Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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)

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+98 83 3845 8428

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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
Dr. Alireza Zebarjadi
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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
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Other areas of specialty/work
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Person responsible for updating data

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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