

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of eight weeks of spinning training and caffeine supplementation on lipid profile, body composition and functional fitness of overweight women

Protocol summary

Study aim

Investigating the effect of eight weeks of spinning exercises on lipid profile and some metabolic indicators and physical fitness of overweight women

Design

Clinical trial with control groups, exercise+placebo, exercise+caffeine and caffeine, with factorial groups, available and targeted sampling but random replacement of people in the groups, with blinding of statistical analyzer, phase 3 on 40 overweight women

Settings and conduct

This study will be done in the sports hall of Shahrood city, spinning exercise will be done on a spinning bike for 2 months, three days a week. Caffeine or placebo will be given to subjects 60 minutes before the start of exercise. The data analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: body mass index (BMI) above 25 and below 35 kg/m² Exclusion criteria: people with a history of cardiovascular disease, respiratory disease, diabetes, pregnancy and breastfeeding, use of anti-inflammatory drugs and special drugs, abnormal blood pressure

Intervention groups

1- The group that had both spinning exercise (indoor cycling) and caffeine supplement use. 2- The group that had both spinning exercise and placebo. 3- The group that only consumed caffeine. 4- Control group (without exercise and taking supplements or placebo)

Main outcome variables

lipid profile (cholesterol, triglyceride, LDL and HDL); Body composition: body fat percentage, waist circumference, hip circumference, abdominal circumference, waist-to-hip ratio and weight (BMI); maximum upper body and lower body strength; upper body and lower body muscular endurance; aerobic power; anaerobic power; balance «نماد» مورد تأیید انجمن»

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220906055902N1**

Registration date: **2023-11-01, 1402/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-01, 1402/08/10**

Update count: **0**

Registration date

2023-11-01, 1402/08/10

Registrant information

Name

Somayeh Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3233 4216

Email address

s.rajabi@iau-shahrood.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-14, 1402/07/22

Expected recruitment end date

2023-12-13, 1402/09/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of spinning training and caffeine supplementation on lipid profile, body composition and functional fitness of overweight women

Public title

The effect of exercise and caffeine on health and performance indicators

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a body mass index between 25 and 35 kg/m²

Exclusion criteria:

History of cardiovascular respiratory disease, diabetes, pregnancy and breastfeeding Taking anti-inflammatory drugs and special drugs

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The study analyst will not be informed of the nature of the groups and we will identify each group with a number.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrood Islamic Azad University

Street address

University Boulevard, Khatam Al Anbia Hospital,
Faculty of Medical Sciences

City

Shahrood

Province

Semnan

Postal code

3614871151

Approval date

2023-01-30, 1401/11/10

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1401.072

Health conditions studied

1

Description of health condition studied

Overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified - Simple obesity NOS

Primary outcomes

1

Description

Lipid profile (cholesterol, triglyceride, LDL and HDL)

Timepoint

Before and after the intervention

Method of measurement

Blood sampling using a diagnostic kit for cholesterol, triglycerides, LDL and HDL

Secondary outcomes

1

Description

Weight

Timepoint

Before and after the intervention

Method of measurement

scales

2

Description

Body Mass Index

Timepoint

Before and after the intervention

Method of measurement

The ratio of weight to the square of height

3

Description

waist circumference

Timepoint

Before and after the intervention

Method of measurement

Meter

4

Description

Abdominal circumference

Timepoint

Before and after the intervention

Method of measurement

Meter

5**Description**

hip circumference

Timepoint

Before and after the intervention

Method of measurement

Meter

6**Description**

Waist to hip ratio

Timepoint

Before and after the intervention

Method of measurement

Meter

7**Description**

fat percentage

Timepoint

Before and after the intervention

Method of measurement

Caliper

8**Description**

upper body strength

Timepoint

Before and after the intervention

Method of measurement

One repetition maximum chest press test

9**Description**

Lower body strength

Timepoint

Before and after the intervention

Method of measurement

One repetition maximum leg press test

10**Description**

Upper body muscular endurance

Timepoint

Before and after the intervention

Method of measurement

60% of one repetition maximum chest press test, repetitions until exhaustion

11**Description**

Lower body muscular endurance

Timepoint

Before and after the intervention

Method of measurement

60% one repetition maximum leg press test, repetitions until fatigue

12**Description**

aerobic power

Timepoint

Before and after the intervention

Method of measurement

Bruce's test

13**Description**

anaerobic power

Timepoint

Before and after the intervention

Method of measurement

Sargent's jump test

14**Description**

balance

Timepoint

Before and after the intervention

Method of measurement

One leg standing test

Intervention groups**1****Description**

Intervention group: Spinning exercise + caffeine; Spinning training will be done by pedaling on special bikes for 8 weeks, 3 sessions a week, with an intensity of 40-85% of the maximum reserve heart rate, 30-40 minutes per session and with a resistance of 50-90 revolutions per minute. In order to comply with the overload principle, the intensity, duration and resistance of the bike will be increased once every two weeks. Caffeine powder at the rate of 5 mg/kg of body weight will be consumed 60 minutes before the start of the activity with a glass of water.

Category

Rehabilitation

2**Description**

Control group: They will do their normal daily activities and will not practice spinning and consume caffeine or placebo.

Category

Other

3

Description

Intervention group: Spinning exercise + placebo; This group will perform the same spinning exercise as the Spinning + Caffeine group. But instead of caffeine, they will use capsules containing dextrose in the amount of 5 mg/kg 60 minutes before the activity as a placebo.

Category

Placebo

4

Description

intervention group: caffeine; This group will use capsules containing caffeine with a dose of 5 mg/kg along with a glass of water at the same hours and days as the other intervention groups.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Club Mahan and Club Nik

Full name of responsible person

Somayeh Rajabi

Street address

No. 126, 9th alley, Student St

City

Shahrood

Province

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Postal code

3614616575

Phone

+98 23 3233 4216

Email

rajabi_66_s@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Maryam Shahri

Street address

Islamic Azad University, Shahrood branch

City

Shahrood

Province

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Postal code

3619943189

Phone

+98 23 3239 4530

Email

shahri_rh17@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Azad University of Shahrood

Proportion provided by this source

100

Public or private sector

Private

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

Somayeh Rajabi

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Islamic Azad University

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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)**

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Somayeh Rajabi

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

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