

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of eight weeks of progressive aerobic activity with consumption of green tea and green coffee on fat oxidation and blood pressure in overweight girls

Protocol summary

Study aim

This study aims to investigate the effect of eight weeks of progressive aerobic activity along with the consumption of green tea and green coffee on fat oxidation and blood pressure in overweight girls.

Design

In order to select a statistical sample, the disease history questionnaire will be distributed in the sports clubs of Kermanshah and they will be asked to participate in this research voluntarily if they wish. Also, in this invitation, explanations about the research method and training program were presented. Based on this, using Morgan's table, 48 people will be invited to participate in the briefing session and randomly divided into four experimental groups 1 (exercise + green coffee, 12 people), experimental group 2 (exercise + green tea, 12 people), experimental group 3 (exercise + green coffee + green tea, 12 people) and control group 4 (exercise, 12 people) will be placed.

Settings and conduct

Anil sports club is located in Kermanshah, Farhangian area, phase one, corner of Amir Kabir intersection

Participants/Inclusion and exclusion criteria

The statistical population will include 200 inactive overweight girls with an age range of 20 to 27 years with a body mass index of 27 ± 2.5 referring to sports clubs in Kermanshah city in 1401.

Intervention groups

Based on this, using Morgan's table, 48 people were invited to participate in the briefing session and randomly divided into four experimental groups 1 (exercise + green coffee, 12 people), experimental group 2 (exercise + green tea, 12 people), Experimental group 3 (exercise + green coffee + green tea, 12 people) and control group 4 (exercise, 12 people) will be placed.

Main outcome variables

Variables of systolic blood pressure, diastolic blood

pressure, HDL, LDL and total cholesterol, body mass index, body fat percentage, waist to hip ratio and triglycerides

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221213056809N1**

Registration date: **2023-01-24, 1401/11/04**

Registration timing: **retrospective**

Last update: **2023-01-24, 1401/11/04**

Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Vahid Kazemizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-26, 1401/07/04

Expected recruitment end date

2022-11-07, 1401/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of progressive aerobic activity with consumption of green tea and green coffee on fat oxidation and blood pressure in overweight girls

Public title

The effect of eight weeks of progressive aerobic activity with consumption of green tea and green coffee on fat oxidation and blood pressure in overweight girls

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

. None of the subjects had a history of chronic diseases such as cardiovascular diseases, diabetes, various cancers, kidney and digestive disorders, or any type of injury or problem that prevents them from participating in physical activities.

Exclusion criteria:**Age**

From **20 years** old to **27 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects were examined in four groups by a simple random selection method. In relation to randomization, the names of 48 subjects are written on special cards and placed in a bag, and the cards are selected one after the other. After choosing each card from the bag, the card was placed in the bag again.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The herbal supplement was distributed to the intervention group and the placebo to the control group by the laboratory officials based on the randomization results announced by the laboratory supervisor, and the researchers did not know the results of the randomization and the type of package they delivered to the subjects. The researcher only had to provide the supplement necessary for the intervention and deliver it to the laboratory supervisor.

Placebo

Used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

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Shahid Beheshti Blvd., Building No. 2 of Medical Sciences, Research and Technology Vice-Chancellor

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Approval date

2022-09-26, 1401/07/04

Ethics committee reference number

IR.KUMS.REC.1401.268

Health conditions studied**1****Description of health condition studied**

overweight girls

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fat oxidation and blood pressure

Timepoint

After grouping the subjects, the first blood draw will be done (one day before training, consumption of green coffee/green tea). At the beginning of the session, the height of the subjects will be measured using a Seka stadiometer, made in Germany, without shoes. Weight measurement will be done without shoes and with a Seka digital scale made in Germany. Then, the body composition of the people was calculated using the body analysis device of Javon model made in South Korea. One day after taking blood in the first stage and measuring the physical and physiological indicators in all four groups, the subjects will participate in progressive aerobic exercises for three days a week for eight weeks. The experimental groups will receive green tea or green coffee or both depending on the experimental group for

eight weeks.

Method of measurement

At the beginning of the session, the height of the subjects will be measured using a Seka stadiometer, made in Germany, without shoes. Weight measurement will be done without shoes and with a Seka digital scale made in Germany. Then, the body composition of the people will be calculated using the body analysis device Javon model made in South Korea. Green coffee and green tea approved by the Food and Drug Organization will be purchased from a reputable store with a special powder grinder, every day 20 minutes before breakfast and 20 Minutes before lunch at the same time, they will receive tea. After finishing the last session in all groups, the second blood sampling will be done before breakfast. Also, the physical and physiological indicators of the subjects will be measured.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: green coffee and green tea approved by the Food and Drug Organization will be purchased from a reputable store with a special grinder, the experimental groups will receive the amount of green coffee equal to 3 mg per kilogram of body weight and the amount of green tea equal to 3 mg per kilogram of body weight. The body will receive 250 ml of boiling water in separate containers every day 20 minutes before breakfast and 20 minutes before lunch at the same time. After finishing the last session in all groups, the second blood sampling was done before breakfast. Also, the physical and physiological indicators of the subjects will be measured. To implement the progressive aerobic exercise program, the subjects of the experimental and control groups in an eight-week aerobic exercise program, three sessions a week, each session 60 minutes with an intensity of 65 to 85% of the maximum heart rate according to table (1) after measurement Anthropometric characteristics will be included. The program of one session included 10 minutes of warm-up, 30 minutes of aerobic exercise (aerobic) running and local movements, and 5 minutes of cooling down, which started with an intensity of 65% of the maximum heart rate and 5% every two weeks. In the last week, reach 85% of the maximum heart rate

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad university

Full name of responsible person

Nasrin Babaei

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Sponsors / Funding sources

1

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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

Islamic Azad 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

Islamic Azad University

Full name of responsible person

Tooraj Mohammad Zamani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Movement behavior

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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

Undecided - It is not yet known if there will be 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

It is possible to share data such as information about the main outcome or the like.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no other conditions

From where data/document is obtainable

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

The access period starts 6 months after the results are published

Comments