

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the effect of high and moderate intensity aerobic exercise with spirulina supplementation on ACE2 receptor sensitivity in obese people during SARS-COVID-2 epidemic

Protocol summary

Study aim

Comparison of training with different intensities with consumption in obese people in order to prevent Covid 19

Design

A randomized, double-blind, randomized controlled clinical trial on 60 healthy obese individuals. Excel software rand function was used for randomization.

Settings and conduct

Sports Medicine Center of Tehran University of Medical Sciences - Obesity Clinic of Shariati Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria are body mass index greater than 30 in people aged 40 to 50 years, no cardiovascular, skeletal, muscular and metabolic diseases limiting exercise, no hypertension and diabetes, no history Regular exercise during the last 6 months and not taking drugs and smoking. Contradiction of any of the above is a condition of non-inclusion in the study.

Intervention groups

1- High intensity aerobic exercise intervention group 2- Medium intensity aerobic exercise intervention group 3- Intervention group only taking spirulina supplement 4- High intensity aerobic exercise intervention group and spirulina consumption 5- Medium intensity aerobic exercise intervention group and spirulina consumption 6- Control group

Main outcome variables

FNDC5 gene expression TRIBL3 gene expression
ACNLRP3 Inflammasome gene expression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220105053631N1**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

Registration date

2022-01-29, 1400/11/09

Registrant information

Name

Fariba Armannia

Name of organization / entity

Ministry of Health

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of high and moderate intensity aerobic exercise with spirulina supplementation on ACE2 receptor sensitivity in obese people during SARS-

COVID-2 epidemic

Public title

The effect of aerobic exercise with different intensities and spirulina supplementation on ACE2 expression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy obese people 40 to 50 years without mobility restrictions

Exclusion criteria:

Any type of disease including cardiovascular, diabetes, hypertension, thyroid and in general any type of acute and chronic diseases Movement restrictions

Age

From **40 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this study will be randomly classified. The number of samples is 72 (36 men and 36 women). Since the expression of the effect of Intervenor may be significantly different according to the sex of individuals, so in sampling we study an equal number of each sex. Also, considering that the age range of the samples in the study is between 40 and 50 years, in order to be able to make comparisons in age ranges, the categories include people aged 40 to 43 years, 44 to 47 years and 48 to 50 years in We do both groups of men and women. Based on this, we divide the sample space into 6 blocks of 12 people. Since in this study, one category belongs to the control group and five categories belong to the intervention group, so each block includes 2 members from each of these categories, which is placed in that category based on gender and age. The sealed envelop online software at <https://www.sealedenvelope.com> is used to randomize the sampling.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to eliminate the error caused by the knowledge of the participants and the researcher about the type of treatment received and its possible effect on the research result, the study was conducted in two ways. We do blind. The placebo and the spirulina supplement are placed inside the capsule in exactly the same way, which is no different, so the participants and the

researcher are not aware of the type of supplement received.

Placebo

Used

Assignment

Factorial

Other design features

This study is designed based on the researcher's idea and its molecular cell pathway is invented by the researcher. Increased exercise-induced irisin increases the expression of the TRIB3 gene, and increased expression of this gene causes changes in the expression of ACE2 (the main receptor of Covid 19). Therefore, reducing the expression of ACE2 as the main receptor of Covid 19 can be effective in preventing Covid 19, especially in obese people. Because obese people naturally have an increase in ACE2 expression.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University, North Tehran Branch

Street address

Vafadar Blvd., Shahid Sadoughi St., Hakimiyeh Exit, Shahid Babaee Highway

City

Tehran

Province

Tehran

Postal code

۱۶۵۱۱۵۳۳۱۱

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.IAU.TNB.REC.1400.102

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Angiotensin converting enzyme 2 expression level

Timepoint

At the beginning of the study; And 8 weeks after starting

spirulina supplementation and aerobic exercise
Method of measurement
reverse transcription-polymerase chain reaction

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: high intensity aerobic exercise; Second intervention group: moderate intensity aerobic exercise; Third intervention group; Spirulina supplementation; Fourth intervention group; High-intensity aerobic exercise with spirulina supplementation; Fifth intervention group; Moderate-intensity aerobic exercise with spirulina supplementation; Sixth intervention group; control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز پزشکی ورزشی بیمارستان شریعتی

Full name of responsible person

Dr. Mohammad Hosseinpour Gharib

Street address

Jalal Al-Ahmad Highway, in front of Dr. Shariati Hospital, Sports Medicine Research Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad The university of Research Sciences Branch

Full name of responsible person

دکتر بابک مظفری

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End of Shahid Sattari Highway, University Square,

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad The university of Research Sciences Branch

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

The university of Islamic Azad University, Research Sciences Branch

Full name of responsible person

Fariba Armannia

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Sport physiology

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the general data of the participants such as demographic information such as age, sex, height, weight and body mass index after being unidentifiable will be shared in the results of the study.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only for information about unrecognizable results and general data

From where data/document is obtainable

Refer to the researcher's email at
phd.armannia@gmail.com

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

It will be available via email no later than one day after the request

Comments