# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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**

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**Email address**

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**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
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No. 126, 9th alley, Student St
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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
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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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No.9, Daneshjo Ave., Shahrood Town
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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