

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of high-intensity interval training and caffeine supplementation on exercise adaptations and ergogenicity of acute caffeine intake in young men

Protocol summary

Study aim

Determining the effect of high-intensity interval training and caffeine supplementation on exercise performance and adaptations as well as ergogenicity of acute caffeine intake

Design

double-blind, placebo-controlled, and randomized-controlled experimental design. n = 80, 20 in each group. After matching based on age, weight and $\dot{V}O_2\text{max}$, participants were randomized on a 1:1:1:1 basis to one of four groups. Phase 4

Settings and conduct

Eighty physically inactive men participated in a parallel, double-blind, placebo-controlled trial conducted in Istanbul, Turkey. Based on age, height, body mass and maximal oxygen consumption, the participants were assigned to 4 groups (n = 20 each): caffeine supplementation, caffeine supplementation + exercise training, placebo and placebo + exercise training. High-intensity interval training (HIT) was performed 5 times per week for 8 weeks. Caffeine supplementation (3 mg/kg/day) was started at the same time as the HIT. Data collection was done in 4 stages: pre-test, mid-test, post-test, and delayed post-test, each consisting of two separate experiment sessions (3 mg/kg of caffeine or placebo). In each experiment session, 45 min after consuming a placebo or caffeine, a 3-km running test was performed at first, followed by a Wingate power test with 20 min rest between assessments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy; inactive; lack of caffeine dependence Exclusion criteria: caffeine habituation; taking medicine or supplements

Intervention groups

Caffeine supplementation (3mg/kg/day) for 8 weeks. Cellulose intake (200mg/day) for 8 weeks. Caffeine supplementation (3mg/kg/day) + high-intensity interval

training for 8 weeks. Cellulose intake (200mg/day) + high-intensity interval training for 8 weeks.

Main outcome variables

3-km running performance; power outputs; rate of perceived exertion; $\dot{V}O_2\text{max}$; body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231004059615N1**

Registration date: **2023-11-08, 1402/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-08, 1402/08/17**

Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Davar Khodadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2263 3583

Email address

davar.khodadadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of high-intensity interval training and caffeine supplementation on exercise adaptations and ergogenicity of acute caffeine intake in young men

Public title

Effect of HIT and caffeine supplementation on exercise performance and adaptations

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy Not consuming caffeine Physically inactive Non-smoker and non-alcoholic

Exclusion criteria:

Not taking any medicine or supplement Smoker and alcoholic Caffeine users Physically active

Age

From **19 years** old to **23 years** old

Gender

Male

Phase

4

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To minimize possible group differences, first, the participants were categorized according to age, body mass, and $\dot{V}O_{2\max}$. Then, the subjects of each category were randomized on a 1:1:1:1 basis to one of four groups: caffeine supplementation, caffeine supplementation + exercise training, placebo and placebo + exercise training.

Blinding (investigator's opinion)

Double blinded

Blinding description

Preparation of the supplement/placebo was done by someone outside the study. Also, all participants received capsules containing caffeine/placebo in the same appearance and weight for the same duration and frequency. In addition, for statistical analysis, the titles of the groups were not clear and only the numbers 1 to 4 were assigned to the groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Istanbul Esenyurt University

Street address

No:1, Adile Naşit Blv

City

Istanbul

Postal code

34513

Approval date

2023-09-28, 1402/07/06

Ethics committee reference number

2023/09-10

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

Caffeine habituation

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

Caffeine habituation

Timepoint

Before starting the intervention (pre-test), After 4 weeks of intervention (mid-test), After 8 weeks of intervention (post-test).

Method of measurement

By food frequency questionnaire

2**Description**

Training adaptations

Timepoint

Before starting the intervention (pre-test), After 4 weeks of intervention (mid-test), After 8 weeks of intervention (post-test).

Method of measurement

Power outputs (The 30 s Wingate Anaerobic Power Test) - Aerobic endurance (The 3-km running time-trial performance) - Body composition (InBody 970 Body Composition Analyzer).

3

Description

Effect of caffeine withdrawal after the 8-week supplementation on caffeine ergogenicity

Timepoint

After one week of caffeine withdrawal (delayed post-test)

Method of measurement

Anaerobic power response in the 30-second Wingate test at delayed post-test and comparison with post-test scores, Aerobic endurance response in the 3 km running performance at delayed post-test and comparison with post-test scores.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group included the caffeine consumption group, which consumed caffeine supplement (3 mg/kg/day) for 8 weeks.

Category

Lifestyle

2

Description

The second intervention group included the exercise training group that performed the high-intensity interval training program 5 sessions per week for 8 weeks.

Category

Lifestyle

3

Description

The third intervention group received a combination of exercise training and caffeine supplementation. They followed a high-intensity interval training program and took caffeine supplements for 8 weeks.

Category

Lifestyle

4

Description

The fourth group was the control group that did not participate in exercise training and received a daily capsule containing 200 mg of cellulose.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Istanbul Esenyurt University

Full name of responsible person

Abdorrezza Eghbal Moghanlou

Street address

No:1, Adile Naşit Blv

City

Istanbul

Postal code

34510

Phone

+90 4449123

Fax

+90 212 699 09 90

Email

abdorrezaeghbalmoghanlou@esenyurt.edu.tr

Web page address

<https://www.esenyurt.edu.tr/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Satar Jadari Salami

Street address

Faculty of Physical Education and Sports Sciences,
Velayat University Complex, Sohani St., Sohank

City

Tehran

Province

Tehran

Postal code

1955847781

Phone

+98 21 7368 1158

Email

sattar.salami@aut.ac.ir

Web page address

<https://ctb.iau.ir/sport/fa>

Grant name

Grant code / Reference number

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

No

Title of funding source

Personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

Sponsor: country of origin

Country of origin

TR

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Davar Khodadadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

Street address

Faculty of Physical Education and Sports Sciences,
Velayat University Complex, Sohani St, Sohank

City

Tehran

Province

Tehran

Postal code

1955847781

Phone

+98 21 2248 1621

Fax

+98 21 2248 1622

Email

davar.khodadadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

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Phone

+98 21 2248 1621

Fax

+98 21 2248 1622

Email

davar.khodadadi@yahoo.com

Person responsible for updating data

Contact

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+98 21 2248 1622

Email

davar.khodadadi@yahoo.com

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

No - There is not 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

Not applicable

Data Dictionary

Not applicable