

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Determining the effectiveness of transcranial direct current stimulation (tDCS) and omega-3 supplementation on executive functions, food craving, and depressive symptoms in patients with depression and overweight

Protocol summary

Study aim

Evaluation of the effectiveness of transcranial direct current stimulation (tDCS) and omega-3 alone and together on executive functions and depression and food craving in patients with depression and overweight

Design

A randomized controlled clinical trial with parallel, double-blind, randomized groups on 65 adult patients with depression and overweight. We used the Excel function rand function for randomization..

Settings and conduct

The study site is the Psychological and Psychiatric Research Center of Roozbeh Hospital. Women 18 years of age and older who are overweight (BMI above 25) and have a Beck Depression Inventory score above 14 At the first visit, after obtaining informed and free consent to participate in the study, the relevant questionnaires will be completed. They are then randomly divided into four groups of control and intervention. Assignment to groups is hidden from the view of researchers and patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with depression (Beck Depression Score above 14), overweight or obese (BMI $\geq$ 25) and age group 18 to 60 years. exclusion criteria: unwillingness and consent to participate in the study, being pregnant or breastfeeding with other major psychiatric illnesses such as bipolar depression, schizophrenia, neurological diseases such as epilepsy, history of major head trauma and neurofeedback in two months Lately.

Intervention groups

We have 4 intervention groups as follows: Group 1: tDCS + omega 3 Group 2: SHAM + placebo Group 3: SHAM + Omega 3 Group 4: tDCS + placebo

Main outcome variables

Symptoms of depression; Food cravings; Weight;

Executive functions; Appetite

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200716048117N1**

Registration date: **2020-10-18, 1399/07/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-18, 1399/07/27**

Update count: **0**

Registration date

2020-10-18, 1399/07/27

Registrant information

Name

Mahla Tabasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effectiveness of transcranial direct current stimulation (tDCS) and omega-3 supplementation on executive functions, food craving, and depressive symptoms in patients with depression and overweight

Public title

The effect of transcranial direct current stimulation (tDCS) and omega-3 supplementation on depression and weight

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with depression (Beck depression score above 14) overweight or obesity (BMI $\geq$ 25) 18 to 60 years old

Exclusion criteria:

Reluctance and satisfaction to participate in the study during pregnancy or lactation Other major psychiatric illnesses such as bipolar depression, Schizophrenia, neurological diseases such as epilepsy History of major head trauma and neurofeedback in the last two months

AgeFrom **18 years** old to **60 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization method: block, randomization unit: individual, tools and randomization sequence: determined by Excel software. Allocation concealment is done by coding.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, participants, the principal investigator, the clinical caregiver, the evaluator, and the data analyst were all blind. Description of how to blind: Group 1: tDCS+ medicine Group 2: SHAM+ placebo Group 3: SHAM+ medicine Group 4: tDCS+ placebo Groups are hidden from the view of the research team and study participants by coding and placebo.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Vice Chancellor for Research and Technology, Tehran University of Medical Sciences

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No. 1, Qods Ave., Keshavarz Blvd., Tehran., Iran.

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Approval date

2019-09-24, 1398/07/02

Ethics committee reference number

IR.TUMS.VCR.REC.1398.564

Health conditions studied**1****Description of health condition studied**

mild Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

2**Description of health condition studied**

Moderate depression

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

3**Description of health condition studied**

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes**1****Description**

Depression score 14 and above in Beck questionnaire

Timepoint

Measurement of depression at the beginning of the study (before the intervention), and 14 and 28 days after receiving brain stimulation and omega-3 intake

Method of measurement

Beck Depression Inventory

Secondary outcomes

1

Description

Scores of executive functions of individuals in Simple Strop computer software and Wisconsin card computer test

Timepoint

Measurement of executive functions at the beginning of the study (before the intervention), and 14 and 28 days after receiving brain stimulation and omega-3 intake

Method of measurement

Simple Strop computer software and Wisconsin card computer test

2

Description

Individual cravings score in the Summary Food Trait Questionnaire (FCQ-T)

Timepoint

Measurement of food craving at the beginning of the study (before the intervention), and 14 and 28 days after receiving brain stimulation and omega-3 intake

Method of measurement

Summary Food Trait Questionnaire (FCQ-T)

3

Description

People weigh in kilograms and their fat percentage with a pneumatic fat analyzer _ Model BF 511

Timepoint

Measurement of weight and fat percentage at the beginning of the study (before the intervention), and 14 and 28 days after receiving brain stimulation and omega-3 intake

Method of measurement

People weigh in kilograms and their fat percentage with a pneumatic fat analyzer _ Model BF 511

4

Description

Appetite score in a simple appetite questionnaire SNAQ

Timepoint

Measurement of appetite at the beginning of the study (before the intervention), and 14 and 28 days after receiving brain stimulation and omega-3 intake

Method of measurement

Simple appetite questionnaire SNAQ

Intervention groups

1

Description

Intervention group 1: 3 sessions of transcranial direct current stimulation (tDCS), one session per week, 4 sessions of stimulation for 15 minutes each time, and omega-3 supplement (5 cc daily, containing 736 mg (EPA) And 460 mg (DHA)).

Category

Treatment - Other

2

Description

Intervention group 2: Intervention group 1: 3 sessions of transcranial direct current stimulation (tDCS), one session per week, 4 sessions of stimulation for 15 minutes each time, And omega-3 placebo supplement (5 cc daily, soybean oil).

Category

Treatment - Other

3

Description

Third Intervention group: 3 sessions of Sham transcranial direct current stimulation (tDCS) of the brain, one session per week, each session consists of 4 episodes of stimulation, each lasting 15 minutes, and omega-3 supplement (5 cc daily, containing 736 mg of eicosapentaenoic acid (EPA) and 460 mg docosahexaenoic acid (DHA)).0 mg DHA).

Category

Treatment - Other

4

Description

Control group: 3 sessions of Sham transcranial direct current stimulation (tDCS) of the brain, one session per week, each session consists of 4 episodes of stimulation, each lasting 15 minutes, and the placebo of omega-3 (5 cc daily, soybean oil).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital Psychology and Psychiatry Research Center

Full name of responsible person

Mahla Tabasi

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Roozbeh Hospital, Psychiatric and Psychological Research Center, South Kargar St., Tehran., Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
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

Tehran 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

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mahla Tabasi

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work

Psychology

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after deleting individual IDs.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The analyzes used in the article are allowed on the delivered data.

From where data/document is obtainable

Requests for data / documentation should only be sent via email to the developer. Responsible person: Dr.

Seyed Ali Mostafavi E-Mail: Mostafavi_a@sina.tums.ac.ir

What processes are involved for a request to access data/document

After sending an e-mail to the given documents or files, this information may be sent to the applicant's e-mail as soon as possible.

Comments