Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of acute non-invasive brain stimulation on cognitive and executive functions in one bout of exhaustive endurance activity in semi-endurance runners

Protocol summary

Study aim

Determining the effects of acute non-invasive brain stimulation on cognitive and executive functions in a single bout of endurance activity in semi-endurance runners.

Design

The clinical trial had two control and sham groups, in order to randomize the order of subject exposure to two different conditions, the website www.randomization.com was used.

Settings and conduct

Attending the laboratory and performing cognitive tests, then, the target area to install the electrodes will be marked using a special EEG cap, and then the electrodes will be installed in the marked areas. To stimulate the left DLPFC area, the anode electrode will be installed in the F3 area and the cathode electrode will be installed in the AF8 area. In the sham stimulation mode, the method of recording the electrodes will be similar to the active stimulation mode

Participants/Inclusion and exclusion criteria

Criteria for entering the research: 1) More than 3 years of active experience in the field of endurance biathlon 2) Age range from 18 to 35 years 3) Body mass index (BMI) 18.5 to 24.9 kilograms per square meter of height 4) Not suffering from color blindness or color vision disorders 5) Being right-handed Criteria for not entering the research: 1) Suffering from any cardiovascular, pulmonary and metabolic diseases 2) history of seizures, epilepsy or other types of neurological diseases 3) The presence of implantable devices or pacemakers in the body 4) Smoking and alcohol consumption

Intervention groups

Subjects will be cross-exposed to two brain stimulation conditions including 1) anodal stimulation of the DLPFC region and 2) sham stimulation.

Main outcome variables

Effect on time to physical exhaustion, heart rate, working memory performance, selective reaction time, bimanual coordination, "countdown" cognitive test, runners' sense of pain, runners' sense of pleasure, rate of perception of pressure (RPE).

General information

Reason for update

Acronym

ETDCSESER

IRCT registration information

IRCT registration number: **IRCT20230629058614N1**
Registration date: **2023-12-20, 1402/09/29**
Registration timing: **retrospective**

Last update: **2023-12-20, 1402/09/29**
Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

Mahdi Esmaeili

Name of organization / entity

Razi University of Kermanshah

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date
2023-06-22, 1402/04/01
Actual recruitment start date
2023-06-05, 1402/03/15
Actual recruitment end date
2023-07-23, 1402/05/01
Trial completion date
2023-07-23, 1402/05/01

Scientific title
The effects of acute non-invasive brain stimulation on cognitive and executive functions in one bout of exhaustive endurance activity in semi-endurance runners

Public title
The effects of acute non-invasive brain stimulation on cognitive and executive functions in one bout of exhaustive endurance activity in semi-endurance runners
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
1) More than 3 years of active experience in the field of endurance biathlon 2) Age range from 18 to 35 years 3) Body mass index (BMI) 18.5 to 24.9 kilograms per square meter of height 4) Not suffering from color blindness or color vision disorders 5) Being right-handed
Exclusion criteria:
1) Suffering from any cardiovascular, pulmonary and metabolic diseases 2) history of seizures, epilepsy or other types of neurological diseases 3) The presence of implantable devices or pacemakers in the body 4) Smoking and alcohol consumption
Age
From **18 years** old to **35 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **18**
Actual sample size reached: **14**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method and description of each method: simple randomization, block (Subjects will be cross-exposed to two brain stimulation conditions including 1) DLPFC anodal stimulation and 2) sham stimulation.)
Blinding (investigator's opinion)
Double blinded
Blinding description
Subjects and the main researcher will not be aware of the type of stimulation received in each session, and this information will only be available to someone outside the research team until the end of the research. In order to hide the order of receiving stimulation from the main researcher, all the steps related to the random determination of the order of receiving stimulation in each subject will be performed by the same person outside the research team. Also, in order to hide the type of stimulation in each session from the subjects, the TDCS device is hidden from the eyes of the subjects with a mask and the main researcher will not be present in the laboratory during the installation of the electrodes and at the end of 20 minutes and the time of removing the electrodes.
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
Kermanshah, Taq Bostan, University St., Razi University, Deputy Research Area
City
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Province
Kermanshah
Postal code
6714414874
Approval date
2023-06-10, 1402/03/20
Ethics committee reference number
IR.RAZI.REC.1402.018

Health conditions studied

1

Description of health condition studied
The effect of acute non-invasive brain stimulation on cognitive and executive functions in a single bout of endurance exercise.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Changes in bimanual coordination
Timepoint
Measurement of bimanual coordination at the beginning of the study in the first week (before the start of the intervention), measurement of bimanual coordination 20 minutes after stimulation, measurement of bimanual

coordination one week after the first intervention and before the sham intervention in the second week, measurement Bimanual coordination 20 minutes after sham intervention (unrealistic stimulation) in the second week.

Method of measurement

Lafayette company's two-handed coordination tool

2

Description

Reaction Time

Timepoint

Measurement of reaction time at the beginning of the study in the first week (before the start of the intervention), measurement of reaction time 20 minutes after stimulation, measurement of reaction time one week after the first intervention and before sham intervention in the second week, measurement of reaction time 20 minutes after From sham intervention (unreal stimulation) in the second week.

Method of measurement

Reaction time device Response Panel (63035A, Lafayette, Indiana)

3

Description

working memory

Timepoint

Measurement of working memory at the beginning of the study in the first week (before the start of the intervention), measurement of working memory 20 minutes after stimulation, measurement of working memory one week after the first intervention and before sham intervention in the second week, measurement of working memory 20 minutes After sham intervention (unreal stimulus) in the second week.

Method of measurement

Stroop word-color test

4

Description

Rate of perceived pressure (RPE)

Timepoint

During the execution of sub-maximal endurance activity, every 3 minutes, the level of perceived pressure is announced and recorded by the subjects. The average pressure perception in each training session is calculated and used for analysis.

Method of measurement

From the image of the Borg scale (0 – 100; RPE)

5

Description

Feeling scale to measure the feeling of pleasure (perceptual response)

Timepoint

During the performance of the sub-maximal endurance activity, every 3 minutes the level of pleasure is declared and recorded by the subjects. The average level of pleasure in each training session is calculated and used for analysis.

Method of measurement

An 11-item emotion scale is used, the answers of which are recorded and analyzed in the range of +5 to -5.

6

Description

Visual analog scale to measure pain sensation

Timepoint

During the performance of sub-maximal endurance activity, the pain level is declared and recorded by the subjects every 3 minutes. The average level of pain sensation in each training session is calculated and used for analysis.

Method of measurement

A 0-10 visual analog scale is used to measure pain

7

Description

Perceived arousal scale to measure arousal (perceptual response)

Timepoint

During the performance of submaximal endurance activity, the level of arousal is announced and recorded by the subjects every 3 minutes. The average level of arousal in each training session is calculated and used for analysis.

Method of measurement

A 6-item scale of perceived arousal is used

8

Description

Countdown cognitive test

Timepoint

During the performance of the endurance activity, when the subject reaches the pressure perception level of 70 on the Borg scale, a countdown cognitive test will be performed.

Method of measurement

During the performance of the endurance activity, in the 4th, 8th and 12th kilometers, a number from 200 to 300 will be randomly announced by the test taker and the test taker will be asked to say loudly for 1 minute. Count backwards and with a distance of 3 from the announced number, then the total number of numbers read by the subject and the number of correct numbers from the total numbers are calculated and used for analysis.

9

Description

اندازه گیری ضربان قلب در حین اجرای فعالیت استقامتی

Timepoint

During the performance of sub-maximal endurance activity, the heart rate is announced and recorded by the subjects every 3 minutes. The average heart rate in each training session is calculated and used for analysis.

Method of measurement

Polar heart rate monitor (made in Finland)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 14 adult semi-endurance male runners, members of the Kermanshah athletics team. The first session will be used to familiarize the subjects with the research process, the method of applying interventions and measuring variables and primary measurements. Then the subjects will be present in the laboratory in 3 separate sessions with an interval of at least 5 days between the sessions. The second session will be for the purpose of measuring the maximum aerobic speed and the next two sessions will be for the purpose of applying interventions and measuring the desired variables. in the third and fourth sessions; Subjects will be randomly exposed to two types of brain stimulation for 20 minutes, including 1) anodal stimulation of the left posterolateral prefrontal cortex (DLPFC) and 2) sham stimulation.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kermanshah athletics team

Full name of responsible person
Ahmad Roshanzadeh

Street address
Kermanshah, Shahid Beheshti Blvd., Kermanshah Azadi Stadium, Kermanshah Province Athletics Committee

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Province
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Razi University of Kermanshah

Full name of responsible person
Dr. Mohammad Nabi Ahmadi

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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 of Kermanshah

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
Mehdi esmaili

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Learning and motor control

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Faculty of Sports Sciences, Razi University, Taq Bostan, University St., Kermanshah, Iran

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

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 if they submit an 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 documents, contact Mehdi Esmaeili, a master's student at Razi University of Kermanshah, by email: m.esmaeili.2911@gmail.com.

What processes are involved for a request to access data/document
In case of submitting an official request, announcing the relevant reasons and mentioning the complete details, the data will be announced via email after 72 hours.

Comments