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

Country
Iran (Islamic Republic of)

Phone
+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**

**Groups**
- 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 University, Marvdasht Branch

**City**
Marvdasht

**Province**
Fars

**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

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Effect of aerobic training and spirulina supplementation on Humanin</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
</tr>
<tr>
<td>2</td>
<td>Effect of aerobic training and spirulina supplementation on mitochondrial ORF of the 12S rRNA type-c (MOTS-c)</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
</tr>
<tr>
<td>3</td>
<td>Effect of aerobic training and spirulina supplementation on Transforming growth factor beta 1 (TGF-β1)</td>
<td>Before and after the protocol</td>
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<td>4</td>
<td>Effect of aerobic training and spirulina supplementation on Tumor necrosis factor alpha (TNF-α)</td>
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<td>Biochemical and laboratory methods</td>
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<tr>
<td>5</td>
<td>Effect of aerobic training and spirulina supplementation on Growth Differentiation Factor 15 (GDF15)</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
</tr>
<tr>
<td>6</td>
<td>Effect of aerobic training and spirulina supplementation on N-terminal pro-brain natriuretic peptide (NTproBNP)</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
</tr>
<tr>
<td>7</td>
<td>Effect of aerobic training and spirulina supplementation on Soluble Vascular Cell Adhesion Molecule-1 (sVCAM-1)</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
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<tr>
<td>8</td>
<td>Effect of aerobic training and spirulina supplementation on E-selectin</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
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<td>9</td>
<td>Effect of aerobic training and spirulina supplementation on Ghrelin</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
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<td>10</td>
<td>Effect of aerobic training and spirulina supplementation on Nesfatin-1</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
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<tr>
<td>11</td>
<td>Effect of aerobic training and spirulina supplementation on Obstatin</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
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<td>Effect of aerobic training and spirulina supplementation on YY peptide</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
</tr>
<tr>
<td>13</td>
<td>Effect of aerobic training and spirulina supplementation</td>
<td>Before and after the protocol</td>
<td>Biochemical and laboratory methods</td>
</tr>
</tbody>
</table>
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
+98 11 4321 7124

Fax
+98 11 4321 7009

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 Daloii

Street address
Ayatollah Amoli Branch, Islamic Azad University

City
Amol

Province
Mazandaran

Postal code
678

Phone
+98 11 4321 7126
Fax
+98 11 4321 7009
Email
abbasi.daloii@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
Street address
Ayatollah Amoli Branch, Islamic Azad University
City
Amol
Province
Mazandaran
Postal code
678
Phone
+98 11 4321 7124
Email
a.abdi@iauamol.ac.ir

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
Street address
Ayatollah Amoli Branch, Islamic Azad University
City
Amol
Province
Mazandaran
Postal code
678
Phone
+98 11 4321 7124
Email
alireza54.barari@gmail.com

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
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Ayatollah Amoli Branch, Islamic Azad University
City
Amol
Province
Mazandaran
Postal code
678
Phone
+98 11 4321 7124
Email
a.abdi@iauamol.ac.ir
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