

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Aerobic Training with Spirulina Supplementation on Mitochondrial-Derived Peptides, Inflammatory factors and Heart damage in Overweight Elderly Men

Protocol summary

Study aim

The aim of this study was to examine the Protective Effect of aerobic training with spirulina supplementation on mitochondrial-derived peptides, inflammatory factors and heart damage in overweight elderly men.

Design

40 obese adult men selected from Anzali and randomly divided into five groups (Control, Overweight, Overweight + Exercise, Overweight + Spirulina and Overweight + Exercise + Spirulina). Training group's perform Aerobic Training for eight weeks, three sessions a week (65% to 75% of the peak heart rate and for 40 min). Overweight + Spirulina and Overweight + Exercise + Spirulina will feed 1000 mg of spirulina supplementation for eight weeks (before breakfast and dinner).

Settings and conduct

Intervention Research, Anzali City, The research site is Takhti Sports Club, which has already been coordinated. In this research, people who work with subjects are blinded.

Participants/Inclusion and exclusion criteria

Age range 50-65 years, BMI more than 25 kg / m², inactive lifestyle (exercise less than 1 hour per week), no drug use in the previous 6 months, no person or family has Covid 19 disease and consent to participate in the study

Intervention groups

Aerobic Training and Spirulina Supplementation

Main outcome variables

Effect of aerobic training with spirulina on indexes such as: Humanin, MOTS-c, TGF- β 1, TNF- α , GDF15, NTproBNP, sVCAM-1, E-selectin

General information

Reason for update

1- Addition of new indicators 2- Receiving the new code of ethics (IR.IAU.M.REC.1400.032)

Acronym

IRCT registration information

IRCT registration number: **IRCT20140415017288N7**

Registration date: **2021-03-06, 1399/12/16**

Registration timing: **prospective**

Last update: **2022-01-09, 1400/10/19**

Update count: **1**

Registration date

2021-03-06, 1399/12/16

Registrant information

Name

Ahmad Abdi

Name of organization / entity

Ayatollah Amoli Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

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+98 11 4321 7126

Email address

a.abdi@iauamol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aerobic Training with Spirulina
Supplementation on Mitochondrial-Derived Peptides,
Inflammatory factors and Heart damage in Overweight
Elderly Men

Public title

Effect of Exercise and Spirulina on Elderly Men

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range in the range of 50-65 years BMI more than 25
kg per square meter Inactive lifestyle (exercise less than
1 hour per week) Do not use the drug in 6 months No
person or family has Covid disease 19 Satisfaction to
participate in the study

Exclusion criteria:

Take supplements and practice before starting the
protocol Detection of other underlying diseases during
the implementation of the protocol, such as
cardiopulmonary problems and musculoskeletal
disorders during exercise that prevent the performance
of the activity Covid 19 disease

Age

From **50 years** old to **65 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **8**

overweight elderly men

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, subjects are selected Simple
randomization by random allocation rule. After
determining the sample size, they will be equally divided
into five groups (1- Control, 2- Overweight, 3- Overweight
+ Exercise, 4- Overweight + Spirulina and 5- Overweight
+ Exercise + Spirulina). Using the lottery method, the
names of the subjects are written on separate papers
and placed in a container, then the names of the
subjects are randomly taken out and placed in the
intervention groups or placebo, respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The Overweight + Spirulina and Overweight + Exercise +
Spirulina patients receive Spirulina (1000 mg/day), two
capsules orally of 500 mg twice daily before breakfast
and dinner for 8 weeks. Control, Overweight and
Overweight + Exercise groups receive placebo in the
same pharmacological presentation. Starch is used as
placebo.

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 -
Marvdasht Branch

Street address

3 km of Marvdasht-Persepolis Boulevard, Islamic Azad
University, Marvdasht Branch

City

Marvdasht

Province

Fars

Postal code

13119-73711

Approval date

2021-03-01, 1399/12/11

Ethics committee reference number

IR.IAU.M.REC.1399.050

2**Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University -
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Approval date

2021-12-26, 1400/10/05

Ethics committee reference number

IR.IAU.M.REC.1400.032

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

overweight elderly men

ICD-10 code

E66.3

ICD-10 code description

Overweight

Primary outcomes

1

Description

Effect of aerobic training and spirulina supplementation on Humanin

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

2

Description

Effect of aerobic training and spirulina supplementation on mitochondrial ORF of the 12S rRNA type-c (MOTS-c)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

3

Description

Effect of aerobic training and spirulina supplementation on Transforming growth factor beta 1 (TGF- β 1)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

4

Description

Effect of aerobic training and spirulina supplementation on Tumor necrosis factor alpha (TNF- α)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

5

Description

Effect of aerobic training and spirulina supplementation on Growth Differentiation Factor 15 (GDF15)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

6

Description

Effect of aerobic training and spirulina supplementation on N-terminal pro-brain natriuretic peptide (NTproBNP)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

7

Description

Effect of aerobic training and spirulina supplementation on Soluble Vascular Cell Adhesion Molecule-1 (sVCAM-1)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

8

Description

Effect of aerobic training and spirulina supplementation on E-selectin

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

9

Description

Effect of aerobic training and spirulina supplementation on Ghrelin

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

10

Description

Effect of aerobic training and spirulina supplementation on Nesfatin-1

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

11

Description

Effect of aerobic training and spirulina supplementation on Obstatin

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

12

Description

Effect of aerobic training and spirulina supplementation on YY peptide

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

13

Description

Effect of aerobic training and spirulina supplementation

on sICAM-1

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

14

Description

Effect of aerobic training and spirulina supplementation on sVCAM-1

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

15

Description

Effect of aerobic training and spirulina supplementation on E-selectin

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

16

Description

Effect of aerobic training and spirulina supplementation on endothelin-1

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

Secondary outcomes

empty

Intervention groups

1

Description

Control group: in this group we have not any intervention during 8 weeks, and will consider this group as placebo.

Category

Placebo

2

Description

Intervention group: Training group (in this group for eight week, three session/weeks, the training start with 10 min warming and then 40 min training with 65% Peak heart rate, which in the final weeks reaches 80% of the heart rate).

Category

Treatment - Other

3

Description

Intervention group: Spirulina supplementation group (in this group eat 1000 mg of spirulina supplementation for eight weeks Twice a day before breakfast and dinner).

Category

Treatment - Other

4

Description

Intervention group: Training+spirulina supplementation group (In this group the Simultaneous intervention, training and spirulina supplementation, will treat with the same protocol that describe at the previous part).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Anzali

Full name of responsible person

Ahmad Abdi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

Islamic Azad University

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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Ahmad Abdi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Alireza Barari

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Associate Professor

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

Islamic Azad University

Full name of responsible person

Ahmad Abdi

Position

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Latest degree

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Other areas of specialty/work

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

Yes - There is 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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The report is submitted to the research department of the university. Also published as a paper.

When the data will become available and for how long

Since 2021	Scientific bases and Ayatollah Amoli Branch, Islamic Azad
To whom data/document is available	University, amol, Iran
All researchers	What processes are involved for a request to access data/document
Under which criteria data/document could be used	Maximum one week
Citing references	Comments
From where data/document is obtainable	