Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of eight weeks aerobic training and omega3 ingestion on the levels of IL-1β and MCP-1 in overweight and obese women

Protocol summary

Study aim
Explaining the effect of eight weeks of aerobic exercise and omega-3 intake on IL-1β and MCP-1 levels in overweight and obese women

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

Settings and conduct
Pre-test blood samples will be collected prior to the 8-week training intervention. In the next stage, the subjects of the aerobic exercise group and aerobic exercise + omega 3 will participate in the desired exercise program for 8 weeks. Each aerobic exercise session will consist of 47 minutes of brisk walking or jogging with an intensity equivalent to 70-60% of the maximum heart rate, which is performed three times a week.Before and after each aerobic exercise session, warm-up and cooling will be performed, respectively. Consumption of omega-3 will be considered 2000 mg per day.48 hours after the last exercise session and in order to eliminate the acute effects of the last session of aerobic exercise and omega 3 consumption, the subjects will be present again in the post-test phase for blood sampling. 7 ml of blood will be taken from each subject while sitting and from a brachial vein. The blood samples are then centrifuged.

Participants/Inclusion and exclusion criteria
Overweight and obese women between the ages of 25 and 40, not participating in regular exercise for the past year, not having type 2 diabetes, not having other chronic diseases such as cancer, not having a history of heart disease, and lack of physical and medical restrictions to participate in exercise

Intervention groups
Subjects will be randomly divided into 4 groups including placebo, omega 3, aerobic exercise and aerobic exercise + omega 3

Main outcome variables
Study level of IL-1β and MCP-1 in overweight and obese women, weight loss, Study the risk of inflammatory diseases

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200806048320N1**
Registration date: **2020-11-22, 1399/09/02**
Registration timing: **retrospective**

Last update: **2020-11-22, 1399/09/02**
Update count: **0**

Registration date
2020-11-22, 1399/09/02

Registrant information

Name
Seyyedeh Fatemeh Abdollah Pouri Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2209 1547

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f.p.hosseini@gmail.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
The effect of eight weeks aerobic training and omega3 ingestion on the levels of IL-1β and MCP-1 in overweight and obese women

Public title
The effect of eight weeks aerobic training and omega3 ingestion on the levels of IL-1β and MCP-1 in overweight and obese women

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
overweight and obese Age range 25-40 years
Exclusion criteria:
Subjects did not participate in regular exercise during the past year No type 2 diabetes No other chronic diseases such as cancer No history of cardiovascular disease No physical or medical restrictions for participating in sports exercises

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

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, using the random number table method, 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

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University Science and Research Branch
Street address
Science and Research Branch, Daneshgah Blvd, Daneshgah Sq., Simon Bulivar Blvd
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Tehran
Province
Tehran
Postal code
1477893855

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

Ethics committee reference number
IR.IAU.SRB.REC.1399.089

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 IL-1B and MCP-1 levels

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 Azad University Science and Research Branch
Full name of responsible person
Mandana GHolami
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Sponsors / Funding sources

1

Sponsor
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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

2

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mandana Gholami

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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
Seyyede Fatemeh Abdollah Pouri Hosseini
Position
M. S. student
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Person responsible for scientific inquiries

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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 IL-1β and MCP-1 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 other research projects

From where data/document is obtainable

Fatemeh Abdollah Pouri Hoseini E-mail address: f.p.hosseini@gmail.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