Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effectiveness of pre-exercise caffeine in maximizing hypertrophy and strength gains from morning resistance training in older adults

Protocol summary

Study aim

To investigate whether acute pre-exercise morning caffeine ingestion, combined with daily multi-ingredient nutritional supplementation (whey protein, creatine monohydrate, and omega-3 PUFAs), enhances hypertrophic and strength adaptations after a 12-week resistance training program in older adults, compared with morning or afternoon training with nutritional supplementation alone (no caffeine).

Design

A randomized, double-blind, placebo-controlled, parallel-group phase 3 study in 60 elderly men. The RAND function in Excel will be used for randomization.

Settings and conduct

Participants will be randomly allocated (1:1:1 stratified by sex and baseline strength) into one of three parallel groups: MOR-CAF, MOR-PLA, or AFT-PLA. They will complete 12 weeks of supervised resistance training (3 sessions/week; ~65–80% 1RM). The study will be conducted in Ankara, Turkey.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Low habitual caffeine intake (<100 mg/day); recreationally active but not accustomed to structured resistance training over the preceding 6 months. Exclusion criteria: uncontrolled cardiovascular, metabolic, or respiratory disease; having sleep disorders; use of medications known to alter neuromuscular function or sleep architecture.

Intervention groups

MOR-CAF group, morning training (8:00) + pre-training caffeine (4 mg/kg) + daily multi-ingredient supplementation; MOR-PLA group, morning training (8:00) + pre-training placebo + daily multi-ingredient supplementation; AFT-PLA group, afternoon training (17:00) + pre-training placebo + daily multi-ingredient supplementation.

Main outcome variables

Maximal strength, muscular endurance, muscle thickness, and body composition will be assessed before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231004059615N11**
Registration date: **2026-08-23, 1405/06/01**
Registration timing: **prospective**

Last update: **2026-08-23, 1405/06/01**
Update count: **0**

Registration date

2026-08-23, 1405/06/01

Registrant information

Name

Davar Khodadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-31, 1405/06/09

Expected recruitment end date

2026-09-06, 1405/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effectiveness of pre-exercise caffeine in maximizing hypertrophy and strength gains from morning resistance training in older adults

Public title
The effectiveness of caffeine for maximizing hypertrophy and strength in older adults.

Purpose
Basic scienece

Inclusion/Exclusion criteria
Inclusion criteria:
Low habitual caffeine intake (<100 mg/day) Recreationally active but unaccustomed to structured resistance training for the preceding 6 months Not a smoker Not an alcohol drinker
Exclusion criteria:
Have uncontrolled cardiovascular, metabolic, or respiratory disease Have severe osteoarthritis Have sleep disorders Current use of medications known to alter neuromuscular function or sleep architecture

Age
From **65 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To minimize potential differences between groups, participants will first be grouped based on their average 1-repetition maximum strength in the squat and bench press. The names of the subjects in each group will be entered into an Excel column; each subject will be randomly assigned a number using the RAND function (=RAND()); then, the numbers will be sorted from smallest to largest. Subjects in each group will then be randomly assigned to one of three groups in a 1:1:1 fashion: caffeine and exercise in the morning, placebo and exercise in the morning, or placebo and exercise in the afternoon.

Blinding (investigator's opinion)
Double blinded

Blinding description
Someone outside the study will prepare the supplement and placebo and will not be known to the participants or researchers until after the data analysis. Also, subjects will receive the supplement and placebo in an opaque capsule with a completely similar appearance and weight, and at the same time of day.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the International Science and Technology University
Street address
Tunahan Mah. Dumlupinar 30 Agustos Cad. No:2, Metromal Business F Blok Office
City
Ankara
Postal code
21,06824

Approval date
2026-08-12, 1405/05/21

Ethics committee reference number
202608-04

Health conditions studied

1

Description of health condition studied
Strength training adaptations

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Body composition

Timepoint
Pre-test and post-test

Method of measurement
Using dual-energy X-ray absorptiometry

2

Description
Skeletal muscle thickness

Timepoint
Pre-test and post-test

Method of measurement
Using an ultrasound instrument

3

Description
Mascular strength

Timepoint
Pre-test and post-test
Method of measurement
Using one-repetition maximum test based on the standardized NSCA protocols

Secondary outcomes

1

Description
Cumulative training volume-load
Timepoint
During the intervention period (all training sessions)
Method of measurement
Calculated as the sum of lifted load using the formula (kilograms × repetitions × sets) accumulated during each training session.

2

Description
Sleep quality
Timepoint
Pre-test and post-test
Method of measurement
By the Pittsburgh Sleep Quality Index (PSQI)

3

Description
Sleep efficiency
Timepoint
Pre-test and post-test
Method of measurement
By wrist-worn actigraphy

4

Description
Functional physical performance
Timepoint
Pre-test and post-test
Method of measurement
Using the Short Physical Performance Battery (SPPB)

5

Description
Muscular endurance
Timepoint
Pre-test and post-test
Method of measurement
By a repetitions-to-failure test on the back squat using a load corresponding to 50% of 1RM.

Intervention groups

1

Description
Intervention group 1: MOR-CAF, morning training (08:00) + pre-workout caffeine (4 mg/kg) + daily multi-ingredient supplementation (whey protein, creatine monohydrate, and omega-3 PUFAs)
Category
Lifestyle

2

Description
Intervention group 2: MOR-PLA, morning training (08:00) + pre-workout placebo + daily multi-ingredient supplementation (whey protein, creatine monohydrate, and omega-3 PUFAs)
Category
Lifestyle

3

Description
Control group: AFT-PLA, afternoon training (17:00) + pre-workout placebo + daily multi-ingredient supplementation (whey protein, creatine monohydrate, and omega-3 PUFAs)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
INTERNATIONAL SCIENCE AND TECHNOLOGY UNIVERSITY
Full name of responsible person
Heidar Sajedi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
INTERNATIONAL SCIENCE AND TECHNOLOGY UNIVERSITY

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Foreign

Category of foreign source of funding
Sponsor: country of origin

Country of origin
IR

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
Davar Khodadadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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

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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
Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data collected during the study will be shareable after de-identifying the subjects.

When the data will become available and for how long

The data will be published after the extracted articles are accepted.

To whom data/document is available

All people

Under which criteria data/document could be used

All data collected during the study will be shareable after de-identifying the subjects. The requester will only be permitted to use the data for meta-analysis reviews.

From where data/document is obtainable

Corresponding author: Davar Khodadadi, Faculty of Physical Education and Sports Sciences, Islamic Azad University Central Tehran Branch, Tehran, Iran. Email: davar.khodadadi@yahoo.com

What processes are involved for a request to access data/document

Sending an email request to the corresponding author: Davar Khodadadi, Email: davar.khodadadi@yahoo.com

Comments