

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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 / m<sup>2</sup>, 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- $\beta$ 1, TNF- $\alpha$ , 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)

##### Phone

+98 11 4321 7126

##### Email address

a.abdi@iautamol.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 -  
Marvdasht Branch

**Street address**

3 km of Marvdasht-Persepolis Boulevard, Islamic Azad  
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**City**

Marvdasht

**Province**

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**Postal code**

13119-73711

**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- $\beta$ 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- $\alpha$ )

#### **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

**Street address**

Ayatollah Amoli Branch, Islamic Azad University

**City**

Amol

**Province**

Mazandaran

**Postal code**

678

**Phone**

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**Email**

a.abdi@iauamol.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Asieeh Abbassi Dalooi

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**Email**

abbasi.dalooi@gmail.com

**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

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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

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**Position**

Associate Professor

**Latest degree**

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**Other areas of specialty/work**

Sport Medicine

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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

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Citing references

**From where data/document is obtainable**

Scientific bases and Ayatollah Amoli Branch, Islamic Azad University, amol, Iran

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

Maximum one week

**Comments**