

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Sep 2026

### Modulation of Psychological and Neural Response for Food Craving among People with Obesity Using Transcranial Direct Current Stimulation (tDCS) on Dorsolateral Prefrontal Cortex (DLPFC): A Randomized Clinical Trial

#### Protocol summary

##### Study aim

To determine whether transcranial direct current stimulation (tDCS) over dorsolateral prefrontal cortex (DLPFC) changes subcortical limbic reactivity to food cues in obesity

##### Design

a double-blind randomized controlled trial with two parallel arms

##### Settings and conduct

This study will be conducted at the National Brain Mapping Lab, Tehran, Iran. Participants who meet all inclusion and exclusion criteria, that previously defined, will enter the study. All participants have a unique code during the study and the group allocation remains indistinguishable to both participants and the investigators. The screen of the tDCS device doesn't display information about stimulation parameters.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age  $\geq 18$  and  $< 61$  years old 2. Persian speaking 3. BMI: 25-35 4. Frequent food cravings ( $\geq 3$  times/day during last month) in the screening self-report 5. Positive response to food cue-reactivity screening ( $\geq 50\%$  craving in visual analog scale)  
Exclusion criteria: 1. Unwillingness or inability to complete any of the major aspects of the study protocol, including magnetic resonance imaging, food cue rating, or behavioral assessment. 2. Comorbid severe psychiatric disorders or unstable medical disorder which are evaluated by a specialist. 3. History of brain injury or seizure 4. History of any brain stimulation

##### Intervention groups

The current level used for the study will not exceed 2mA. The stimulator ramps up the current over 30 seconds. In the sham setting, the current is ramped down again. In the real setting, the current stays at the same level. The stimulation will proceed for 20 minutes, at which point

the current is slowly ramped down over 30 seconds.

##### Main outcome variables

Primary Outcome Measures: 1. Blood oxygen level dependent (BOLD) signal changes in contrast between food and non-food images 2. Food Craving Self Report

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121020011172N4**

Registration date: **2020-06-04, 1399/03/15**

Registration timing: **retrospective**

Last update: **2020-06-04, 1399/03/15**

Update count: **0**

##### Registration date

2020-06-04, 1399/03/15

##### Registrant information

##### Name

Hamed Ekhtiari

##### Name of organization / entity

The center of molecular and cellular imaging

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-19, 1398/11/30  
**Expected recruitment end date**  
 2020-05-18, 1399/02/29  
**Actual recruitment start date**  
 empty  
**Actual recruitment end date**  
 empty  
**Trial completion date**  
 empty

**Scientific title**  
 Modulation of Psychological and Neural Response for Food Craving among People with Obesity Using Transcranial Direct Current Stimulation (tDCS) on Dorsolateral Prefrontal Cortex (DLPFC): A Randomized Clinical Trial

**Public title**  
 Examining the effect of electrical brain stimulation on food cue-induced craving by MRI

**Purpose**  
 Basic science

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 1. Age  $\geq 18$  and  $< 61$  years old  
 2. Persian speaking  
 3. BMI: 25-35  
 4. Frequent food cravings ( $\geq 3$  times/day during last month) in the screening self-report  
 5. Positive response to food cue-reactivity screening ( $\geq 50\%$  craving in visual analog scale)  
 6. Willing and capable of interacting with the informed consent process  
**Exclusion criteria:**  
 1. Unwillingness or inability to complete any of the major aspects of the study protocol, including magnetic resonance imaging (i.e., due to claustrophobia), food cue rating, or behavioral assessment  
 2. Comorbid severe psychiatric disorders (e.g. severe depression, bipolar, psychosis or background of suicide) Which is evaluated by a specialist  
 3. Active suicidal ideation with intent or plan determined by self-report or assessment by PI or study staff during the initial screening or any other phase of the study  
 4. Any active skin disorder that affects skin integrity of the scalp  
 5. Unstable medical disorder reported in subject's medical history or by a clinician assessment  
 6. Non-correctable vision or hearing problems  
 7. History of brain injury or seizure  
 8. History of any brain stimulation  
 9. Any other condition the PI or study staff feel would put the subject at risk for entering the study

**Age**  
 From **18 years** old to **61 years** old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
 Target sample size: **65**

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

**Randomization description**  
 Randomization will be a randomized block design with 6 blocks, the sequence of randomization will be determined through sealed envelope.com site and based on this, the researcher considers eligible subjects for the two study groups.

**Blinding (investigator's opinion)**  
 Double blinded

**Blinding description**  
 The subject and researcher is not aware of the actual or sham stimulation. In fact, the screen of the device is the same in both cases (real stimulation or sham) and only the supervisor is aware of the type of intervention.

**Placebo**  
 Used

**Assignment**  
 Parallel

**Other design features**

**Secondary Ids**  
 empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
 Ethics committee of Iran University of Medical Sciences  
**Street address**  
 Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN  
**City**  
 Tehran  
**Province**  
 Tehran  
**Postal code**  
 ۱۴۴۹۶۱۴۵۳۵

**Approval date**  
 2018-02-12, 1396/11/23

**Ethics committee reference number**  
 IR.IUMS.REC.1396.0459

**Health conditions studied**

**1**

**Description of health condition studied**  
 Food craving and obesity

**ICD-10 code**  
 E66

**ICD-10 code description**  
 Overweight and obesity

**Primary outcomes**

## 1

### **Description**

Blood oxygen level dependent (BOLD) signal changes in the contrast between food and non-food images

### **Timepoint**

Before and after of intervention

### **Method of measurement**

BOLD signal differences with voxel-wise analysis in the regions of interests (ROIs) (Prefrontal cortex, Insula, Striatum, Thalamus and Extended Amygdala) in craving > neutral contrast in event-related design food cue exposure fMRI task

## 2

### **Description**

Food Craving Self-Report

### **Timepoint**

Before and after of intervention

### **Method of measurement**

Subjective response to "On a scale of 0-100, How much "food craving" are you experiencing RIGHT NOW" measured on a visual analog scale (0-100)

## **Secondary outcomes**

## 1

### **Description**

Cortical-Subcortical Connectivity in Resting State fMRI

### **Timepoint**

Before and after of intervention

### **Method of measurement**

Correlation between resting-state average Blood oxygen level dependent (BOLD) signal time series in subcortical ROIs and voxels within prefrontal cortex and Insula

## 2

### **Description**

Cortical-Subcortical Task-based Connectivity in Cue Exposure fMRI

### **Timepoint**

Before and after of intervention

### **Method of measurement**

Psychophysiological Interaction (PPI) between average blood oxygen level dependent (BOLD) signal time series in subcortical ROIs and voxels within prefrontal cortex and Insula measured before and after tDCS (active and sham)

## 3

### **Description**

RAI )Allocation Index (RAI) in Resting State fMRI

### **Timepoint**

Before and after of intervention

### **Method of measurement**

The correlation among default mode network (DMN), saliency network (SN) and Executive Control Network (ECN) in resting state fMRI

## 4

### **Description**

Area Under Electrode Connectivity in Resting State fMRI

### **Timepoint**

Before and after of intervention

### **Method of measurement**

Voxel-wise Psychophysiological Interaction (PPI) between average blood oxygen level dependent (BOLD) signal in the cortical area under the Anode electrode and whole brain in craving > neutral contrast in event-related design food cue exposure fMRI task

## 5

### **Description**

Food Craving Control Self-Report

### **Timepoint**

Before and after of intervention

### **Method of measurement**

Subjective response to "On a scale of 0-100, How much "control" do you feel you have over your "food craving" RIGHT NOW?"

## 6

### **Description**

Desire for Food Self Report

### **Timepoint**

Before and after of intervention

### **Method of measurement**

Response to the Food Craving Questionnaire (FCQ)

## **Intervention groups**

## 1

### **Description**

Intervention group (active tDCS): The current level used for the study will not exceed 2mA. The stimulator ramps up the current over 30 seconds. In the sham setting, the current is ramped down again. In the real setting, the current stays at the same level. The stimulation will proceed for 20 minutes, at which point the current is slowly ramped down over 30 seconds.

### **Category**

Other

## 2

### **Description**

Control group (sham tDCS): The stimulator ramps up the current over 30 seconds and then the current is slowly ramped down over 30 seconds. The set-up for sham and real stimulation sessions are exactly the same.

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

**Name of recruitment center**

Iran National Brain Mapping Centre

**Full name of responsible person**

Nastaran Malmir

**Street address**

NBML, South Side of the Electrical Engineering  
Faculty, College of Engineering, North Kargar St,  
Tehran, Iran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Cognitive Sciences & Technologies Council

**Full name of responsible person**

Dr Hamed Ekhtiari

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Tehran, Iran

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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**

Cognitive Sciences & Technologies Council

**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**

Other

**Person responsible for general inquiries****Contact****Name of organization / entity**

Laureate Institute for Brain Research

**Full name of responsible person**

Dr Hamed Ekhtiari

**Position**

Associate Investigator-Laureate Institute for Brain  
Research

**Latest degree**

Specialist

**Other areas of specialty/work**

Neuroimaging

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**Full name of responsible person**

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Associate Investigator

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iranian National Center for Addiction Studies (INCAS)

**Full name of responsible person**

Nastaran Malmir

**Position**

Student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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Iranian National Center for Addiction Studies (INCAS),  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available