Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of combined training and consumption of three types of tea on the serum levels of FGF21 and PGC1α in overweight and obese men

Protocol summary

Study aim

Comparing the simultaneous effect of combined exercise (aerobic and resistance) and types of tea (green, white and sour) on body composition variables (weight, waist-to-hip ratio, fat percentage, body mass index) and biochemical markers (FGF21 and PGC1α) in overweight and obese men

Design

A clinical trial with a control group, with parallel, unblinded, randomized groups, in four groups: training group + green tea (15 people), training group + white tea (15 people), training group + sour tea (15 people) and training group (15 people). The research randomizer software (www.randomizer.com) was used for randomization.

Settings and conduct

The subjects of the combined exercises + tea groups performed the combined exercises protocol for 8 weeks (3 days a week) and drank 2 times a day (each time 2 grams in 240 ml of water) tea (according to the type of tea in the group they are in). they consume All sports exercises are done in the gym, and other measurements such as blood sampling will be done in the clinic under the supervision of a specialist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male, age between 30 and 50 years, body mass index between 25 and 35 kg/m2, inactivity (less than 30 minutes of sports activity per week), completion of informed consent form Exclusion: suffering from known metabolic and inflammatory diseases, taking any kind of medicine and nutritional supplements, undergoing surgery to reduce obesity, consuming alcohol and smoking, allergic to tea, participating in sports activities other than the sports program of the present study

Intervention groups

Training group + green tea (15 people), training group + white tea (15 people), training group + sour tea (15 people) and training group (15 people)

Main outcome variables

Body composition (weight, waist to hip ratio, fat percentage, body mass index) and biochemical markers (FGF21 and PGC1α)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230131057292N2**
Registration date: **2024-08-20, 1403/05/30**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-20, 1403/05/30**
Update count: **0**

Registration date

2024-08-20, 1403/05/30

Registrant information

Name

Shima Mojtahedi

Name of organization / entity

The University of Tehran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-30, 1403/03/10

Expected recruitment end date
2024-08-31, 1403/06/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of combined training and consumption of three types of tea on the serum levels of FGF21 and PGC1α in overweight and obese men

Public title
Comparison of the effect of combined exercise and consumption of three types of tea on overweight men
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men aged between 30 and 50 years Body mass index between 25 and 35 kg/m2 Inactivity (less than 30 minutes of sports activity per week)
Exclusion criteria:
Taking any kind of medicine and food supplement Performing surgery to reduce obesity Consumption of alcoholic beverages and cigarettes Subjects' unwillingness to continue the research protocols Allergy to tea Participating in sports activities other than the sports program of the present study
Age
From **30 years** old to **50 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, patients will be selected by the method of random allocation law and using the principles of random sampling. So that after determining the sample size, people will be divided into four equal groups by lottery. The names of the candidates are written on separate sheets and placed in a container. Then, randomly, the sheets are removed from the container without replacement and the created sequence is recorded, and people are randomly placed in the intervention or control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both patients and health care workers and exercise professionals will be unaware of the patient's exposure. Each patient will be assigned an ID, based on which the desired intervention (helping with various types of tea) will be carried out during the research.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research, Faculty of Physical Education and Sports Sciences, University of Tehra
Street address
Faculty of Physical Education and Sport Sciences, between 15th and 16th St., North Kargar St., Tehran, Islamic Republic
City
Tehran
Province
Tehran
Postal code
1439813117
Approval date
2024-05-28, 1403/03/08
Ethics committee reference number
IR.UT.SPORT.REC.1403.032

Health conditions studied

1

Description of health condition studied
Overweight and obesity
ICD-10 code
E66.9
ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
Serum levels of PGC1α
Timepoint
48 hours before and after the last training session after 12 hours of fasting
Method of measurement
Using the human ELISA diagnostic kit related to the variable

2

Description
Serum levels of FGF21
Timepoint
48 hours before and after the last training session after 12 hours of fasting
Method of measurement
48 hours before and after the last training session after 12 hours of fasting

Secondary outcomes

1

Description
Weight changes
Timepoint
At the beginning of the study (before the start of the intervention) and 8 weeks after the start of the research
Method of measurement
scale

2

Description
Waist to hip ratio
Timepoint
At the beginning of the study (before the start of the intervention) and 8 weeks after the start of the research
Method of measurement
Waist to hip ratio

3

Description
Body mass index
Timepoint
At the beginning of the study (before the start of the intervention) and 8 weeks after the start of the research
Method of measurement
Bioelectrical impedance device

4

Description
Fat index
Timepoint
At the beginning of the study (before the start of the intervention) and 8 weeks after the start of the research
Method of measurement
Bioelectrical impedance device

Intervention groups

1

Description
Intervention group: combined exercises + green tea for 8 weeks and will perform 3 times of combined exercises every week. The combined exercises of each session include 10 minutes of warm-up (gentle running and stretching), the aerobic training program includes 20 minutes of running on the treadmill with an intensity of 60 to 80% of the maximum heart rate, and strength training includes 4 stationary movements with an intensity of 55 to 75 per repetition. The maximum is 3 sets with 8 to 12 repetitions and a rest interval of 60 seconds between each set and 2 minutes between each station. In addition, 2 servings of green tea in the amount of 2 grams dissolved in 240 ml of water are consumed every day.
Category
Prevention

2

Description
Intervention group: combined exercises + white tea for 8 weeks and will do 3 times of combined exercises every week. The combined exercises of each session include 10 minutes of warm-up (gentle running and stretching), the aerobic training program includes 20 minutes of running on the treadmill with an intensity of 60 to 80% of the maximum heart rate, and strength training includes 4 stationary movements with an intensity of 55 to 75 per repetition. The maximum is 3 sets with 8 to 12 repetitions and a rest interval of 60 seconds between each set and 2 minutes between each station. In addition, 2 servings of white tea in the amount of 2 grams dissolved in 240 ml of water are consumed every day.
Category
Prevention

3

Description
Intervention group: combined exercises + sour tea for 8 weeks and will do 3 times of combined exercises every week. The combined exercises of each session include 10 minutes of warm-up (gentle running and stretching), the aerobic training program includes 20 minutes of running on the treadmill with an intensity of 60 to 80% of the maximum heart rate, and strength training includes 4 stationary movements with an intensity of 55 to 75 per repetition. The maximum is 3 sets with 8 to 12 repetitions and a rest interval of 60 seconds between each set and 2 minutes between each station. In addition, 2 servings of sour tea in the amount of 2 grams dissolved in 240 ml of water are consumed every day.
Category
Prevention

4

Description
Control group: They will do combined exercises 3 times a week for 8 weeks. The combined exercises of each session include 10 minutes of warm-up (gentle running and stretching), the aerobic training program includes 20 minutes of running on the treadmill with an intensity of 60 to 80% of the maximum heart rate, and strength training includes 4 stationary movements with an intensity of 55 to 75 per repetition. The maximum is 3 sets with 8 to 12 repetitions and a rest interval of 60

seconds between each set and 2 minutes between each station.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
University of Tehran

Full name of responsible person
شیما مجتهدی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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تهران - خیابان کارگر شمالی - بالاتر از تقاطع جلال آل احمد - بین خیابان پانزدهم و شانزدهم- روبروی کوی دانشگاه تهران

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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
University of Tehran

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
University of Tehran

Full name of responsible person
zahra Hosseini

Position
master student

Latest degree
Bachelor

Other areas of specialty/work
Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available