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 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-β1, 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

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Iran (Islamic Republic of)

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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

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
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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

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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-β1)
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
Effect of aerobic training and spirulina supplementation on sICAM-1

**Timepoint**
Before and after the protocol

**Method of measurement**
Biochemical and laboratory methods

**Description**
Effect of aerobic training and spirulina supplementation on sICAM-1

Effect of aerobic training and spirulina supplementation on E-selectin

**Timepoint**
Before and after the protocol

**Method of measurement**
Biochemical and laboratory methods

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

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

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**
Shahid Beheshti Hospital in Anzali
**Full name of responsible person**
Ahmad Abdi
**Street address**
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Sponsors / Funding sources

1

**Sponsor**
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**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
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Person responsible for scientific inquiries

Contact
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Islamic Azad University
Full name of responsible person
Alireza Barari
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine

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

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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Ph.D.
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

**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**