Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effects of Transcranial Pulsed Current Stimulation on Athletic and Cognitive Performance in male trained cyclists

Protocol summary

Study aim
Investigating the effects of Transcranial Pulsed Current Stimulation on Athletic and Cognitive Performance in male trained cyclists

Design
A clinical trial with a control group, with a within-group design, counterbalanced, double-blind, randomized, on 15 subjects. Latin square was used for randomization.

Settings and conduct
This study is conducted at Razi University. After recruiting subjects and their familiarization, each subject is exposed to 3 different conditions of brain electrical stimulation in random order and then, they will perform an endurance activity.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Gender Male, regular endurance cycling training in 6 months before the beginning of the research, The age range is 18 to 44 years, Getting the certification of no prohibition of participating in the exercise training program from a specialist. Exclusion Criteria: history of sports injury in the past month, 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, Having color blindness

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 1/5 milliamperes intensity.

Main outcome variables
Changes in endurance performance,perceived exertion, electromyography, cognitive function including Stroop Color-Word Test and countdown test, reaction time, pain scale, pleasure and arousal scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230731058985N1**
Registration date: **2023-08-11, 1402/05/20**
Registration timing: **prospective**

Last update: **2023-08-11, 1402/05/20**
Update count: **0**

Registration date
2023-08-11, 1402/05/20

Registrant information

Name
Hanie Nozari

Name of organization / entity
Razi University

Country
Iran (Islamic Republic of)

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+98 918 223 0658

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-22, 1402/06/31

Expected recruitment end date
2023-11-21, 1402/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effects of Transcranial Pulsed Current Stimulation on Athletic and Cognitive Performance in male trained cyclists

Public title
Transcranial Pulsed current stimulation on Athletic and cognitive performance

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
regular endurance cycling training in 6 months before the beginning of the research. The age range is 18 to 44 years Getting the certification of no prohibition of participating in the exercise training program from a medical doctor Male gender

Exclusion criteria:
history of sports injury in the past month 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 Having color blindness

Age
From **18 years** old to **44 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 subject exposure to 3 different conditions (3 different types of electrical stimulation of the brain) will be randomized by Latin square method. For this purpose, first, using the www.random.org website, a number between 1 and 15 will be randomly assigned to each of the subjects as an identification code. Then, the English letters B, A 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 number 1 to 5 are placed in the sequence of the first row, participants number 6 to 10 are placed in the sequence of the second row, and participants number 11 to 15 are placed in the sequence of the third 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 present study, the Neurostim stimulation device was used to induce direct current electrical stimulation in three separate sessions and 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) will be used. For this purpose, a person outside the research team will be responsible for applying electrical stimulation in three 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, Research Vice-Chancellor

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Approval date
2023-05-03, 1402/02/13

Ethics committee reference number
IR.RAZI.REC.1402.017

Health conditions studied

1

Description of health condition studied
Participants are healthy and trained cyclists

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Changes in endurance performance
Timepoint
During test execution
Method of measurement
Using endurance test

2

Description
Amplitude of muscle electromyography
Timepoint
During endurance testing
Method of measurement
16-channel wireless electromyography device (Noraxon model, Scottsdale, AZ85260)

3

Description
Rating of Perceived Exertion
Timepoint
During the execution of the endurance test and the time to reach the dead end
Method of measurement
By use of 6 to 20 perceived exertion Borg scale

4

Description
Cognitive function
Timepoint
Before and after the application of stimulation and after the execution of the test
Method of measurement
by the use of Stroop Color-Word Test

5

Description
choice reaction time
Timepoint
Before and after the application of stimulation and after the execution of the test
Method of measurement
By the use of Response Panel (63035A, Lafayette, Indiana) reaction time device

6

Description
Pleasure sensation
Timepoint
During the execution of the endurance test and the time to reach the dead end
Method of measurement
By the use of 11-item Feel Scale

7

Description
pain sensation
Timepoint
During the execution of the endurance test and the time to reach the dead end
Method of measurement
Using a scale of 0 to 10

8

Description
Countdown cognitive test
Timepoint
During test execution
Method of measurement
Countdown to the distance of 3 numbers from the announced random number for one minute

9

Description
The degree of arousal
Timepoint
During the execution of the endurance test and the time to reach the dead end
Method of measurement
By the use of 6-item Felt Arousal Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, all subjects will be exposed to two intervention conditions with an interval of one week, 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 1/5 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
Razi University

Full name of responsible person
Hanie Nozari

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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
Vahid Tadibi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work
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hanie nozari

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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-analysis research

From where data/document is obtainable
If you need to receive documents, send an email to hanie nozari, research researcher, with the email address: hana.nozari1997@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