# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 2026

## Comparison of the Effects of Single-Site and Dual-Site Transcranial Direct Current Stimulation on Exercise Performance and Psychophysiological Responses of Trained Men in an Endurance Exercise

## Protocol summary

**Study aim**
Comparison the Effects of Single-Site and Dual-Site Transcranial Direct Current Stimulation on Exercise Performance and Psychophysiological Responses in an Endurance Exercise

**Design**
In the present study, with within-subjects design, counterbalanced and double-blind design, 12 subjects will be randomly exposed to four different conditions.

**Settings and conduct**
This research will be done in Razi University. After selecting the subjects and familiarizing themselves with the research process, each subject will be exposed to four different conditions of electrical stimulation of the brain with a random combination. Then, the subjects will perform a time trial endurance activity. The principal investigator and subjects will not be aware of the type of stimulation received in each session.

**Participants/Inclusion and exclusion criteria**
Criteria for entering: Age range from 18 to 35 years. Endurance trained men with a history of at least one year of regular training. No color blindness or color vision disorders. being right-handed Criteria for not entering: Having any cardiovascular, pulmonary and metabolic disease. History of seizures, epilepsy or other types of neurological diseases. The presence of implantable devices or pacemakers in the body. Smoking and alcohol consumption.

**Intervention groups**
This study is an intra-group and counterbalanced study in which the subjects are exposed to four different conditions of brain stimulation including: 1) anodal stimulation of the primary motor cortex, 2) anodal stimulation of the posterior-lateral prefrontal cortex, 3) two-zone anodal stimulation, 4) sham stimulation (placebo effect) will be placed. Also, the duration of brain stimulation will be 20 minutes and its intensity will be 2 milliamps.

**Main outcome variables**
change in endurance performance; the degree of perception of pressure; electromyography; cognitive function; reaction time

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230729058958N1**
Registration date: **2023-08-03, 1402/05/12**
Registration timing: **prospective**

Last update: **2023-08-03, 1402/05/12**
Update count: **0**

**Registration date**
2023-08-03, 1402/05/12

**Registrant information**

**Name**
Hosna Khoshchehreh

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Razi University

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-08-23, 1402/06/01

**Expected recruitment end date**

2023-09-01, 1402/06/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effects of Single-Site and Dual-Site Transcranial Direct Current Stimulation on Exercise Performance and Psychophysiological Responses of Trained Men in an Endurance Exercise

**Public title**

Single-Site and Dual-Site Transcranial Direct Current Stimulation and Endurance Exercise

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Endurance trained men with a history of at least one year of regular training. Body mass index (BMI) 18.5 to 24.9 kg per square meter of height. obtaining a certificate of non-prohibition of participating in sports training programs from a doctor. Not suffering from color blindness or color vision disorders. The age range is 18 to 35 years. being right-handed.

**Exclusion criteria:**

Having any cardiovascular, pulmonary and metabolic disease. History of seizures, epilepsy or other types of neurological diseases. The presence of implantable devices or pacemakers in the body. Smoking and alcohol consumption.

**Age**

From **18 years** old to **35 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**

In this study, in order to randomize the order of subject exposure to four different conditions (4 different types of electrical stimulation of the brain), the Latin square method will be used. For this purpose, first, using the website www.random.org, each subject will be randomly assigned a number between 1 and 12 as an identification code. Then, the English letters D, C, B, A are assigned to four intervention conditions and a Latin square will be created with four rows and four columns. After creating the Latin square, participants number 1 to 3 in the sequence of the first row, participants 4 to 6 in the sequence of the second row, participants 7 to 9 in the sequence of the third row and participants 10 to 12 in the sequence of the fourth row will be placed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this double-blind study, the researcher and participants will be blinded to the type of transcranial electrical stimulation used and the location of stimulation in each session. In the present study, the Neurostim stimulation device was used to induce direct current electrical stimulation in four separate sessions and four different modes including: 1) anodal stimulation of the primary motor cortex, 2) anodal stimulation of the posterior-lateral prefrontal cortex, 3) anodal stimulation of the two regional, 4) sham stimulation (placebo) will be used. For this purpose, a person outside the research team will be responsible for applying electrical stimulation in four experimental sessions. In order to blind the participants, after they sit on a special chair, the electrical stimulation device of the brain is hidden from their sight and covered by a cover completely, and the electrodes will be placed on the desired areas by the examiner. In order to blind the researcher, before the intervention, the researcher leaves the laboratory and returns to the test site after the stimulation period has passed and the electrodes are removed and the stimulation device is turned off. Also, in the sham stimulation mode, according to standard protocols, the active current is induced on the head for 30 seconds to induce the same sensation as the active stimulation mode, and then the current is cut off and the stimulation is deactivated.

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Razi University Research Ethics Committee

**Street address**

Iran, Kermanshah, Taq Bostan, University St., Razi University

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714414971

**Approval date**

2023-05-10, 1402/02/20

**Ethics committee reference number**

IR.RAZI.REC.1402.007

## Health conditions studied

### 1

**Description of health condition studied**
The participants are healthy people.
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Time gained in time trial endurance performance
**Timepoint**
After finishing the time trial endurance activity
**Method of measurement**
Record the time and distance using a bicycle car meter

### 2

**Description**
Amplitude of muscle electromyography
**Timepoint**
Every three kilometers and for 30 seconds
**Method of measurement**
8-channel wireless electromyography device (model 85260 Noraxon, Scottsdale, AZ)

### 3

**Description**
The degree of perception of pressure
**Timepoint**
Once every three kilometers
**Method of measurement**
Using a pressure perception scale of 0 to 100 borg

### 4

**Description**
Cognitive function
**Timepoint**
Before and after endurance activity
**Method of measurement**
Using color-word Stroop test

### 5

**Description**
Countdown cognitive test to measure hypofrontality
**Timepoint**
During the performance of endurance activity in kilometers 4, 8 and 12
**Method of measurement**
A number from 200 to 300 will be randomly announced by the examinee out loud and the subject will be asked to count out loud for 1 minute in reverse and with a distance of 3 from the announced number.

## Secondary outcomes

### 1

**Description**
Selective reaction time
**Timepoint**
Before and after endurance activity
**Method of measurement**
Using selective reaction time device

### 2

**Description**
Pleasure scale
**Timepoint**
Once every three kilometers
**Method of measurement**
Using an 11-item emotion scale

### 3

**Description**
Arousal scale
**Timepoint**
Once every three kilometers
**Method of measurement**
Using a 6-item scale of perceived arousal

### 4

**Description**
pain scale
**Timepoint**
Once every three kilometers
**Method of measurement**
Using a visual analog scale of 0 to 10

## Intervention groups

### 1

**Description**
Intervention group: In this study, all the subjects were exposed to all three intervention conditions with an interval of one week, including: 1) anodal stimulation of the primary motor cortex, 2) anodal stimulation of the posterior-lateral prefrontal cortex, 3) bilateral cerebral anodal stimulation. will get In all three conditions, the duration of stimulation will be 20 minutes with an intensity of 2 mA. In order to stimulate, the Neurostim stimulation device manufactured by Medina Teb Company will be used. The target areas in the brain are identified using the 10-20 international brain mapping system, and the target areas are stimulated using special stimulation electrodes and a special electroencephalogram cap.
**Category**
Treatment - Devices

**2**

**Description**
Control group: In this study, in addition to three intervention sessions, all subjects will be exposed to one control session including brain electrical stimulation in sham (placebo) mode. All the details of the implementation of the protocol in the control mode will be similar to the intervention mode, with the difference that in the control mode, the electrical stimulation of the brain is not done and the electrical current of the stimulating device will be deactivated after 30 seconds. The duration of the control condition will be 20 minutes.

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Faculty of Sports Sciences, Razi University

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## Sponsors / Funding sources

**1**

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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**
Sport Medicine

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## Person responsible for updating data

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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 can be shared after de-identifying subjects.
**When the data will become available and for how long**
6 months after printing the results
**To whom data/document is available**
Researchers
**Under which criteria data/document could be used**
For meta-analytic research
**From where data/document is obtainable**
If you need to receive documents, send an email to Hasna Khoshchehre, research researcher, with the email address: h.khoshchehre98@gmail.com.
**What processes are involved for a request to access data/document**
In case of an official request, stating the relevant reasons and mentioning the complete details, the data will be sent via email after 72 hours.
**Comments**