

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Aug 2026

Effects of Transcranial Direct Current Stimulation on Athletic and Cognitive Performance in Normobaric Hypoxia Condition

Protocol summary

Study aim

Effects of transcranial direct current stimulation of the primary motor cortex and dorsolateral prefrontal cortex on time to exhaustion, the amplitude of muscle electromyography, perceived exertion, pleasure sensation, arousal, cognitive function, and choice reaction time after exhausting endurance activity in hypoxia

Design

A within-subject, counterbalanced, and double-blind study. Fifteen subjects will be randomly exposed to 3 different conditions. Randomizing the situations is done via www.randomization.com.

Settings and conduct

This study is conducted at Razi University. After recruiting the subjects and their familiarization, each subject is exposed to 3 different conditions of electrical stimulation of the brain in random order and then, will perform one bout of endurance activity until exhaustion in normobaric hypoxia.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Aged between 18 to 30 years old
Student of sports sciences, third semester or higher
Reside in Kermanshah Not climbing to an altitude of more than 2000 meters in the past month Getting the certification of no prohibition of participating in the exercise
Exclusion Criteria: Suffering from any cardiovascular, pulmonary, and metabolic diseases
History of seizures, epilepsy, or other neurological diseases
Existence of implantable devices or pacemakers in the body
Tobacco and alcohol consumption
Refusal to give informed consent

Intervention groups

In this within-subject and counterbalanced study, participants will be exposed to 3 different conditions of brain stimulation including 1) Anodal stimulation of the primary motor cortex, 2) Anodal stimulation of the dorsolateral prefrontal cortex, 3) Sham stimulation (placebo effect) for 20 minutes and 2 milliamperes

intensity.

Main outcome variables

Change in time to exhaustion, perceived exertion, electromyography, cognitive function, and reaction time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210617051606N6**

Registration date: **2022-02-17, 1400/11/28**

Registration timing: **retrospective**

Last update: **2022-02-17, 1400/11/28**

Update count: **0**

Registration date

2022-02-17, 1400/11/28

Registrant information

Name

Ehsan Amiri

Name of organization / entity

Razi University

Country

Iran (Islamic Republic of)

Phone

+98 83 3845 8428

Email address

e.amiri@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-27, 1400/11/07

Expected recruitment end date

2022-02-06, 1400/11/17

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Transcranial Direct Current Stimulation on Athletic and Cognitive Performance in Normobaric Hypoxia Condition

Public title
Transcranial direct current stimulation and athletic performance in hypoxia

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Aged between 18 to 30 years old Student of physical education and sport sciences, third semester or higher Reside in Kermanshah city Not climbing to an altitude of more than 2000 meters in the past month Getting the certification of no prohibition of participating in the exercise training program from a specialist
Exclusion criteria:
Suffering from any cardiovascular, pulmonary and metabolic diseases History of seizures, epilepsy or other neurological diseases Existence of implantable devices or pacemakers in the body Tobacco and alcohol consumption Refusal to give informed consent

Age
From **18 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the order of subjects' exposure to 3 different conditions (3 different types of electrical stimulation of the brain) will be randomized by the Latin Squares method. To do so, first using the site www.random.org, a number between 1 and 15 will be randomly allocated to each subject as an identification code. Then, the English letters A, B, and C will be assigned to the three intervention conditions and a Latin Square will be created. In this case, a Latin square with three rows and three columns is created. Finally, participants 1 to 5 will be placed in the sequence of the first row, participants 6 to 10 will be placed in the sequence of the second row, and participants 11 to 15 will be placed in the sequence of the third row.

Blinding (investigator's opinion)
Double blinded

Blinding description

In this double-blind study, the investigator and participants will be blinded to the type and target areas of transcranial electrical stimulation used in each session. In the present study, a Neurostim stimulator will be used to induce direct current electrical stimulation in three separate sessions and in three different modes, including 1) Anodal stimulation of the primary motor cortex (M1), 2) Anodal stimulation of the dorsolateral prefrontal cortex (DLPFC), 3) sham stimulation (Placebo effect). To do so, an individual outside the research team will be responsible for applying electrical stimulation in three test sessions. In order to blind the participants, after they sit on a special chair, the stimulator will be hidden from their view and wrapped by a cover, and the electrodes will be placed on the target areas by that individual. In order to blind the investigator, before the intervention, the investigator leaves the laboratory and returns to the test site after the termination of the stimulation time, removal of the electrodes, and turning off the stimulator. Also, in Sham stimulation mode, according to standard protocols, active current will be applied for 30 seconds in order to induce a feeling similar to active stimulation modes, and then the current is cut off and the stimulation will be deactivated.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Kermanshah Razi University
Street address
Room. 73, Faculty of Sport Sciences, Razi University, University Str, Taq-e-bostan, Kermanshah, Iran
City
Kermanshah
Province
Kermanshah
Postal code
6714414971
Approval date
2021-12-29, 1400/10/08
Ethics committee reference number
IR.RAZI.REC.1400.093

Health conditions studied

1

Description of health condition studied
The participants are healthy

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Change in time to exhaustion in a sub-maximal endurance activity

Timepoint

Upon reaching exhaustion while performing a sub-maximal endurance activity

Method of measurement

Recording time using a stopwatch

2

Description

Amplitude of muscle electromyography

Timepoint

During and after reaching exhaustion in a sub-maximal endurance activity

Method of measurement

Sixteen channels wireless electromyography device (Noraxon, Scottsdale, AZ85260)

3

Description

Rating of Perceived Exertion

Timepoint

During a sub-maximal endurance activity

Method of measurement

By use of 6 to 20 perceived exertion Borg scale

4

Description

Cognitive function

Timepoint

After reaching exhaustion in a sub-maximal exhausting activity

Method of measurement

by the use of Stroop Color-Word Test

Secondary outcomes

1

Description

Choice reaction time

Timepoint

Before and after exhaustion in a sub-maximal endurance activity

Method of measurement

By the use of Response Panel (63035A, Lafayette, Indiana) reaction time device

2

Description

Pleasure sensation

Timepoint

Before and after exhaustion in a sub-maximal endurance activity

Method of measurement

By the use of 11-item Feel Scale

3

Description

The degree of arousal

Timepoint

Before and after exhaustion in a sub-maximal endurance activity

Method of measurement

By the use of 6-item Felt Arousal Scale

Intervention groups

1

Description

Intervention group: In this study, all subjects will be exposed to two intervention conditions with an interval of at least 72 hours, including 1) anodal electrical brain stimulation of the primary motor cortex, 2) anodal electrical brain stimulation of the dorsolateral prefrontal cortex. In both conditions, the stimulation duration will be 20 minutes and its intensity will be 2 milliamperes. A Neurostim stimulator device made by Medina Teb Company will be used for brain stimulation. Target areas in the brain are identified using the International Brain Mapping 10-20 System. The stimulation of target areas is performed using two special electrodes and a special electroencephalogram (EEG) cap.

Category

Treatment - Devices

2

Description

Control group: In this study, in addition to two intervention sessions, all subjects were exposed to a control session including sham electrical brain stimulation (placebo effect). All details of the control session will be similar to the intervention sessions, except that in the control session, the brain is not electrically stimulated and the electrical current of the stimulator device will be deactivated after 30 seconds. The duration of control conditions will also be 20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Sport Sciences of Razi University

Full name of responsible person

Mohammad Azizi
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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

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
Ehsan Amiri

Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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 are shared after the de-identification of the participants

When the data will become available and for how long

3 months after publication

To whom data/document is available

All individuals upon formal request

Under which criteria data/document could be used

Data sharing requests are accepted for any purposes

From where data/document is obtainable

To obtain any data/document, please send an e-mail to Ehsan Amiri, a faculty member at Razi University, through the following e-mail address: e.amiri@razi.ac.ir

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

Upon formal request, mentioning due reasons, and providing full personality details, data will be sent after 72 h via e-mail

Comments