Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of transcranial direct current stimulation and acetazolamide consumption on exercise and cognitive performance, and physiological and perceptual responses of mountaineers in simulated altitude

Protocol summary

Study aim

Determining the separate and combined effects of acetazolamide administration and transcranial direct current stimulation (tDCS) on athletic and cognitive performance, as well as physiological and perceptual responses, in mountaineers under simulated high-altitude conditions

Design

Within-subject (crossover), double-blind design: 1) Acetazolamide + M1 stimulation 2) Acetazolamide + DLPFC stimulation 3) Acetazolamide + sham stimulation 4) Placebo + M1 stimulation 5) Placebo + DLPFC stimulation 6) Placebo + sham stimulation

Settings and conduct

The laboratory of the Faculty of Physical Education and Sport Sciences. Both the participant and the researcher were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male participants aged 18–44 years old; active mountaineers (history of ascents to altitudes above 4,000 m); regular aerobic training at least three sessions per week (including mountaineering and hiking); previous history of acute mountain sickness (AMS) during overnight stays at altitudes above 3,000 m; medical clearance certifying no contraindication for participation in the exercise training program. Exclusion criteria: overnight stay at altitudes above 2,700 m within two weeks prior to the start of the study; use of acetazolamide within two weeks prior to the start of the study; allergy to acetazolamide or sulfonamides; history of any cardiovascular, pulmonary, or metabolic disease; presence of any implanted medical devices or pacemakers.

Intervention groups

Normobaric Hypoxia; Acetazolamide; tDCS

Main outcome variables

Time to exhaustion; EMG amplitude; choice reaction time; Continuous Performance Test; Stroop word–color test; perceived exertion; arterial oxygen saturation; pleasure, arousal; balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250812066837N1**
Registration date: **2025-09-05, 1404/06/14**
Registration timing: **prospective**

Last update: **2025-09-05, 1404/06/14**
Update count: **0**

Registration date

2025-09-05, 1404/06/14

Registrant information

Name

Rezvan Kheirandish

Name of organization / entity

The University of razi

Country

Iran (Islamic Republic of)

Phone

+98 61 5272 7465

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of transcranial direct current stimulation and acetazolamide consumption on exercise and cognitive performance, and physiological and perceptual responses of mountaineers in simulated altitude

Public title

Effects of tDCS Stimulation and Acetazolamide consumption on Exercise Performance

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Men aged 18 to 44 years Active mountaineers (with a history of ascents to altitudes above 4,000 meters and regular mountaineering activities in the past year) Regular aerobic training at least three sessions per week (including mountaineering and hiking) History of acute mountain sickness (AMS) during previous overnight stays at altitudes above 3,000 meters Obtaining a medical certificate of fitness for participation in the exercise training program

Exclusion criteria:

Overnight stay at an altitude above 2,700 meters within two weeks prior to the start of the study Use of acetazolamide within two weeks prior to the start of the study Allergy to acetazolamide or sulfonamides Presence of any cardiovascular, pulmonary, or metabolic disease History of seizures, epilepsy, or other types of neurological disorders Presence of implanted medical devices or pacemakers

Age

From **18 years** old to **44 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the order in which participants are exposed to the four different conditions, the Latin square method will be used. First, using the website www.random.org, each participant will be randomly assigned a number between 1 and 12 as an identification code. Then, the English letters A, B, C, D, E, and F will be assigned to the six intervention conditions, and a 6×6 Latin square will be created. After generating the Latin square, participants numbered 1 and 2 will follow the sequence of the first row, participants numbered 3 and 4 will follow the sequence of the second row, participants numbered 5 and 6 will follow the sequence of the third row, participants numbered 7 and 8 will follow the sequence of the fourth row, participants numbered 9 and 10 will follow the sequence of the fifth row, and participants numbered 11 and 12 will follow the sequence of the sixth row

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study will be conducted in a double-blind manner. Neither the participants nor the principal investigator will be aware of the type of stimulation administered in each session, and this information will be accessible only to an individual outside the research team until the completion of the study. To conceal the stimulation order from the principal investigator, all procedures related to the random determination of the stimulation sequence for each participant will be carried out by the same individual outside the research team. Furthermore, to conceal the type of stimulation in each session from the participants, the tDCS device will be hidden from their view using a cover, and the principal investigator will not be present in the laboratory during electrode placement or at the end of the 20-minute session when the electrodes are removed.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Biomedical Research, Razi University

Street address

No. 1, Razi University, University Street, Taq-Bostan, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

۶۷۱۴۴۱۴۹۷۱

Approval date

2023-02-01, 1401/11/12

Ethics committee reference number

IR.RAZI.REC.1401.075

Health conditions studied

1

Description of health condition studied
Healthy Mountaineers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Continuous Performance Test (CPT)
Timepoint
During exercise
Method of measurement
Computerized Continuous Performance Test (CPT)

2

Description
EMG amplitude
Timepoint
During exercise
Method of measurement
16-channel wireless electromyography (EMG) device (Noraxon, Scottsdale, AZ 85260, Germany

3

Description
Choice reaction time
Timepoint
After brain stimulation, after exercise
Method of measurement
Choice Reaction Time Apparatus, Model (Indiana, Lafayette, 63035A, Panel Respon)

4

Description
Time to exhaustion
Timepoint
During exercise
Method of measurement
Running on a treadmill until reaching 90% of maximum heart rate or a rating of 19 on the Borg Rating of Perceived Exertion scale

5

Description
SpO2
Timepoint
During brain stimulation, During fatiguing exercise
Method of measurement
Pulse oximeter (Nonin, USA)

6

Description
Stroop Color–Word
Timepoint
After brain stimulation, after exercise
Method of measurement
Computerized Stroop Test

7

Description
Borg Rating of Perceived Exertion
Timepoint
During fatiguing exercise
Method of measurement
Borg Rating of Perceived Exertion (RPE) scale, 6–20

8

Description
Sense of pleasure
Timepoint
During fatiguing exercise
Method of measurement
The Feeling Scale (FS; ranging from –5 to +5) was used, with responses recorded on a 5-point Likert-type scale.

9

Description
Felt Arousal Scale
Timepoint
During fatiguing exercise
Method of measurement
The Felt Arousal Scale (FAS; ranging from +1 to +6) was used, and its mean scores were analyzed on a 6-point Likert-type scale.

10

Description
Heart rate
Timepoint
During fatiguing exercise
Method of measurement
Polar heart rate monitor

11

Description
Y-Balance
Timepoint
After brain stimulation, after exercise
Method of measurement
The maximum reach of the stance and non-stance leg was measured in three specified directions: (1) anterior, (2) posteromedial, and (3) posterolateral.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1 : Acetazolamide + stimulation of M1 Before each exercise session, participants must take seven 125 mg capsules of acetazolamide. Administration will begin three days before the start of the test (one capsule in the morning and one capsule in the evening), and on the morning of the test day, the capsule will be taken. Acetazolamide will be obtained from Mehr Darou Company, establishment license No. 91988/665. Acetazolamide and placebo will be prepared in identical capsules. To precisely stimulate the M1 and DLPFC areas, the international 10–20 EEG brain mapping system and a dedicated EEG cap will be used. According to the type of stimulation, the target areas for electrode placement will be marked using the EEG cap, and then the electrodes will be placed on the marked areas. For stimulation of the right M1, the anodal electrode will be placed over FC2, and the cathodal electrode will be placed on the left shoulder. For stimulation of the left DLPFC, the anodal electrode will be placed over F3, and the cathodal electrode will be placed over AF8. In the sham stimulation condition, the electrode placement will be similar to that of the DLPFC condition.

Category

Other

2

Description

Intervention 2: Acetazolamide + stimulation of the DLPFC Before each exercise session, participants must take seven 125 mg capsules of acetazolamide. Administration will begin three days before the start of the test (one capsule in the morning and one capsule in the evening), and on the morning of the test day, the capsule will be taken. Acetazolamide will be obtained from Mehr Darou Company, establishment license No. 91988/665. Acetazolamide and placebo will be prepared in identical capsules. To precisely stimulate the DLPFC area, the international 10–20 EEG brain mapping system and a dedicated EEG cap will be used. According to the type of stimulation, the target areas for electrode placement will be marked using the EEG cap, and then the electrodes will be placed on the marked areas. For stimulation of the left DLPFC, the anodal electrode will be placed over F3, and the cathodal electrode will be placed over AF8.

Category

Other

3

Description

Intervention 3: Acetazolamide + sham stimulation Before each exercise session, participants must take seven 125 mg capsules of acetazolamide. Administration will begin three days before the start of the test (one capsule in the morning and one capsule in the evening), and on the morning of the test day, the capsule will be taken. Acetazolamide will be obtained from Mehr Darou Company, establishment license No. 91988/665. Acetazolamide and placebo will be prepared in identical capsules. In the sham stimulation condition, electrode placement will be identical to that of the DLPFC stimulation condition. In sham stimulation, the current is ramped up for a few seconds and then decreased, producing sensations of itching and tingling similar to those experienced during active stimulation. In active stimulation, these sensations fluctuate as the participant adapts to the current, whereas in sham stimulation, the sensations disappear because the current is gradually stopped.

Category

Other

4

Description

Intervention 4: Placebo + stimulation of M1 Before each exercise session, participants must take seven 125 mg capsules of placebo. Administration will begin three days before the start of the test (one capsule in the morning and one capsule in the evening), and on the morning of the test day, the capsule will be taken. The placebo will follow the same dosing protocol. The placebo will consist of lactose powder (seven 125 mg capsules). Both acetazolamide and placebo will be prepared in identical capsules. To precisely stimulate the M1 area, the international 10–20 EEG brain mapping system and a dedicated EEG cap will be used. According to the type of stimulation, the target areas for electrode placement will be marked using the EEG cap, and then the electrodes will be placed on the marked areas. For stimulation of the right M1, the anodal electrode will be placed over FC2, and the cathodal electrode will be placed on the left shoulder.

Category

Other

5

Description

Intervention 5: Placebo + stimulation of DLPFC Before each exercise session, participants must take seven 125 mg capsules of placebo. Administration will begin three days before the start of the test (one capsule in the morning and one capsule in the evening), and on the morning of the test day, the capsule will be taken. The placebo will follow the same dosing protocol. The placebo will consist of lactose powder (seven 125 mg capsules). Both acetazolamide and placebo will be prepared in identical capsules. To precisely stimulate the DLPFC area, the international 10–20 EEG brain mapping system and a dedicated EEG cap will be used. According to the type of stimulation, the target areas for electrode placement will be marked using the EEG cap, and then the electrodes will be placed on the marked areas. For stimulation of the left DLPFC, the anodal electrode will be placed over F3, and the cathodal electrode will be placed over AF8.

Category

Other

6

Description

Control group: Placebo + stimulation of sham stimulation Before each exercise session, participants must take

seven 125 mg capsules of placebo. Administration will begin three days before the start of the test (one capsule in the morning and one capsule in the evening), and on the morning of the test day, the capsule will be taken. The placebo will follow the same dosing protocol. The placebo will consist of lactose powder (seven 125 mg capsules). Both acetazolamide and placebo will be prepared in identical capsules. In the sham stimulation condition, electrode placement will be identical to that of the DLPFC stimulation condition. In sham stimulation, the current is ramped up for a few seconds and then decreased, producing sensations of itching and tingling similar to those experienced during active stimulation. In active stimulation, these sensations fluctuate as the participant adapts to the current, whereas in sham stimulation, the sensations disappear because the current is gradually stopped.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi University, Kermanshah

Full name of responsible person
Vahid Tadibi

Street address
No. 1, Razi University, University Street, Taq-Bostan, Kermanshah

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Province
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Postal code
6714414971

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+98 83 3427 7605

Email
info@razi.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellor for Research, Razi University

Full name of responsible person
vahid tadibi

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No. 1, Razi University, University Street, Taq-Bostan, Kermanshah

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info@razi.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice-Chancellor for Research, 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
The Razi University of Kermanshah

Full name of responsible person
Rezvan Kheirandish

Position
Graduate in Physical Education

Latest degree
Master

Other areas of specialty/work
Exercise Physiology

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No. 1, Razi University, University Street, Taq-Bostan, Kermanshah

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Person responsible for updating data

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Graduate in Physical Education

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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
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
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

Title and more details about the data/document
Title: Psychological and Physiological Study Data Details: Includes questionnaire scores, exercise performance, and physiological indices of participants.

When the data will become available and for how long
The data will be available to qualified researchers after completion of the study and

To whom data/document is available
Access will be granted to qualified researchers and individuals with ethical approval

Under which criteria data/document could be used
The data will be used solely for research and scientific purposes, and access is conditional on compliance with ethical regulations and maintaining participant confidentiality.

From where data/document is obtainable
To access the data, researchers may contact the corresponding author of the study.

What processes are involved for a request to access data/document
Requests for data must be sent to the corresponding author. After reviewing ethical compliance and researcher qualifications, the data will be provided in a de-identified format.

Comments
All data will be stored and shared in accordance with data protection regulations and research ethics principles.