Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of eight-week sprint exercise snacks a long 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 Bactoroidetes 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

h_irandoost@sbu.ac.ir

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
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. glycocondeoxycholic acid(GCDCA), bile acid conjugated with taurine i.e. taurosodeoxycholic 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/Bactoroidetes 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

City

Qazvin

Province

Qazvin

Postal code

۱۹۹۸۹۶۳۳۴۱

Phone

+98 28 3333 0679

Fax

+98 28 3333 0679

Email

info@cfu.ac.ir

Web page address

https://qazvin.cfu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Shahid Behshti

Full name of responsible person

Afshar Jafari

Street address

Evin, Shahid Shahriari Square

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 29901

Fax

+98 21 2243 1607

Email

pr-office@sbu.ac.ir

Web page address

https://www.sbu.ac.ir

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

Street address

Evin, Shahid Shahriari Square

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 29901

Fax

+98 21 2243 1607

Email

hamid.irandoost@gmail.com

Web page address

https://www.sbu.ac.ir/

Person responsible for scientific

inquiries

Contact

Name of organization / entity
The University of Shahid Beheshti
Full name of responsible person
Hamid Irandoost
Position
Ph,D Candidate Student
Latest degree
Master
Other areas of specialty/work
Exercise Physiology
Street address
Evin, Shahid Shahriari Square
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 29901
Fax
+98 21 2243 1607
Email
hamid.irandoost@gmail.com
Web page address
https://www.sbu.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
The University of Shahid beheshti
Full name of responsible person
Hamid Irandoost
Position
PhD Candidate Student
Latest degree
Master
Other areas of specialty/work
Exercsie Physiology
Street address
Evin, Shahid Shahriari Square
City
قزوین
Province
Tehran
Postal code
1983969411
Phone
+98 21 2990 5823
Fax
+98 21 2243 1607
Email
hamid.irandoost@gmail.com
Web page address
https://www.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
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