

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effects of aerobic training along with spirulina supplementation on markers of hepatic, cardiovascular, lipid profile and anthropometric indices in women with overweight and obesity

Protocol summary

Study aim

Determining of the effects of aerobic training along with spirulina supplementation on markers of hepatic, cardiovascular, lipid profile and anthropometric indices in women with overweight and obesity

Design

Clinical trial with control group, with factorial groups, single-blind, randomized, phase 3 on 40 people. For randomization, block design is used.

Settings and conduct

Referral to a private clinic in Ramsar in 1399, selection of 40 people based on inclusion criteria, randomization into 4 groups, intervention and aerobic training for 8 weeks, completion of the individual consent, physical activity and 24-hour recall questionnaires, receiving 5 Cc of blood before and after the intervention. Blinding of statistical analyzer, coding by a third party who does not know the details.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study
Women between 20 to 50 years old
Body mass index (BMI) between 25 to 35 (kg / m²),
Exclusion criteria: Use of other dietary supplements, probiotics and anti-inflammatory drugs, Use of any antioxidant supplements in the last 3 months, Use of immunosuppressive drugs, Following of special diets, Pregnancy, lactation, Smokers, Menopause, Metabolic and chronic diseases

Intervention groups

Supplement: Three capsules 500 mg/d of spirulina, 2)
Placebo: (three capsules 500 mg/d containing starch), 3)
Aerobic training (three times/week, 1 hour each time) and three capsules 500 mg/d of spirulina, 4)
Aerobic training (three times/week, 1 hour each time) and placebo (three capsules 500 mg/d containing starch)

Main outcome variables

Markers of hepatic, cardiovascular, lipid profile and anthropometric indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210103049933N1**

Registration date: **2021-05-19, 1400/02/29**

Registration timing: **prospective**

Last update: **2021-05-19, 1400/02/29**

Update count: **0**

Registration date

2021-05-19, 1400/02/29

Registrant information

Name

zeinab porasgari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5525 1015

Email address

porasgarizeynab@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-24, 1400/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of aerobic training along with spirulina supplementation on markers of hepatic, cardiovascular, lipid profile and anthropometric indices in women with overweight and obesity

Public title

The effects of aerobic training along with spirulina supplementation in women with overweight and obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Women between 20 to 50 years old Body mass index (BMI) between 25 to 35 (kg / m2)

Exclusion criteria:

Use of other dietary supplements, probiotics and anti-inflammatory drugs Use of any antioxidant supplements in the last 3 months Use of immunosuppressive drugs Following of special diets Pregnancy, lactation Smokers Menopause Having a history of diabetes, cancer, liver, kidney, thyroid and gastrointestinal diseases

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of people in each of the study groups (supplement, placebo, aerobic training and supplement, aerobic training and placebo) will be done by "Random allocation software" using classified randomized blocking method (block size: 4). In addition, in order to reduce selection bias error, allocation concealment will be used. This will be done by assigning unit codes (two codes A and B) to each person's capsules. In this way, 60 people will be randomly allocated to supplement (n = 10), placebo (n = 10), aerobic training and supplement (10), aerobic training and placebo (n = 10) groups. In fact, each person will receive a can containing code A or B, and eventually 20 people will receive cans containing code A and 30 people will receive cans containing code B. Also, 20 people in two groups will receive aerobic training in addition to supplement or placebo.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, the statistical analyst will be blinded to the study groups. Before starting the study, the cans containing the respective capsules will be coded by a person other than the researcher (this person will not aware of the details of the research) to A and B, so that the type of received capsules in each group will be

blinded for researcher. Also, placebo and supplement capsules will be similar in terms of color, shape, size and taste. In addition, cans containing the supplement and placebo will be quite similar.

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 of Tehran

Street address

Velayat University Complex, Shahid Sohani St., Army Blvd, Imam Ali highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۱۴۸۹۶۳۵۳۷

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.SSRC.REC.1400.024

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

Weight

Timepoint

Before and after the intervention

Method of measurement

Seca scale

2

Description

Body mass index

Timepoint

Before and after the intervention
Method of measurement
Weight divided by the square of height in meters (kg / m²)

3

Description
Waist and hip circumference
Timepoint
Before and after the intervention
Method of measurement
Tape metre (cm)

4

Description
Liver enzymes (alanine aminotransferase, aspartate aminotransferase and gamma glutamyl transferase)
Timepoint
Before and after the intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

5

Description
Lipid profile (HDL-c, LDL-c, TG, total cholesterol and VLDL)
Timepoint
Before and after the intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

6

Description
Serum homocysteine
Timepoint
Before and after the intervention
Method of measurement
ELISA

7

Description
Serum levels of C-reactive protein
Timepoint
Before and after the intervention
Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Three capsules 500 mg/d of spirulina after each meal for 8 weeks (Made by the

German Rocket company)

Category
Lifestyle

2

Description
Control group: Three capsules 500 mg/d containing starch after each meal for 8 weeks (Made by the Faculty of Pharmacy, Mazandaran University of Medical Sciences)
Category
Placebo

3

Description
Intervention group 2: Aerobic training (three times/week, 1 hour each time) and three capsules 500 mg/d of spirulina after each meal for 8 weeks (Made by the German Rocket company)
Category
Lifestyle

4

Description
Intervention group 3: Aerobic training (three times/week, 1 hour each time) and placebo (three capsules 500 mg/d containing starch) after each meal for 8 weeks (Made by the Faculty of Pharmacy, Mazandaran University of Medical Sciences)
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Private clinic
Full name of responsible person
Zeynab Porasgari
Street address
No. 133, Mehregan Medical Building, Motahari St., Ramsar, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Ali Kashi

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Velayat University Complex, Army Blvd, Shahid
Sohani St., Imam Ali highway, Tehran,

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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
1

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
Ali Kashi

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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
99

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
Zeynab Porasgari

Position
Master of Science

Latest degree
Master

Other areas of specialty/work
Sports Physiology (Sports Nutrition)

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Person responsible for scientific inquiries

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Full name of responsible person
Zeynab Porasgari

Position
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Latest degree
Master

Other areas of specialty/work
Nutrition

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

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Latest degree

Master

Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable