

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of high intensity interval training with spirulina supplementation on cardiovascular metabolic risk factors and body composition of obese elderly women.

Protocol summary

Study aim

The purpose of this study is to investigate the protective effect of high intensity interval training with spirulina supplement on cardiovascular metabolic risk factors of obese elderly women.

Design

A clinical trial with a control group, with parallel groups (supplement plus training, placebo plus training, supplement and control), double-blind on 40 elderly people. A table of random numbers was used for randomization.

Settings and conduct

After selecting 40 obese elderly women who meet the conditions to enter and refer to the health centers of Birjand city and grouping people, for eight weeks, training groups have three exercise sessions with an intensity of 65 to 75% of the reserve heart rate and spirulina groups will also follow the daily intake of 1000 mg of the supplement. For double-blinding, before the start of the research, the packages containing the supplement and placebo will be marked by a person other than the researcher, and the consumption of the supplement and placebo will be done under the supervision of the same person.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range is 60-75 years BMI more than 25 kg/m² Having general physical and mental health Inactive lifestyle Exclusion criteria: Using aids for walking Using the drug in the previous 6 months Having cardiovascular diseases

Intervention groups

Intervention group 1: training with spirulina, two 500 mg spirulina capsules daily and high intensity interval training 3 times a week Intervention group 2: spirulina, two 500 mg spirulina capsules daily Intervention group 3: training with placebo, two placebo capsules of 500 mg daily and high intensity interval training 3 times a week

Control group: following daily activities without taking supplements and training

Main outcome variables

Angiopoietin-like factor-4, lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220322054338N1**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **prospective**

Last update: **2024-02-07, 1402/11/18**

Update count: **0**

Registration date

2024-02-07, 1402/11/18

Registrant information

Name

elham ghasemi

Name of organization / entity

University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

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+98 54 3123 2080

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-04-18, 1403/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of high intensity interval training with spirulina supplementation on cardiovascular metabolic risk factors and body composition of obese elderly women.

Public title

The effect of high intensity interval training and spirulina supplementation on cardiovascular metabolic risk factors and body composition of obese elderly women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range is 60-75 years BMI more than 25 kg/m²
Inactive lifestyle (exercise activity less than 1 hour per week) Having general physical and mental health

Exclusion criteria:

Using aids for walking Using the drug in the previous 6 months Having chronic diseases, especially cardiovascular diseases

Age

From **60 years** old to **75 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

The number of 40 elderly women volunteers eligible to participate in the study by non-probability sampling method (easy and accessible) and based on the purpose of selection and then randomly divided into four equal groups of supplement plus training, placebo plus training, supplement and control. A table of random numbers will be used for randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the supplement consuming groups will receive 2 capsules of 500 mg of spirulina in 2 times in the morning and in the evening for eight weeks (1000 mg of spirulina supplement per day), while in the placebo groups, 2 capsules containing starch will be taken daily. Before the start of the research, the cans with supplements and placebo will be marked by a person other than the researcher so that the researcher and participants are not informed about the type of capsules received. Supplement and placebo were taken

under the supervision of the same person.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Sport Sciences
Research Institute

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street,
Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2023-09-20, 1402/06/29

Ethics committee reference number

IR.SSRC.REC.1402.166

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

Obese elderly

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

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

Angiopoietin-like factor-4

Timepoint

The beginning and end of the study after 8 weeks

Method of measurement

ELISA

2**Description**

Lipid profile

Timepoint

The beginning and end of the study after 8 weeks

Method of measurement

Secondary outcomes

1

Description

Weight

Timepoint

The beginning and end of the study after 8 weeks

Method of measurement

digital scale

2

Description

Fat percentage

Timepoint

The beginning and end of the study after 8 weeks

Method of measurement

Body composition analysis device model IOI 353 made by South Korea Jawon Medical company.

Intervention groups

1

Description

Intervention group: training with spirulina, two 500 mg spirulina capsules daily and high intensity interval training 3 times a week for 8 weeks

Category

Treatment - Other

2

Description

Intervention group: spirulina, two 500 mg spirulina capsules daily for 8 weeks

Category

Treatment - Other

3

Description

Intervention group: training with placebo, two placebo capsules of 500 mg daily and high intensity interval training 3 times a week for 8 weeks

Category

Treatment - Other

4

Description

Control group: following daily activities without taking supplements and training for 8 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Zabol city

Full name of responsible person

Elham Ghasemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Zabol

Full name of responsible person

Dr Majid Erfanian

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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

The University of Zabol

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

University of Zabol

Full name of responsible person

Elham Ghasemi

Position

Assistant Professor of department of Sport Sciences,
Facu

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Subjects' information will be made available to other
researchers after being de-identified

When the data will become available and for how long

After the publication of the final research report.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Citing the findings by citing the source

From where data/document is obtainable

Those interested in more information can contact the
following email and address: Postal address: University of
Zabol Email: elhamghasemi@uoz.ac.ir

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

Send the request to the given postal address or email to
Dr Elham Ghasemi and after the approval of the research
team members, the data will be sent

Comments