Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 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 ≥18 and <61 years old 2. Persian speaking 3. BMI: 25-35 4. Frequent food cravings (≥3times/day during last month) in the screening self-report 5. Positive response to food cue-reactivity screening (≥ 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)

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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 scienece

Inclusion/Exclusion criteria

Inclusion criteria:

1. Age ≥18 and <61 years old2. Persian speaking3. BMI: 25-354. Frequent food cravings (≥3times/day during last month) in the screening self-report5. Positive response to food cue-reactivity screening (≥ 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 assessment6. Non-correctable vision or hearing problems7. 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 sealedenvelope.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 designfood 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
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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
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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
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
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Dr Hamed Ekhtiari
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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