Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of acute and short-term supplementation of choline on responses of the autonomic and hemodynamic system to sprint interval exercise in overweight and obese individuals

Protocol summary

Study aim

The effects of acute and short-term supplementation of choline on responses of the autonomic and hemodynamic system to sprint interval exercise in overweight and obese individuals

Design

The study will be conducted by a single group (12 participants) consuming both choline supplements and placebo in a randomized (Using a random number table), double-blind cross-over design in two phases. The participants will acutely consume 1000 mg of choline supplement in the first phase and then perform an exercise test. In the second phase, participants will take 600 mg of choline supplement for seven days and then repeat the exercise test.

Settings and conduct

The study will be conducted to evaluate choline's influences on cardiac autonomic function in the exercise physiology laboratory of Shahid Beheshti University. An independent coordinator who will not be involved in the study will assign the participant to supplement or placebo.

Participants/Inclusion and exclusion criteria

body mass index (BMI) > 27, no regular exercise/physical activity in the last year, nonsmoker, no alcohol consumption in the last two months, and no experiences or diagnosed illness (Hypertension, diabetes, etc.), especially cardiovascular diseases.

Intervention groups

Participants will consume a single dose of choline (1000 mg) or placebo supplement in the first phase and then perform an exercise test. In the second phase, the similar group will take 600 mg of choline or placebo for seven days and then repeat the exercise test. The study's variables (Heart rate variability and hemodynamic indices) will be measured before and after supplement or placebo consumption and following 120 min (every 15 min) after the exercise test.

Main outcome variables

Heart rate variability indices, hemodynamic variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160606028290N2**
Registration date: **2022-02-15, 1400/11/26**
Registration timing: **prospective**

Last update: **2022-02-15, 1400/11/26**
Update count: **0**

Registration date

2022-02-15, 1400/11/26

Registrant information

Name
Sajad Ahmadizad
Name of organization / entity
Shahid Beheshti University
Country
Iran (Islamic Republic of)
Phone
+98 21 2990 2931
Email address
s_ahmadizad@sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-09-16, 1401/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of acute and short-term supplementation of choline on responses of the autonomic and hemodynamic system to sprint interval exercise in overweight and obese individuals

Public title

The effect of choline supplement on autonomic system

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

body mass index (BMI) > 27 no regular exercise/physical activity in the last year according to the recommendation of the American College of Sport Medicine for exercise (150 min moderate-intensity exercise or 75 min vigorous exercise per week) nonsmoker no alcohol consumption in the last two month no experiences or diagnosed illness (Hypertension, diabetes, etc.), especially cardiovascular diseases

Exclusion criteria:

If they used high choline diets (According to 48 hours food frequency questioner) dietary supplements, or medication that could affect the study's cardiac autonomic function and hemodynamics variables

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each participant will be taking part in both supplement and placebo groups. Thus two samples will be taken from them.

Randomization (investigator's opinion)

Randomized

Randomization description

We will use a single group in a randomized cross-over design for the study. The participants will be allocated randomly (Using a random number table) to supplement or placebo groups in the first week. Following a one-week wash-out, the placebo participants will use the supplement, and those who consumed the supplement will use the placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be performed in a double-blind design which non of the authors, researchers who will be involved in this study, and the participants will not know about the supplement or placebo consumption. An independent coordinator who will not be involved in the study will assign participants randomly to the supplement or placebo groups.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahid Beheshti University

Street address

Evin, Shahid Shahriari Square, Shahid Beheshti University, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2022-01-15, 1400/10/25

Ethics committee reference number

IR.SBU.REC.1400.228

Health conditions studied

1

Description of health condition studied

The cardiac autonomic system of overweight or obese women with body mass index (BMI) 27<, and their age be between 20 to 40.

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Heart rate variability (HRV): Changes in heart rate signals in the time interval between two consecutive heartbeats that are recorded using a heart rate Holter

device and represent the quality of the cardiac autonomic system and the time-based method (domain time) frequency-based (frequency domain) is used to measure it. The main HRV variables in the current study will be included: Standard Deviation of RR wave intervals (SDNN), high frequency (HF), low frequency (LF), the ratio of LF to HF (LF/HF) bands, and percentage of interval differences of adjacent RR intervals greater than 50 ms (pNN50).

Timepoint

In the acute phase, the HRV variables will be measured before using choline supplement or placebo, 60 min after consuming choline supplement or placebo, immediately after the exercise test, 120 min following it (every 15 min). In the chronic phase, the HRV variables will be measured before starting consuming choline or placebo for seven days, after seven days, before using the last dose of choline or placebo on the seventh day, 60 min after consuming choline or placebo, immediately after the exercise test, 120 min following it (every 15 min).

Method of measurement

myPatch®sl Holter monitor (dms-service, made in USA)

2

Description

Hemodynamic variables which in the current study will be included: systolic blood pressure and diastolic blood pressure.

Timepoint

In the acute phase, the hemodynamic variables will be measured before using choline supplement or placebo, 60 min after consuming choline supplement or placebo, immediately after the exercise test, 120 min following it (every 15 min). In the chronic phase, the hemodynamic variables will be measured before starting consuming choline or placebo for seven days, after seven days, before using the last dose of choline or placebo on the seventh day, 60 min after consuming choline or placebo, immediately after the exercise test, 120 min following it (every 15 min).

Method of measurement

Automatic Arm Blood Pressure Monitor JPN500, OMRON. Made in Japan.

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will consume Alpha-GPC Choline supplement in acute (single dose) and chronic (seven days) phases. Participants will consume Alpha-GPC Choline (1000 mg) which will be dissolved in 250 ml of water after eating breakfast in the acute phase. In the second phase, participants will consume 600 mg of Alpha-GPC (Two capsules per day) with their meals for six days in the morning and evening. Participants will arrive at the laboratory on the seventh day between 7:30 and 8:00 in a fasting state (12 h). After measuring the autonomic and hemodynamic variables, the final dose of Choline (600 mg) will be taken.

Category

Prevention

2

Description

Control group: The same participants with one-week intervals will be used as a control group. The control group will consume a placebo in acute (single dose) and chronic (seven days) phases. Participants will consume a placebo which will be dissolved in 250 ml of water with a similar color and flavor with choline supplement after eating breakfast in the acute phase. In the second phase, participants will consume two capsules (similar color and flavor with choline supplement) of placebo with their meals for six days in the morning and evening. Participants will arrive at the laboratory on the seventh day between 7:30 and 8:00 in a fasting state (12 h). After measuring the autonomic and hemodynamic variables, the final dose of placebo (600 mg) will be taken.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University- Tehran

Full name of responsible person

Sajad Ahmadizad

Street address

Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2990 5821

Fax

+98 21 2243 1953

Email

s_ahmadizad@sbu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Babak Shokri

Street address
Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2990 5821
Fax
+98 21 2243 1953
Email
s_ahmadizad@sbu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University

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
Shahid Beheshti University
Full name of responsible person
Sajad Ahmadizad
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise Physiology
Street address
Department of Biological Sciences in Sport, Faculty of Sport Sciences and Health, Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2990 5821
Fax
+98 21 2243 1953
Email
s_ahmadizad@sbu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University
Full name of responsible person
Sajad Ahmadizad
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise Physiology
Street address
Department of Biological Sciences in Sport, Faculty of Sport Sciences and Health, Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2990 5821
Email
s_ahmadizad@sbu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University
Full name of responsible person
Sajad Ahmadizad
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise Physiology
Street address
Department of Biological Sciences in Sport, Faculty of Sport Sciences and Health, Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2990 5821
Email
s_ahmadizad@sbu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

The study's data and supplementary information will be available after making personal information of participants unrecognizable whenever they are requested

When the data will become available and for how long

The current study's data will be available immediately after publishing.

To whom data/document is available

The study's data and supplementary information will be available for both people working in academic institutions and people working in businesses whenever they request them.

Under which criteria data/document could be used

The study's data and supplementary information will be available publicly. However, those who want to use them should respect copyright, do not manipulate them, and cite the study's original articles which will be published.

From where data/document is obtainable

The raw data and supporting information of this study will be available by request of the corresponding author, without undue reservation. The corresponding author is Professor Sajad Ahmadizad, Department of Biological Sciences in Sport, Faculty of Sports Sciences and Health, Shahid Beheshti University, Velenjak, Tehran, Iran. Email: s_ahmadizad@sbu.ac.ir. Postcode: 1983963113 Tel: 0098-21-29905821 Fax: 0098-21-22431953

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

This study's raw data and supporting information will be available up to two weeks after the request.

Comments