

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of eight-week sprint exercise snacks along with caloric restriction on serum bile acids in overweight men

#### Protocol summary

##### Study aim

Determining the effect of eight weeks of speed-exercise snacks along with caloric restriction on serum bile acids in overweight men.

##### Design

A clinical trial with a control group, with fractal groups (intervention and control group), without a blind strain, will be conducted on 40 healthy overweight men in a non-random manner within two months.

##### Settings and conduct

The current research is of an applied type in the form of four-group semi-experimental designs, with two interventions (exercise snacks and caloric restriction) and repeated measurement and comparison between groups before and after 8 weeks of exercise-speed snack training with caloric restriction. It will be performed on overweight men of Qazvin city. In the intervention group, exercise snacks will be performed daily in two 15-second bout at 7:00 AM and 7:00 PM. Blood and stool samples will be taken before and after 2 months of intervention.

##### Participants/Inclusion and exclusion criteria

healthy men, no history of regular exercise training in the last 6 months and not taking antibiotics in the last 6 months. History of taking illegal drugs and substances, history of specific diseases such as alcoholic or non-alcoholic fatty liver, gallstones, diabetes, cardiovascular failure, metabolic syndrome, gastrointestinal syndrome

##### Intervention groups

1- The intervention group of exercise snacks training - 15-second two-bout speed with calorie restriction (25%)  
2- The intervention group of exercise snacks training - 15-second two-bout speed along with a normal diet  
3- Control group with calorie restriction (25%)  
4- Control group along with normal diet

##### Main outcome variables

Exercise snacks, caloric restriction, bile acids, 19-fibroblast growth factor, 7-alpha hydroxycholesten-3-1(C4), insulin sensitivity, ratio of Firmicutes to Bacteroidetes bacteria and overweight.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231015059733N1**

Registration date: **2023-10-19, 1402/07/27**

Registration timing: **prospective**

Last update: **2023-10-19, 1402/07/27**

Update count: **0**

##### Registration date

2023-10-19, 1402/07/27

##### Registrant information

##### Name

Hamid Irandoost

##### Name of organization / entity

The University of Shahid beheshti

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2990 5823

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-06, 1402/08/15

##### Expected recruitment end date

2024-01-05, 1402/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of eight-week sprint exercise snacks a long with caloric restriction on serum bile acids in overweight men

## Public title

The effect of eight-week sprint exercise snacks a long with caloric restriction on serum bile acids in overweight men

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

healthy men. Body mass index 25-30 kg/m<sup>2</sup>. Not participating in regular exercise training during the past 6 months before the implementation of the research project. Not taking antibiotics in the last 6 months

### Exclusion criteria:

History of taking illegal drugs and substances History of specific diseases such as alcoholic or non-alcoholic fatty liver, gallstones, diabetes, cardiovascular failure, metabolic syndrome, gastrointestinal syndrome

## Age

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

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Factorial

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research ethics committee of Shahid Beheshti University

##### Street address

Tehran, Evin, Shahid Shahriari Square

##### City

Tehran

##### Province

Tehran

## Postal code

1983969411

## Approval date

2023-05-29, 1402/03/08

## Ethics committee reference number

IR.SBU.REC.1402.124

## Health conditions studied

### 1

#### Description of health condition studied

Overweight

#### ICD-10 code

E66.3

#### ICD-10 code description

Overweight

## Primary outcomes

### 1

#### Description

Bile acids, the final product of cholesterol catabolism, are made by liver cells and stored in the gallbladder. In this research, selected species are included, primary bile acid i.e. chenodeoxycholic acid(CDCA), secondary bile acid i.e. lithocholic acid(LCA), bile acid conjugated with glycine i.e. glycoconodeoxycholic acid(GCDCA), bile acid conjugated with taurine i.e. taurosoodeoxycholic acid(TUDCA), total bile acids(TBA)

#### Timepoint

before and after 8 weeks of intervention and control

#### Method of measurement

Liquid chromatography-mass spectrometry (LC-MS/MS) and Enzymatic assays

## Secondary outcomes

### 1

#### Description

Fibroblastic growth factor 19 regulates the production of bile acids.

#### Timepoint

before and after 8 weeks of intervention and control

#### Method of measurement

By ELISA method

### 2

#### Description

7-alpha hydroxycholesten-3-1 is a confirmed indicator of CYP7A1 enzyme activity of cholesterol 7 alpha hydroxylase (an enzyme that leads to the production of bile acids from cholesterol).

#### Timepoint

before and after 8 weeks of intervention and control

#### Method of measurement

Liquid chromatography-mass spectrometry (LC-MS/MS)

### 3

#### **Description**

The maximum effect of insulin is defined by the response and its necessary concentration to create half of the maximum effect, is insulin sensitivity .

#### **Timepoint**

before and after 8 weeks of intervention and control

#### **Method of measurement**

By evaluating the homeostasis model (HOMA-IR), insulin sensitivity will be obtained using serum glucose and insulin concentrations.

### 4

#### **Description**

They are one of the most abundant filamicrobiomes in the human intestine .

#### **Timepoint**

before and after 8 weeks of intervention and control

#### **Method of measurement**

In this research, an extraction kit will be used to extract genomic DNA from stool samples. Finally, the V4 region of the bacterial 16S rRNA genes will be subjected to PCR amplification to determine the characteristics of the microbiota. The community composition of each sample and the abundance of OTUs at the levels of phylum, class, order, family, genus and species will be counted. Finally, the ratio of Firmicutes/Bacteroidetes will be determined

## **Intervention groups**

### 1

#### **Description**

Intervention group: Before the start of 8 weeks of training, the subjects of the intervention groups of speed exercise snacks training along with caloric restriction and the intervention groups of speed exercise snacks training with a normal diet as a test on a day determined at the place of exercise snacks exercises They will be present. Considering the favorable effects of stair climbing snack exercises on cardio-respiratory fitness, stair climbing snack exercises will be used. According to the available scientific documentation, stair climbing snack exercises are one of the available exercises and similar to people's daily activities. Therefore, the staircase of a selected building similar to the subjects' workplace will be used for training. In the staircase of the training place, in accordance with the national and international standards for the construction of stairs (national and international building regulations) in relation to the number of each step in each section (Flight) and the height of each step (Rise), safety considerations and reducing possible accidents during the implementation of the exercise will be considered After preparing the above preparations and controlling the risk and possibility of falling during training by using relevant safety equipment in the staircase of the training place and determining the number of standard stairs climbed in the all-out intensity of each person, the subjects for two weeks and 3 The weekly session of two-bout speed exercise snacks ,

following the principle of gradual progress of exercises similar to the main training protocol, and with sufficient familiarity and necessary adaptation to the desired exercises, then he performed his exercises daily for a period of 8 weeks. Every day, in the stairwell of the selected building, climbing the stairs with all-out intensity will be done in two stages (7:00 am and 7:00 pm) for 15 seconds in each bout. In this way, after a 5-minute warm-up including 2 minutes of slow climbing with stairs or steps, 10 jumps in place, 10 lateral lunges and 10 chair squats, they will perform 15 seconds of all-out climbing and After finishing the 15-second bout, they will cool down for 2 to 1 minutes in the form of stretching movements. The total time of the main exercise (speed-exercise snacks ) and warm-up and cool-down will be about 10 minutes. All the subjects in the intervention groups of speed exercise snacks training with caloric restriction and the intervention groups of exercise snack-speed exercise with a normal diet while climbing stairs in the first week without extra load only carried out their exercises by carrying an empty backpack. will give, from the second week according to the table below with an increase in extra load on a weekly basis until the eighth week in the form of carrying a bag containing sand based on a percentage of the subject's body weight, all the steps of the exercise snacks - two-bout speed of stair climbing will be done .

#### **Category**

Prevention

### 2

#### **Description**

Intervention group: One-week food recall forms and food frequency will be distributed among the subjects. The content of the food plan and the eating habits of the subjects will be determined, the intervention groups will be given speed-exercise snacks with caloric restriction and the control groups will be given a caloric -restricted diet with a reduction of about 25% of the previous daily calorie intake. . In the calorie restriction groups, they will be instructed to receive about 75% of their total energy expenditure. For this purpose, the energy cost of rest will be estimated based on Cunningham's equation and by adding and adjusting the cost of the daily physical activity and non-sports physical activity of the subjects, the energy cost of the total daily cost will be calculated. Then 25% of the estimated calories of daily energy expenditure (resting energy expenditure plus physical activity) is subtracted and according to the positive effects of a high protein diet on weight loss and maintaining muscle mass, the remaining calories are 50% from carbohydrates, 30% It will be distributed from protein and 20% from fat. Then, the meals of each group will be determined and, taking into account the number of each group, several meal plans will be prescribed to the subjects.

#### **Category**

Prevention

### 3

#### **Description**

Control group: The control group with 25% caloric restriction and the control group with normal diet will not exercise.

**Category**

Prevention

**4****Description**

Control group: In the normal diet group, energy expenditure and intake will be distributed based on zero caloric balance and the amount of physical activity without weight change in the form of 50% of carbohydrates, 30% of protein and 20% of fat, and the above food plan is also divided into groups It will be prescribed with a normal diet.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Farhangian University of Qazvin Province, Shahid Rajaei Pesran campus

**Full name of responsible person**

Dr. Hamidreza Mashhadhi

**Street address**

Shahid Nawab Safavi Street - below Shahid Hasanpour Square - Farhangian University

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

The University of Shahid Behshti

**Full name of responsible person**

Afshar Jafari

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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**

The University of Shahid Behshti

**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 Shahid Behshti

**Full name of responsible person**

Hamid Irandoost

**Position**

Ph.D Candidate Student of Exercise Physiology

**Latest degree**

Master

**Other areas of specialty/work**

Exercise Physiology

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

The University of Shahid Beheshti

**Full name of responsible person**

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Ph,D Candidate Student

**Latest degree**

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## **Person responsible for updating data**

### **Contact**

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The University of Shahid beheshti

**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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**

After collecting and analyzing the research data, the main data related to bile acids will be shared.

### **When the data will become available and for how long**

The access period starts one year after the results are published

### **To whom data/document is available**

All healthy and sick people

### **Under which criteria data/document could be used**

In case of exercise intervention in sick and healthy people

### **From where data/document is obtainable**

Call 0098 9127886036.

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

In the first stage, contact and provide the necessary documents to qualify to use the data of this research and then send the information via email

### **Comments**