

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluating the Effects of Transcranial Direct Current Stimulation and Exercise Training on Food Craving and Impulsivity in Overweight and Obese Females

#### Protocol summary

##### Study aim

Effect of transcranial direct current stimulation and exercise training on food craving, impulsivity, risky decision making, depression, self-concept, and cognitive flexibility in overweight and obese females

##### Design

The randomized trial, with the control group, parallel groups, double-blind on 36 patients. Randomization was performed using the randomization.com website.

##### Settings and conduct

This study is conducted at Razi University, Kermanshah, Iran. Study variables are measured before and after brain stimulation and exercise training for 4 weeks. Participants and investigators will be blinded about brain stimulation procedure.

##### Participants/Inclusion and exclusion criteria

Inclusion: Aged between 18 to 50 years Resident of Kermanshah Body mass index between 25 to 34.9 kg/m<sup>2</sup> Being right handed Having food cravings Getting the certification of no prohibition of participating in the exercise training program from a specialist Exclusion: En History of seizures, epilepsy, or other neurological diseases Existence of implantable devices or pacemakers in the body Tobacco, alcohol, and drug consumption Existence of musculoskeletal disorders Participation in regular exercise training program or weight loss program in the last 6 months Menopause

##### Intervention groups

Group 1: 5 sessions of anodal brain stimulation in 5 consecutive days, followed by 4 weeks and 3 sessions of aerobic exercises every week with an intensity of 50 to 60% of the heart rate reserve. Group 2: 5 sessions of sham brain stimulation in 5 consecutive days followed by 4 weeks and 3 sessions of aerobic exercises every week with an intensity of 50 to 60% of the heart rate reserve. Group 3: did not receive any intervention and will have a normal routine of life during the research period.

##### Main outcome variables

Changes in food craving, impulsivity, risky decision-making, depression, self-concept, and cognitive flexibility

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210617051606N7**

Registration date: **2023-02-04, 1401/11/15**

Registration timing: **prospective**

Last update: **2023-02-04, 1401/11/15**

Update count: **0**

##### Registration date

2023-02-04, 1401/11/15

##### Registrant information

##### Name

Ehsan Amiri

##### Name of organization / entity

Razi University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3845 8428

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-09, 1401/11/20

##### Expected recruitment end date

2023-02-19, 1401/11/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluating the Effects of Transcranial Direct Current Stimulation and Exercise Training on Food Craving and Impulsivity in Overweight and Obese Females

**Public title**  
Effect of aerobic exercise and brain stimulation on food craving

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Aged between 18 to 50 years Resident of Kermanshah  
Body mass index between 25 to 34.9 kg/m<sup>2</sup> Being right handed Having food cravings (total score of 108 or above according to the 15-item food craving questionnaire and 12-point visual analog food craving questionnaire)  
Getting the certification of no prohibition of participating in the exercise training program from a specialist  
**Exclusion criteria:**  
History of seizures, epilepsy, or other neurological diseases Existence of implantable devices or pacemakers in the body Tobacco, alcohol, and drug consumption Existence of ant musculoskeletal disorders Participation in regular exercise training program or weight loss program in last 6 months Menopause

**Age**  
From **18 years** old to **50 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **36**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, permuted block randomization via the www.randomization.com website will be used. To do so, first, a unique number will be allocated to each subject as the identifier code and, a 36-digit sequence (equal to the sample size) will be created. Then, treatment labels including 1) Exercise + anodal stimulation group; 2) Exercise + sham stimulation group; and 3) Control group will be entered in the relevant section on the website. After defining the treatment groups and avoiding potential problems associated with equal block sizes, permuted block randomization with different block sizes will be applied. In this case, by knowing the sample size, the block sizes will be unequal and a multiple of the number of treatment groups (for example, block sizes of 2, 4, or 6). The website has the ability to specify the

sequence of blocks with different sizes randomly. In the final step and upon performing the 'Generate Plan' on the website, all subjects will be randomly assigned to blocks of different sizes that already have a random sequence. Finally, the group (treatment) of each subject will be specified by the use of the identifier code and by checking out the blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this double-blind study, the investigator and the participants will be blinded to the type of transcranial electrical stimulation used in the two experimental groups. In the current study, the Neurostim stimulation device will be used to induce direct current electrical stimulation in two conditions including 1) anodal and 2) sham in two experimental groups. For this purpose, an individual outside the research team and fully familiar with how to use the brain stimulation device will be responsible for applying the stimulation for 5 consecutive days. In order to blind the participants, after they sit on a special chair, the stimulating device is hidden from their view 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, the induction of brain stimulation will be done without the presence of the researcher and the relevant information will be available to the same person outside the research team. 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, but the electrodes are used until the end of the same time as the stimulation. Anodal will remain on the head.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of Kermanshah Razi University

**Street address**

Room. 73, Faculty of Sport Sciences, Razi University, University Str, Taq-e-bostan, Kermanshah, Iran

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714414971

**Approval date**

2022-04-20, 1401/01/31

**Ethics committee reference number**

IR.RAZI.REC.1401.014

**Health conditions studied****1****Description of health condition studied**

Overweight and obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

**Primary outcomes****1****Description**

Change in food craving

**Timepoint**

Before and after interventions

**Method of measurement**

Standard questionnaires of food craving

**2****Description**

Impulsivity

**Timepoint**

Before and after interventions

**Method of measurement**

Go/ No Go cognitive test software

**3****Description**

Risky decision-making

**Timepoint**

Before and after interventions

**Method of measurement**

IOWA gambling cognitive test software

**Secondary outcomes****1****Description**

Depression

**Timepoint**

Before and after interventions

**Method of measurement**

Center for epidemiologic studies depression scale

**2****Description**

self-concept

**Timepoint**

Before and after interventions

**Method of measurement**

Robson self-concept questionnaire

**3****Description**

Cognitive flexibility

**Timepoint**

Before and after interventions

**Method of measurement**

cognitive flexibility questionnaire

**Intervention groups****1****Description**

Intervention group 1: this group will receive 5 sessions of anodal stimulation over the dorsolateral prefrontal cortex in 5 consecutive days, and then perform 3 exercise sessions every week for 4 weeks with an intensity of 50 to 60% of the heart rate reserve. The duration of each training session will be 20 minutes in the first week, 25 minutes in the second week, 30 minutes in the third week, and 35 minutes in the fourth week.

**Category**

Lifestyle

**2****Description**

Intervention group 2: this group will receive 5 sessions of sham stimulation over the dorsolateral prefrontal cortex in 5 consecutive days, and then perform 3 exercise sessions every week for 4 weeks with an intensity of 50 to 60% of the heart rate reserve. The duration of each training session will be 20 minutes in the first week, 25 minutes in the second week, 30 minutes in the third week, and 35 minutes in the fourth week.

**Category**

Lifestyle

**3****Description**

Control group: This group did not receive any intervention during the research period and will have a normal routine of life.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Faculty of Sport Sciences of Razi University

**Full name of responsible person**

Ali Heirani

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## Sponsors / Funding sources

### 1

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b.mostafaei@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**  
Ehsan Amiri  
**Position**  
Assistant Professor  
**Latest degree**

Ph.D.

#### Other areas of specialty/work

Sport Medicine

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#### City

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#### Province

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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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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 are shared after the de-identification of the participants

**When the data will become available and for how long**

3 months after publication

**To whom data/document is available**

All individuals upon formal request

**Under which criteria data/document could be used**

Data sharing requests are accepted for any purposes

**From where data/document is obtainable**

To obtain any data/document, please send an e-mail to Ehsan Amiri, a faculty member at Razi University, through the following e-mail address: e.amiri@razi.ac.ir

**What processes are involved for a request to access data/document**

Upon formal request, mentioning due reasons, and providing full personality details, data will be sent after 72 h via e-mail

**Comments**