# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effect of One Session of Aerobic Exercise and Anodal Stimulation of Dorsolateral Prefrontal Cortex under Hypoxic Condition on Food Craving and Some of its Related Pyschological Factors in Overweight and Obses Men

## Protocol summary

**Study aim**
Determining the Effect of One Session of Aerobic Exercise and Anodal Stimulation of Dorsolateral Prefrontal Cortex under Hypoxic Condition on Food Craving and Some of its Related Pyschological Factors in Overweight and Obses Men

**Design**
Clinical trial, within-group, counterbalanced, control group, crossover, double-blind on 20 patients. Randomization.com website will be used for randomization.

**Settings and conduct**
This study will be conducted at Razi University of Kermanshah. Each subject will be exposed to 2 different conditions of electrical brain stimulation in a random order and then will perform a 30-minute endurance exercise session on an ergometer bike.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age range 18 to 50 years; resident of Kermanshah city center; body mass index (BMI) 25 to 34.9 kg/m2; having food cravings (scoring a total score of 108 or higher on the 15-item food craving questionnaire and the 12-item visual analog food craving questionnaire); obtaining a certificate of non-restriction from a physician to participate in an exercise program. Exclusion criteria: history of seizures, epilepsy, or other types of neurological diseases; presence of implantable devices or pacemakers in the body; smoking, alcohol, and drug use; presence of musculoskeletal abnormalities or disorders; participation in weight loss programs in the past 6 months; participation in a regular exercise program in the past 6 months.

**Intervention groups**
In this study, subjects will be exposed to two brain stimulation conditions: 1) anodal stimulation (intervention group) and 2) sham stimulation or placebo effect (control group) in the DLPFC region. The stimulation duration will be 20 minutes and its intensity will be 2 mA.

**Main outcome variables**
Changes of food craving, impulsivity, risk-taking decision-making, food oreference, appetite, and cognitive flexibility

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20241213064044N1**
Registration date: **2024-12-26, 1403/10/06**
Registration timing: **prospective**

Last update: **2024-12-26, 1403/10/06**
Update count: **0**

**Registration date**
2024-12-26, 1403/10/06

**Registrant information**

**Name**
Mohammad javad Biglari

**Name of organization / entity**
Razi University of Kermanshah

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-01-01, 1403/10/12
**Expected recruitment end date**
2025-01-19, 1403/10/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect of One Session of Aerobic Exercise and Anodal Stimulation of Dorsolateral Prefrontal Cortex under Hypoxic Condition on Food Craving and Some of its Related Pyschological Factors in Overweight and Obses Men

**Public title**
Effect of One Session of Aerobic Exercise and Anodal Stimulation of Dorsolateral Prefrontal Cortex on Food cravings in overweight and obese men under hypoxic conditions
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age range 18 to 50 years Resident in Kermanshah city center Body mass index (BMI) 25 to 34.9 kg/m2 Have food cravings (score of 108 or higher on the 15-item food craving questionnaire and the 12-item visual analog food craving questionnaire) Obtain a certificate of non-restriction from a physician to participate in an exercise program
**Exclusion criteria:**
History of seizures, epilepsy or other types of neurological diseases Presence of implantable devices or pacemakers in the body Consumption of cigarettes, alcohol and various drugs Presence of musculoskeletal abnormalities or disorders Participation in weight loss programs in the past 6 months Participation in a regular exercise program in the past 6 months
**Age**
From **18 years** old to **40 years** old
**Gender**
Male

**Phase**
2
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, the order in which subjects will be exposed to 2 different conditions (2 different types of electrical brain stimulation) will be randomized using the Latin square method. For this purpose, first, each subject will be randomly assigned a number between 1 and 20 as an identification code using the website www.random.org. Then, the English letters A and B will be assigned to the two intervention conditions and a Latin square will be created. In this case, a Latin square with two rows and two columns will be created. Finally, participants numbered 1 to 10 will be placed in the first row sequence, and participants numbered 11 to 20 will be placed in the second row sequence.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In this study, participants are blinded by the principal investigator to the type of brain stimulation they will receive in each session. To do this, in each session, the investigator will hide the tDCS device from the participants' view with a cloth cover after placing the electrodes and starting it.
**Placebo**
Used
**Assignment**
Crossover
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Razi University of Kermanshah
**Street address**
Razi University of Kermanshah, University street, Taq Bostan
**City**
Kermanshah
**Province**
Kermanshah
**Postal code**
6714414971
**Approval date**
2024-09-18, 1403/06/28
**Ethics committee reference number**
IR.RAZI.REC.1403.028

## 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**
Obesity in Food craving
**Timepoint**
Before, immediately, 24 and 48 hours after interventions
**Method of measurement**
15-item food craving questionnaire and 12-item visual analogue food craving questionnaire

**2**

**Description**
Food preference
**Timepoint**
Before and immediately interventions
**Method of measurement**
Leeds Food Preference Questionnaire Online Application

**3**

**Description**
Appetite level
**Timepoint**
Before, immediately, 1, 2, 4, 24 and 48 hours after the interventions
**Method of measurement**
Visual Analogue Subjective Scale of Appetite

## Secondary outcomes

**1**

**Description**
Impulsiveness
**Timepoint**
Before and after interventions
**Method of measurement**
Go/No Go Cognitive Testing Software

**2**

**Description**
Risky decision making
**Timepoint**
Before and after interventions
**Method of measurement**
Iowa Gambling Cognitive Test Software

**3**

**Description**
Cognitive flexibility
**Timepoint**
Before and after interventions
**Method of measurement**
20-question cognitive flexibility questionnaire

**4**

**Description**
Sense of pleasure
**Timepoint**
Before applying the interventions and every 3 minutes during aerobic exercise and immediately, 1, 2, 4, 24 and 48 hours after completing aerobic exercise
**Method of measurement**
11-item emotion scale

**5**

**Description**
Arousal level
**Timepoint**
Before applying the interventions and every 3 minutes during aerobic exercise and immediately, 1, 2, 4, 24 and 48 hours after completing aerobic exercise
**Method of measurement**
6-point scale of perceived arousal

## Intervention groups

**1**

**Description**
Intervention group: In this study, all subjects will be exposed to interventional conditions of direct current anodal electrical brain stimulation for 20 minutes and an intensity of 2 mA. For stimulation, a Neurostim stimulator manufactured by Medina Teb Company will be used. Target areas in the brain are identified using the 20-10 international brain mapping system and stimulation of the target areas is performed using two special stimulation electrodes and a special electroencephalogram cap.
**Category**
Treatment - Devices

**2**

**Description**
Control group: Control group: In this study, all subjects will be exposed to a control session including electrical brain stimulation in a sham mode (placebo effect) in addition to the intervention session. All details of the protocol implementation in the control mode will be similar to the intervention mode, with the difference that in the control mode, electrical brain stimulation will not be performed and the electrical current of the stimulating device will be deactivated after 30 seconds. The duration of the control condition will also be 20 minutes.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Faculty of Sport Sciences of Razi University of Kermanshah
**Full name of responsible person**
Ehsan Amiri

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Faculty of Sport Sciences, Razi University of Kermanshah, Daneshgah Street, Taq Bostan
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Razi University of Kermanshah
**Full name of responsible person**
Mostafa Mostafaei
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Razi University of Kermanshah, Daneshgah Street, Taq Bostan
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**Email**
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 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 of Kermanshah
**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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Postal code**
6714414971

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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**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available

**Title and more details about the data/document**
All data can be shared after subjects are de-identified.

**When the data will become available and for how long**
6-9 months after results are printed

**To whom data/document is available**
Supervisor and research student

**Under which criteria data/document could be used**
Meta-analysis

**From where data/document is obtainable**
If you need to receive documents, please send an email to Ehsan Amiri, a faculty member at Razi University, at the following email address: e.amiri@razi.ac.ir.

**What processes are involved for a request to access data/document**
In case of formal request, stating the relevant reasons and providing full details, the data will be sent via email after 72 hours.

**Comments**