerobic training group (participation in aerobic training program- not taking omega3 supplements):The training program including 8 weeks of aerobic training(Running or fast walking) every week 3 sessions. Intensity of training in the first two weeks 50 to 55%, in the second two weeks 55 to 60%, in the third two weeks 60 to 65% and in the fourth two weeks 65 to 70% maximum heart rate is designed and the duration of each exercise session is about 25 It is minutes. Before and after each exercise session, 10 minutes of warm-up and eight minutes of cooling are performed, respectively.During this week, take placebo capsules morning and night. (Similar to omega-3 capsules but containing oral paraffin).Made by Darogster Company

Category

Prevention

3

Description

Intervention group: Aerobic training group + omega 3 supplement (taking omega 3 supplement and simultaneously participating in aerobic training program): for 8 weeks and daily 2000 mg of omega 3 fatty acid supplement in the form of two 1000 mg capsules containing 360 mg of Eicosa pentanoic acid and 240 mg of Docosa hexaenoic acid (morning and night) made by Karen) in addition to the training program including 8 weeks of aerobic training (Running or fast walking)every week 3 sessions. Intensity of training in the first two weeks 50 to 55%, in the second two weeks 55 to 60%, in the third two weeks 60 to 65% and in the fourth two weeks 65 to 70% maximum heart rate is designed and the duration of each exercise session is about 25 It is minutes. Before and after each exercise session, 10 minutes of warm-up and eight minutes of cooling are performed, respectively.

Category

Prevention

4

Description

Control group: Placebo group (not participating in aerobic exercise program, not taking omega 3 supplements)
During these 8 weeks, take placebo capsules morning and night. (Similar to omega-3 capsules but containing oral paraffin) Made by Darogster Company, In addition to daily life activities.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman University of Medical Sciences

Full name of responsible person

Shila montazer

Street address

Campus of Kerman University of Medical Sciences, at the beginning of Haft Bagh axis

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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?

No

Title of funding source

Vice Chancellor for Research, Faculty of Literature, Tehran University of Research Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shila Montazer

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Contact

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Position

Assistant Professor

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Exercise Physiology

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North Alley 2 West 2, Elahieh Street, Nasr Boulevard

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Kerman

Postal code

7618698181

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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

Not applicable