Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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elham ghasemi
Name of organization / entity
University of Sistan and Baluchestan
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Iran (Islamic Republic of)
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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

Biochemical and laboratory methods

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
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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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Assistant Professor of department of Sport Sciences, Faculty of Literature and Humanities, Universit

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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