

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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](http://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](http://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  
**Street address**  
University St, Taq-e-Bostan  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Razi University  
**Full name of responsible person**  
Dr. Alireza Zebarjadi  
**Street address**  
University St, Taq-e-Bostan  
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**Email**  
zebarjadiali@yahoo.com  
**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**  
Sport Medicine  
**Street address**  
No. 73, Faculty of Sport Sciences, Razi University,  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Ehsan Amiri  
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Assistant Professor  
**Latest degree**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Ehsan Amiri  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**

Sport Medicine

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**City**

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**Email**

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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**