Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of Transcranial Direct Current Stimulation on Endurance and Cognitive Performance of Trained Men with and without Mental Fatigue

Protocol summary

Study aim

Determining the effects of transcranial direct current electrical stimulation on the endurance and cognitive performance of trained men with and without mental fatigue

Design

The current research will be conducted with a cross-over design with random distribution, in a double-blind manner and with the control of the placebo effect (sham) and it will be conducted on 16 athletes, and www.randomization.com will be used for randomization.

Settings and conduct

This study will be done in Razi University. After selecting the subjects and familiarizing themselves with the research process, each person will be exposed to 4 different conditions randomly and then will perform a bout of endurance activity until exhaustion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Endurance trained men with a history of one year regular training, body mass index (BMI) 18.5 to 24.9 kg/m2, obtaining a certificate of non-prohibition from participating in sports training programs from a doctor, being right-handed, not suffering from color vision disorders Entry ban criteria: Suffering from any chronic disease, history of convulsions, epilepsy or other types of neurological diseases, presence of implantable devices or pacemakers in the body, smoking and alcohol consumption

Intervention groups

subjects are exposed to 4 different conditions:1) induction of mental fatigue + anodal stimulation + running until reaching exhaustion; 2) induction of mental fatigue + sham stimulation + running until reaching exhaustion; 3) anodal stimulation + running until exhaustion (without inducing mental fatigue); 4) Stimulation + running will be until reaching exhaustion (without inducing mental fatigue). The duration of stimulation will be 20 minutes and its intensity will be 2 mA.

Main outcome variables

Change in time to exhaustion, pressure perception, electromyography, cognitive function and reaction time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220724055538N1**
Registration date: **2022-08-04, 1401/05/13**
Registration timing: **prospective**

Last update: **2022-08-04, 1401/05/13**
Update count: **0**

Registration date

2022-08-04, 1401/05/13

Registrant information

Name

Armin Amirian

Name of organization / entity

Razi uinversity of kermanshah

Country

Iran (Islamic Republic of)

Phone

+98 83 3423 9003

Email address

arminamiriyan76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Transcranial Direct Current Stimulation on Endurance and Cognitive Performance of Trained Men with and without Mental Fatigue

Public title

Non-invasive brain stimulation and endurance performance

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Endurance training men with at least one year of regular training Body mass index (BMI) 18.5 to 24.9 kg/m2 Obtaining a certificate of non-prohibition of participating in sports training programs from a doctor Being right-handed Absence of color blindness or color vision disorders Age range from 18 to 30 years

Exclusion criteria:

Suffering from any chronic disease History of seizures, epilepsy or other types of neurological diseases Presence of implantable devices or pacemakers in the body Smoking and alcohol consumption

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: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the order of subject exposure to 4 different conditions (4 different types of electrical stimulation of the brain) will be randomized by the Latin square method. For this purpose, a number between 1 and 16 will be randomly assigned to each of the subjects as an identification code using www.random.org. Then, the English letters B, A, C, and D will be assigned to the four intervention conditions and a Latin square will be created. In this case, a Latin square with four rows and four columns is created. Finally, participants number 1 to 4 are placed in the sequence of the first row, participants number 5 to 8 are placed in the sequence of the second row, participants number 8 to 12 are placed in the sequence of the third row, and participants 13 to 16 are placed in the sequence of the fourth row.

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 current study, the neurostimulator device was used to induce direct current electrical stimulation in four separate sessions and four different modes, including: 1) induction of mental fatigue + brain anodal stimulation + running until reaching paralysis; 2) induction of mental fatigue + sham stimulation + running until reaching exhaustion; 3) cerebral anodal stimulation + running until exhaustion (without inducing mental fatigue); 4) Stimulation + running will be until reaching exhaustion (without inducing mental fatigue). 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 stimulating device is hidden from their sight and is completely covered by a cover, and the electrodes are 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

Ethics Committee of Razi University

Street address

unit 1, next to the cooperative office, rural, second station, Farhangian phase 2, Kermanshah, Iran

City

kermanshah

Province

Kermanshah

Postal code

6715773159

Approval date

2022-07-06, 1401/04/15

Ethics committee reference number

IR.RAZI.REC.1401.024

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
Changes in endurance performance
Timepoint
After endurance activity
Method of measurement
Laboratory treadmill (CosMed, T300, Italy)

2

Description
Amplitude of muscle electromyography
Timepoint
Every five minutes for 30 seconds
Method of measurement
16-channel wireless electromyography device (Noraxon model, Scottsdale, AZ85260)

3

Description
The degree of perception of pressure
Timepoint
Every three minutes
Method of measurement
Using a pressure perception scale of 6 to 20 borg

4

Description
Cognitive function
Timepoint
Before and after maximal aerobic test
Method of measurement
Using the color-word Stroop test

Secondary outcomes

1

Description
Selective reaction time
Timepoint
Before and after endurance activity
Method of measurement
Using the response time device of Response Panel (63035A, Lafayette, Indiana)

2

Description
sense of pleasure
Timepoint
Every three minutes
Method of measurement
Using an 11-item emotion scale

3

Description
Arousal level
Timepoint
Every three minutes
Method of measurement
Using a 6-item scale of perceived arousal

Intervention groups

1

Description
Intervention group: 1) induction of mental fatigue + brain anodal stimulation + running until reaching paralysis; 2) induction of mental fatigue + sham stimulation + running until reaching exhaustion; 3) cerebral anodal stimulation + running until exhaustion (without inducing mental fatigue); 4) Stimulation + running will be until reaching exhaustion (without inducing mental fatigue).
Category
Treatment - Devices

2

Description
Control group: In this research, in addition to three intervention sessions, all subjects are exposed to one control session including electrical stimulation of the brain in a sham state (placebo effect). 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
Ali Heirani
Street address
Taq Bostan, University Street
City

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Province
Kermanshah
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Phone
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Email
a.heirani@razi.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razi university
Full name of responsible person
Mostafa Mostafaei
Street address
Taq Bostan, University Street
City
Kermanshah
Province
Kermanshah
Postal code
6714414971
Phone
+98 83 3427 4515
Email
bouck58@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 of Kermanshah
Full name of responsible person
Armin Amirian
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Sport Medicine
Street address
unit 1, next to the cooperative office, rural, second station, Farhangian phase 2, Kermanshah, Iran
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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
3 months after printing the results
To whom data/document is available
All people upon official request
Under which criteria data/document could be used
Requesting access to data for any purpose is permitted
From where data/document is obtainable
If you need to receive the documents, send an email to Armin Amiryan, the researcher, with the email address: arminamiriyan76@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