Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Acute Caffeine Consumption Combined with Adherence to a Low-Glycemic Index Diet on Time to Exhaustion, Perceived Exertion, and Fatigue-Related Physiological Indices in Active Women

Protocol summary

Study aim
To investigate the effect of acute caffeine consumption combined with adherence to a low glycemic index diet on time to exhaustion, perceived exertion, and fatigue related physiological indices in active women.

Design
After 3 days of a low-glycemic diet and consumption of a standard low-glycemic breakfast, participants received a capsule of pure caffeine (5 mg/kg body weight) orally with water 60 minutes after breakfast, and 60 minutes after capsule ingestion, an incremental exercise test to exhaustion will be performed.

Settings and conduct
After providing informed consent, participants will follow a 3-day low-glycemic diet and, on the test day, will receive a standard low-glycemic breakfast after an overnight fast. Sixty minutes later, the caffeine group will consume a capsule of pure caffeine (5 mg/kg body weight) and the control group will consume a placebo. Sixty minutes after that, an incremental exercise test to exhaustion will be performed on a cycle ergometer.

Participants/Inclusion and exclusion criteria
Participants were non-professional active women aged 20–30 with a history of regular exercise (at least 3 sessions per week for 6 months), physical and mental health, no smoking, alcohol, or hormonal medication use, regular menstrual cycles, no caffeine sensitivity, and no pregnancy.

Intervention groups
Intervention group: Following 3 days of adherence to a low glycemic index diet and consumption of the standardized low glycemic index breakfast on the testing day, participants will receive one capsule containing pure caffeine at a dose of 5 milligrams per kilogram of body weight orally with one glass of water, 60 minutes after breakfast. The graded exercise test to exhaustion will then be performed 60 minutes after capsule administration.

Main outcome variables
Time to exhaustion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260713070155N1**
Registration date: **2026-09-30, 1405/07/08**
Registration timing: **prospective**

Last update: **2026-09-30, 1405/07/08**
Update count: **0**

Registration date
2026-09-30, 1405/07/08

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

Expected recruitment end date
2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Acute Caffeine Consumption Combined with Adherence to a Low-Glycemic Index Diet on Time to Exhaustion, Perceived Exertion, and Fatigue-Related Physiological Indices in Active Women

Public title

The Effect of Caffeine and Low-Glycemic Diet on Fatigue and Exercise Performance in Active Women

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 20 to 30 years Having at least three regular exercise sessions per week over the past 6 months Each session at least 30 minutes of moderate to vigorous intensity No professional, semi-professional, national team, or official league activity No history or diagnosis of cardiovascular, respiratory, neurological, or metabolic diseases No smoking or alcohol consumption No known hypersensitivity to caffeine No medical contraindication for caffeine consumption Having regular menstrual cycles (25 to 35 days) No use of hormonal medications in the last 3 months Completing the PAR-Q questionnaire with no positive responses to high-risk questions Not being pregnant and no planning for pregnancy during the study period

Exclusion criteria:

Occurrence of any injury or medical complication during the study Non-adherence to the dietary protocol or supplement consumption guidelines Use of other medications or supplements that could affect metabolism, athletic performance, or hormonal balance Use of any hormonal medication (including oral contraceptive pills) within the past 3 months Use of stimulants, antidepressants, or any medication that has a pharmacological interaction with caffeine Consumption of caffeine or caffeinated beverages within 24 hours prior to testing Known hypersensitivity to caffeine or medical contraindication to its use

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Following screening and confirmation of participants' eligibility, participants will be individually allocated using block randomization to two equal-sized groups: an intervention group receiving caffeine and a control group receiving placebo. The purpose of using block randomization is to ensure a balanced number of participants in the two groups. The unit of randomization is the individual participant, and cluster randomization will not be used. Stratified randomization will not be used in this study. The study will be conducted using a single-blind design, such that participants will be unaware of the type of capsule they receive (caffeine or placebo), whereas the principal researcher will be aware of the participants' group allocation. The placebo capsules (cellulose powder) will be identical in appearance to the caffeine capsules.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind, placebo-controlled, parallel-group randomized clinical trial. Only participants will be blinded and will not be informed about the type of capsule they receive (caffeine or placebo). To implement blinding, caffeine and placebo capsules will be prepared identical in shape, weight, color, and packaging, and will be administered to participants by the main researcher one hour before the exercise test. The main researcher will be aware of the group allocation and will conduct the outcome measurements; however, objective outcomes such as time to exhaustion and heart rate will be automatically recorded using standard devices, and subjective outcomes (rating of perceived exertion and local muscle discomfort) will be reported by the blinded participants themselves, thereby reducing the risk of bias. A physician will also be present during the test sessions to monitor participant safety; the physician's role is limited to safety monitoring and managing any potential adverse events, and they will not be involved in the group allocation process or outcome assessments, thus having no impact on participant blinding.

Placebo

Used

Assignment

Parallel

Other design features

This study will be conducted as a quasi-experimental, parallel, block-randomized, single-blind, placebo-controlled trial. All participants will adhere to a standardized low-glycemic index diet for 72 hours (3 days) before the main test. Energy intake will be calculated based on individual energy requirements for weight maintenance, and a standard low-glycemic breakfast (~400 kcal, consisting of oatmeal, low-fat milk, and apple) will be provided on the test day. Exercise tests will be performed during the early follicular phase of the menstrual cycle (days 3–8 after menstruation onset) for all participants. After receiving caffeine (5 mg/kg) or placebo (cellulose powder) capsules one hour before exercise, an incremental test to exhaustion will be performed using a cycle ergometer (Monark 894E), starting at 75 W with 25 W increments every 2 minutes until volitional exhaustion.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Razi University of Kermanshah

Street address
No. 8, Razi University, Daneshgah Boulevard, Taq Bostan Street, Kermanshah, Iran

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Approval date
2026-07-14, 1405/04/23

Ethics committee reference number
IR.RAZI.REC.1405.037

Health conditions studied

1

Description of health condition studied
Fatigue and Endurance Exercise Performance

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Time to Exhaustion (TTE): The total duration from the beginning of the graded exercise test on a cycle ergometer until the termination of the test according to the predefined exhaustion criterion. The test will start at a workload of 75 W, with the workload increasing by 25 W every 2 minutes. Pedaling cadence will be maintained between 70 and 80 revolutions per minute. Exhaustion will be defined as the inability of the participant to maintain a pedaling cadence above 60 revolutions per minute for more than 10 consecutive seconds despite standardized verbal encouragement. Time to exhaustion will be recorded from the start of the test until termination, with an accuracy of 0.01 seconds, and reported in minutes.

Timepoint
Time to Exhaustion (TTE) will be measured on the main testing day, after 3 days of adherence to the low-glycemic index diet and 60 minutes after ingestion of the caffeine or placebo capsule, during the graded exercise test to exhaustion on a cycle ergometer. Time to Exhaustion will be recorded from the beginning of the test until test termination.

Method of measurement
Time to exhaustion will be measured using a digital stopwatch during the graded exercise test on a cycle ergometer. The time will be recorded from the beginning of the test until test termination according to the predefined exhaustion criterion. The measured time will be recorded to the nearest 0.01 second and reported in minutes.

Secondary outcomes

1

Description
Perceived exertion will be measured during the graded exercise test using the modified Borg scale ranging from zero to ten. Perceived exertion will be recorded during the final 15 seconds of each two-minute exercise stage and immediately after test termination.

Timepoint
Perceived exertion: During the final 15 seconds of each two-minute stage of the graded exercise test and immediately after test termination.

Method of measurement
Modified Borg scale for assessing perceived exertion, ranging from zero to ten.

2

Description
Local muscle discomfort, primarily in the quadriceps muscles, will be measured using the Numeric Rating Scale ranging from zero to ten. This variable will be assessed after the warm-up and before the exercise test, immediately after test termination, and at the fifth and tenth minutes of the recovery period.

Timepoint
Local muscle discomfort: After completion of the warm-up and before the main exercise test, immediately after test termination, and at the fifth and tenth minutes of the recovery period.

Method of measurement
Numeric Rating Scale for assessing the intensity of local muscle discomfort, ranging from zero to ten.

3

Description
Heart rate will be continuously recorded during the warm-up, main exercise test, and recovery period using a Polar chest-strap heart rate monitor manufactured in Finland. The highest heart rate recorded during the main exercise test will be considered the peak heart rate.

Timepoint
Peak heart rate: Continuously recorded during the warm-up, main exercise test, and recovery period, with the highest value recorded during the main exercise test considered as peak heart rate.

Method of measurement
Polar chest-strap heart rate monitor manufactured in Finland, with continuous recording of heart rate throughout the exercise test.

4

Description
Heart rate recovery will be measured as the change in heart rate from the end of the exercise test to the first and second minutes of the recovery period. Heart rate recorded at the end of the test will be compared with heart rate recorded at the first and second minutes of recovery to determine heart rate recovery.

Timepoint
Heart rate recovery: At the end of the main exercise test and at the first and second minutes of the recovery period.

Method of measurement
Polar chest-strap heart rate monitor manufactured in Finland, with heart rate recovery calculated from the change in heart rate between the end of exercise and the first and second minutes of the recovery period.

Intervention groups

1

Description
Intervention group: Following 3 days of adherence to a low-glycemic index diet, participants will undergo 10 to 12 hours of overnight fasting on the test day and will receive a standardized low-glycemic index breakfast. Sixty minutes after breakfast, participants will orally receive, in a single administration, one capsule containing pure caffeine powder at a dose of 5 milligrams per kilogram of body weight, with one glass of water. Following capsule administration, a 60-minute resting period will be provided, followed by the graded exercise test to exhaustion.

Category
Treatment - Drugs

2

Description
Control group: Following 3 days of adherence to the low-glycemic index diet and consumption of the standardized low-glycemic index breakfast on the test day, participants will receive one placebo capsule containing cellulose powder (dextrose) with one glass of water, orally and as a single administration, 60 minutes after breakfast. The placebo capsule will be identical to the caffeine capsule in shape, weight, color, and packaging.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi University

Full name of responsible person
Rastegar Hoseini

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Sponsors / Funding sources

1

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Full name of responsible person
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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
Razi 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
Razi University

Full name of responsible person
Rastegar Hoseini

Position

Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Exercise Physiology

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data will be entered into SPSS and will be available for presentation

When the data will become available and for how long
Access will begin 9 months after the publication of all articles

To whom data/document is available
Only available for researchers in academic and scientific institutions

Under which criteria data/document could be used
All data can be used as a reference

From where data/document is obtainable
mirazizitara@gmail.com

What processes are involved for a request to access data/document
If the explanation for the data request would be convincing it will be given in 3 days.

Comments