Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of chlorella vulgaris algae supplementation, HIIT exercises and their combination on the serum levels of PGC-1α, FGF21, SIRT1, nutritional status, body composition and aerobic power in young women with overweight and obesity

Protocol summary

Study aim

The aim of the present study is to investigate the effect of chlorella vulgaris algae supplementation, HIIT exercises and their combination on the serum levels of PGC-1α, FGF21, SIRT1, nutritional status, body composition and aerobic power in young women with overweight and obesity.

Design

Randomized clinical trial, double blinded with four parallel groups

Settings and conduct

The intervention will be conducted at gym of the University of Medical Sciences and Faculty of Physical Education of Tabriz University for 8 weeks. Supplements and placebo will be coded by the person in charge, and the main investigators and patients will be blind to the type of supplement used.

Participants/Inclusion and exclusion criteria

44 participants with BMI between 25 and 34.9 will be included in the study. Individual consent and inclination to cooperation is an inclusion criteria Bone and joint problems will not be included.

Intervention groups

Intervention group 1: Supplementation of Chlorella Vulgaris from the Green Iranian's future Company (900 mg / day, 300 mg) and HIIT performance (three sessions per week for 60 minutes). Intervention group 2: HIIT performance (similar protocol) exercises and receive the placebo from Iranian's Green future. Intervention group 3: Receive chlorella vulgaris (900 mg / day, 300 mg). Control group: Will receive the same placebo with the same protocol.

Main outcome variables

Time to get tired with Bruce test; Maximum oxygen consumption; Aerobic power ; Anthropometric indices and body composition (FM, FFM, BW); Basal Metabolic Rate (BMR); Blood pressure; Heart rate; Food intake (energy, carbohydrate, protein and fat).); Physical activity; fasting blood glucose, lipid profile (TC, HDL-C, TG, LDL-C), serum level of Sirtuin1(SIRT-1), Fibroblast Growth Factor 21 (FGF21) and Peroxisome proliferator-activated receptor gamma coactivator 1-alpha (PGC-1α).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190224042821N1**
Registration date: **2019-03-09, 1397/12/18**
Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**
Update count: **1**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name
Ali Barzegar
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of chlorella vulgaris algae supplementation, HIIT exercises and their combination on the serum levels of PGC-1α, FGF21, SIRT1, nutritional status, body composition and aerobic power in young women with overweight and obesity

Public title

Effect of chlorella vulgaris algae and HIIT exercises on overweight and obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Tendency and the ability of cooperation The age range of 18 to 35 BMI in the range of overweight to type 1 obesity (25-34.9)

Exclusion criteria:

Joint and bone disease

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Selection would be simple allocation with blocking.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the main investigators (including the student, and her supervisor and adviser professors) as well as the patients will be blinded to the type of the supplement (chlorella vulgaris or placebo) received by each group. The person responsible for preparing the supplement boxes(who is completely unrelated to the study) will be asked to assign a three digit code to each of the two powders (chlorella vulgaris and placebo), and keep the codes for himself until the end of the study and data analyses.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar Neyshabouri Ave, Golgasht Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166/1573113

Approval date

2019-02-05, 1397/11/16

Ethics committee reference number

IR.TBZMED.REC.1397.922

Health conditions studied

1

Description of health condition studied

Overweight and obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Time to reach the fatigue

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

The time to reach the fatigue or maximum power of a person is done using the Bruce test with the help of treadmill. The test results are reported in minutes and indicate the cardiovascular power.

2

Description

VO2 maximum or aerobic power

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Maximum oxygen consumption (VO2max) or maximum aerobic power is the highest oxygen content used in extreme exercise and is the most important aerobic fitness index, cardiovascular health and endurance ability. VO2max can be measured by direct and indirect methods. Here using the indirect method, the Bruce test on the treadmill, which measures the VO2max from the time of performance or the maximum power output.

3

Description
Anthropometric measures
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of height and weight without shoes and with minimum clothes on, by Seca stadiometer and scale, respectively. Measurement of waist and hip circumferences by a tape measure. Calculation of waist to hip ratio (WHR) by dividing waist circumference by hip circumference, and body mass index (BMI) by dividing weight (Kg) by height squared (m2).

4

Description
Body composition
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Bioelectrical Impedance Analysis (BIA) to determine Fat mass (FM), Fat free mass (FFM), and Body water (BW)

5

Description
Resting metabolic rate
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Indirect calorimetry

6

Description
Blood pressure
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
It is done using a medical barometer.

7

Description
Heart rate
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
It is done using a digital barometer.

8

Description
Blood glucose
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic method

9

Description
Lipid profile
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of total cholesterol, HDL-cholesterol and triglyceride through enzymatic methods and calculation of LDL-cholesterol by Friedewald equation

10

Description
Blood insulin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA

11

Description
Insulin resistance
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
By the use of formula

12

Description
SIRT1
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA

13

Description
FGF21
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA

14

Description
PGC-1alpha
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA

15

Description
Serum Irisin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA

16

Description
Total antioxidant capacity
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Participants will receive daily chlorella vulgaris supplement provided by the Iranian's Green Future company (900 mg/day in 300 mg pills after three main meals) and HIIT exercises (three sessions per week for 60 minutes) for 8 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2: Participants will perform HIIT exercises (three sessions per week for 60 minutes) and they will receive a placebo similar to the supplement provided by the Iranian's Green Future company with the same protocol (three times a day) for 8 weeks.
Category
Treatment - Other

3

Description
Intervention group 3: : Participants will receive daily Chlorella Vulgaris supplement provided by the Iranian's Green future Company (900 mg/day in 300 mg pills after three main meals) for 8 weeks
Category
Treatment - Drugs

4

Description
Control group:Receive the same placebo with supplements provided by the Iranian's Green Future company with the same protocol (three times a day) for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Physical Education, Tabriz University and use of recall
Full name of responsible person
Dr. Ramin Amirsasan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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nut-rc@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
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
Tabriz University of Medical Sciences

Full name of responsible person
Mahzad Sanayei

Position
Ph.D Student

Latest degree
Master

Other areas of specialty/work
Nutrition

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Faculty of Nutrition and Food Sciences, Attar Neyshabouri Av., Golgasht St.

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Full name of responsible person
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Person responsible for updating data

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Position
Ph.D. candidate in Nutritional Sciences

Latest degree
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Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data collected for the primary outcomes will be shared.

When the data will become available and for how long
access starting 12 months after publication

To whom data/document is available
The data will only be available for people working in academic institutions.

Under which criteria data/document could be used
The data of the present study will only be accessible by other researchers, for conducting Meta-analysis.

From where data/document is obtainable
To access the required data, the researchers can contact Ms. Mahzad Sanayei: email address: mahzad.sanayei@gmail.com cellphone number: 0098 9132210641

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

The applicant should provide a brief description of the aims and methods of his Meta-analysis. His request will be assessed by the researchers, and if all of them agree to the request, the requested data will be emailed to the applicant in an Excel file format. All these procedures will take no longer than 15 days.

Comments