Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of caffeine supplementation on corticomuscular coherence at specific levels of perceived exertion during cycling to exhaustion in active women

Protocol summary

Study aim

General Objective:The effect of caffeine supplementation on corticomuscular coherence at specified RPE scales during cycling to exhaustion in active women.

Design

A randomized, double-blind, crossover clinical trial conducted on 15 participants.

Settings and conduct

This study will be conducted at the Exercise Physiology Laboratory of Alzahra University. In the familiarization session. An incremental cycling test will be performed to determine the anaerobic threshold using the V-slope method, starting with a 4-minute warm-up at 75 watts (70 rpm), followed by 25-watt increments every 2 minutes until exhaustion (RPE = 10) or inability to maintain cadence above 50 rpm. In the main session, participants will have EEG and EMG electrodes placed (according to SENIAM method), and baseline resting EEG will be recorded. They will then consume caffeine or placebo, and maximum voluntary contraction will be measured. After 60 minutes, resting EEG and heart rate will be recorded. The bicycle will be adjusted for participant comfort. The fatigue protocol involves a 4-minute warm-up at 60% of anaerobic threshold, followed by cycling at a constant workload (anaerobic threshold + 5%) until exhaustion, with RPE reported throughout.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:Physically active (150–300 min/week moderate aerobic exercise), healthy, normal BMI, no tobacco/alcohol/CNS-active drugs/sports supplements, moderate caffeine intake (≤70 mg/day), regular menstrual cycles (26–32 days).Exclusion Criteria: Acute illness/injury preventing participation, or unwillingness to cooperate.

Intervention groups

Caffeine capsule (6 mg/kg bw) and placebo capsule (wheat bran), identical to caffeine

Main outcome variables

Time to exhaustion during cycling; Corticomuscular coherence in the rectus femoris and gastrocnemius and vastus medialis and biceps femoris muscle at specified RPE scales

General information

Reason for update

Acronym

ECSCC

IRCT registration information

IRCT registration number: **IRCT20260809070591N1**
Registration date: **2026-10-29, 1405/08/07**
Registration timing: **prospective**

Last update: **2026-10-29, 1405/08/07**
Update count: **0**

Registration date

2026-10-29, 1405/08/07

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-06, 1405/08/15

Expected recruitment end date
2027-01-21, 1405/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of caffeine supplementation on corticomuscular coherence at specific levels of perceived exertion during cycling to exhaustion in active women

Public title
The effect of caffeine supplementation on corticomuscular coherence
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Here is the translation:- Possessing physical health, absence of musculoskeletal abnormalities, absence of neuromuscular and cardiopulmonary diseases, and absence of mental disorders. Being physically active (engaging in regular exercise that includes an average of 150 to 300 minutes of moderate-intensity aerobic activity and muscle-strengthening exercises, or 75 to 150 minutes of high-intensity activity per week, such that all major muscle groups of the body are involved). Having a normal weight according to body mass index (BMI of 18–23 kg/m²). Not using tobacco, alcohol, drugs affecting the central nervous system (such as anti-anxiety medications), or sports supplements. Consuming caffeine at a moderate and usual level (a maximum of 70 mg per day) (47) – which was assessed via a standard caffeine consumption questionnaire. Having a regular menstrual pattern with cycles of 26 to 32 days, in order to control for hormonal effects on physiological variables.
Exclusion criteria:
Developing an acute illness or physical injury that makes continued participation in the study impossible or unsafe Lack of willingness to cooperate on the part of the participant
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
Given the randomized crossover design of the study, participants were randomly assigned to one of two treatment sequences, AB or BA. For this purpose, seven X codes and eight Y codes were prepared, mixed thoroughly, and randomly assigned to the participants by an individual who was independent of the intervention procedures and outcome assessment. The correspondence between the X and Y codes and the treatment sequences was maintained by an independent individual and remained concealed until completion of data collection. In the AB sequence, participants received caffeine in the second session and placebo in the third session, whereas in the BA sequence, placebo was administered in the second session and caffeine in the third session. Thus, the treatment sequence was randomly allocated, and both the participants and outcome assessor were blinded to the intervention received in each session.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants in the study and the outcome assessor are kept blinded to the study groups and have no information regarding the type of capsule consumed (caffeine or placebo) by the participants.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alzahra University
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Alzahra University, Deh Vanak Street, Tehran Town
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Approval date
2025-11-05, 1404/08/14
Ethics committee reference number
IR.ALZAHRA.REC.1404.092

Health conditions studied

1

Description of health condition studied
Corticomuscular coherence
ICD-10 code
Z00.6
ICD-10 code description
Encounter for examination for normal comparison and

control in clinical research program

Primary outcomes

1

Description
Time to exhaustion (in seconds or minutes) during cycling at a constant workload.
Timepoint
The test begins 60 minutes after caffeine or placebo consumption. Time to exhaustion is measured in seconds, from the start of the fatigue protocol until the moment of test termination (RPE = 10 or reaching maximum heart rate).
Method of measurement
by cronometer

2

Description
Corticomuscular coherence in the rectus femoris muscle at specified RPE scales.
Timepoint
60 minutes after caffeine or placebo ingestion
Method of measurement
Using EEG and EMG devices, with simultaneous synchronization of both signals.

3

Description
Corticomuscular coherence in the gastrocnemius muscle at specified RPE scales
Timepoint
60 minutes after caffeine or placebo ingestion
Method of measurement
Using EEG and EMG devices, with simultaneous synchronization of both signals.

4

Description
Corticomuscular coherence in the vastus medialis muscle at specified RPE scales
Timepoint
60 minutes after caffeine or placebo ingestion
Method of measurement
Using EEG and EMG devices, with simultaneous synchronization of both signals.

5

Description
Corticomuscular coherence in the biceps femoris muscle at specified RPE scales
Timepoint
60 minutes after caffeine or placebo ingestion
Method of measurement
Using EEG and EMG devices, with simultaneous synchronization of both signals.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1:Participants assigned to this sequence attended a familiarization session (Session 1), during which they became familiar with the testing procedures and equipment and received no intervention. In Session 2, they received a caffeine capsule, and in Session 3, they received a placebo capsule. Caffeine was administered in the form of a capsule containing pure caffeine powder at a dose of 6 mg/kg body weight. The placebo consisted of a capsule containing wheat bran powder. The caffeine and placebo capsules were identical in appearance, size, and taste. Each capsule was consumed with one glass of water 60 minutes before the cycling exercise test. A one-week washout period was maintained between Sessions 2 and 3. Each study session lasted approximately 90–120 minutes. The caffeine powder used in the study was obtained from Pooyan Nutrition Co.
Category
N/A

2

Description
Intervention Group 2: In this sequence, participants first attended Session 1 as a familiarization session, during which they were introduced to the study protocol, testing procedures, and equipment used. No supplement was administered during this session. In Session 2, participants received the placebo, followed by a one-week washout period, after which caffeine was administered in Session 3. The placebo consisted of capsules containing wheat bran powder, whereas caffeine was provided in capsules containing pure caffeine powder at a dose of 6 mg/kg body weight. Both types of capsules were identical in appearance, size, and taste and were indistinguishable from each other. The capsules were consumed with one glass of water 60 minutes before the cycling exercise test. Each study session lasted approximately 90–120 minutes. The caffeine powder used in this study was obtained from Pooyan Nutrition Co.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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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
Alzahra 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

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Name of organization / entity
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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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available