

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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**

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University

##### **Full name of responsible person**

Babak Shokri

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Shahid Beheshti University, Shahid Shahriari 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**

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

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Shahid Beheshti University

**Full name of responsible person**

Sajad Ahmadizad

**Position**

Professor

**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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**Latest degree**

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## 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**