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/m2 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)

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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/m2 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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Ehsan Amiri
Position
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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