

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 Khoshchereh

Name of organization / entity

Razi University

Country

Iran (Islamic Republic of)

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+98 83 3432 7161

Email address

h.khoshchehre98@gmail.com

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

Full name of responsible person

Hosna Khoshchehreh

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Taq Bostan, University Street, Razi University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

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

Sport Medicine

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Hosna Khoshchehre

Position

Student

Latest degree

Master

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 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