

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 918 223 0658

Email address

hana.nozari1997@gmail.com

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

Street address

Razi University, Faculty of Sports Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3427 7605

Email

hana.nozari1997@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

Farzaneh Gandomi

Street address

Taq Bostan, University Street, Razi University

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3427 7605

Email

gandomif@razi.ac.ir

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

Street address

Taq Bostan, University Blvd., Razi University, Faculty of Sports Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3427 9265

Email

vtadibi@yahoo.com

Person responsible for scientific 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

Street address

Taq Bostan, University Blvd., Razi University, Faculty of Sports Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3427 9265

Email

vtadibi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Razi University

Full name of responsible person

hanie nozari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiology

Street address

Kermanshah Khaleej Fars Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6718979577

Phone

+98 918 223 0658

Email

hana.nozari1997@gmail.com

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