

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluating the effectiveness of transcranial direct current stimulation(tDCS) and oxytocin on cognitive, emotion and weight control in food addicts: A double-blind Randomized clinical trial.

Protocol summary

Study aim

Determining the effectiveness of cranial direct current stimulation and oxytocin on cognitive, emotional and weight control performance in obese food addicts.

Design

Clinical trial without group of control, parallel-group, double-blind, randomized, phase 2 in 45 patients will be conducted using Stata 9.0 statistical software.

Settings and conduct

The place of evaluation and interventions will be Shahid Beheshti Hospital, Zanjan. During the intervention, in order to maintain the concealment mechanism, sequentially numbered and prepackaged containers that have the same appearance will be used. The interventionist and the researcher do not know about the contents of the envelope and the type of group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female participants aged between 20 and 65 years and BMI>30 and are known 'food addiction' based on the questionnaire (YFAS). Not having diabetes, malignancy, heart disease, uncontrolled blood pressure, psychiatric disease. Exclusion criteria: Sensitivity to oxytocin, lack of cooperation, occurrence of emergency factors, if pregnant or pregnant during the study

Intervention groups

The study of all men and women in Zanjan city, who are between 20 and 65 years old and have a BMI>30 and will be diagnosed food addiction based on the questionnaire (YFAS). First, the first group will receive tDCS and at the same time they will receive oxytocin in the form of placebo (sodium chloride). The second group will receive oxytocin and receive sham tDCS at the same time. Finally, the third group will receive (OXT-tDCS) intervention.

Main outcome variables

Cognitive performance variable by go/no test and

dotprob, emotion variable by Gross and John emotion regulation questionnaire, weight control by BMI table and scale, food addiction by Yale questionnaire and craving by food craving questionnaire - attribute will be measured

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220816055725N1**

Registration date: **2022-10-04, 1401/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-04, 1401/07/12**

Update count: **0**

Registration date

2022-10-04, 1401/07/12

Registrant information

Name

Ali Mehranpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of transcranial direct current stimulation(tDCS) and oxytocin on cognitive, emotion and weight control in food addicts: A double-blind Randomized clinical trial.

Public title

Evaluating the effectiveness of transcranial direct current stimulation(tDCS) and oxytocin in food addicts.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Female or male participants aged 20 to 65 years and BMI>30 who are obese by the relevant tests and body mass measurement and will be identified "food addiction" based on the food addiction questionnaire (YFAS). Not having significant illnesses including diabetes, malignancy (any cancer or tumor diagnosed by a medical professional), heart disease, uncontrolled blood pressure, psychiatric illness (based on whether they had previously been diagnosed with a mental illness, not having symptoms of psychotic spectrum and bipolar disorder, Alzheimer and dementia), previous head injury that led to a loss of brain function or the presence of any metal in the head area due to injury or surgery that interfered with the results of brain waves or the use of TDCS slowness or any other significant medical condition will be excluded from the study. Obese participants had not received any obesity intervention at the time of data collection. Having minimum literacy to fill out self-report forms means minimum literacy of 9th grade.

Exclusion criteria:

Oxytocin sensitivity, non-cooperation, emergency occurrence, being pregnant or being pregnant during the study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

All the participants were completely randomized in a 6-block classification type (due to the allocation of at least three groups and the parallelism of the design and to

control the gender variable), the randomization sequence was created using Stata 9.0 statistical software (StataCorp, College Station, TX). and will be classified using block sizes of 6 with 1:1 allocation and three groups will be formed. Then the treatment plan will be implemented. During the intervention, in order to maintain the allocation concealment mechanism, containers with consecutive numbering will be pre-packed and will have the same appearance. And waxed and stapled will be hidden. Aluminum foil is used inside the envelope so that the envelope is impervious to strong light. In order to prevent confusion in the order of allocation, the participant's name and date of birth are written on the envelope and a video tape is recorded of the sealed envelope with the participant's information. Block randomization will be performed by a list of computer-generated random numbers prepared by an investigator with no clinical involvement in the trial.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding of researcher and participant: The drugs are presented to the participants in a completely similar container and coded by the design partners, the participants and the partner who applies the drug have no knowledge about the contents of the drug, the intervening partner in the application of TDCS at the defined hours. will apply the intervention method and has no knowledge about the division of the group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zanjan University of Medical Sciences

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Technology Vice-Chancellor, Zanjan University of Medical Sciences, Gavazang road

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Postal code

4513956184

Approval date

2022-08-02, 1401/05/11

Ethics committee reference number

IR.ZUMS.REC.1401.155

Health conditions studied

1

Description of health condition studied

Food addicts

ICD-10 code

F50

ICD-10 code description

Eating disorders

Primary outcomes

1

Description

Cognitive function

Timepoint

Before and after receiving oxytocin and of transcranial direct current stimulation

Method of measurement

By go/no go test and dot probe task

Secondary outcomes

1

Description

Emotional performance

Timepoint

Before and after receiving oxytocin and transcranial direct current stimulation (tDCS)

Method of measurement

By Gross and John emotion regulation questionnaire

2

Description

Weight control

Timepoint

Before and after receiving oxytocin and transcranial direct current stimulation (tDCS)

Method of measurement

By BMI table and scales

3

Description

Craving for food

Timepoint

Before and after receiving oxytocin and transcranial direct current stimulation (tDCS)

Method of measurement

Food craving questionnaire-trait

4

Description

Food addiction

Timepoint

Before and after receiving oxytocin and transcranial direct current stimulation (tDCS)

Method of measurement

Yale Food Addiction Scale

Intervention groups

1

Description

The first group will receive transcranial direct current stimulation (tDCS) for 10 20-minute sessions, five consecutive sessions and five sessions every other day, and at the same time, they will receive oxytocin in the form of a placebo (sodium chloride) in the amount of 40 daily units. (to reduce the placebo effect). The second group will receive oxytocin through intranasal spray in the amount of 40 units daily for 10 days, and at the same time transcranial direct current stimulation (tDCS) in sham for 10 sessions of 20 minutes in five consecutive sessions and They will receive five sessions every other day. The third intervention group will receive transcranial direct current stimulation (tDCS) for 10 sessions and oxytocin (OXT) in the amount of 40 units daily for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Zanzan Hospital and related public and private centers

Full name of responsible person

Ali Mehranpour

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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
Zanjan University of Medical Sciences
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
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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