

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Oct 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)

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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/m². 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

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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. glycochenodeoxycholic acid(GCDCA), bile acid conjugated with taurine i.e. taurochenodeoxycholic 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

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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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Web page address

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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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Full name of responsible person

Hamid Irandoost

Position

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Latest degree

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Other areas of specialty/work

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Full name of responsible person

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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