Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of transcranial direct current stimulation (tDCS) and a standard hypocaloric diet on food craving, appetite sensation, and glycemic control in patients with type 2 diabetes

Protocol summary

Study aim
Explore the effect of tDCS on food craving, obesity and glycemic control in patients with T2DM

Design
A controlled clinical trial, with parallel groups, double-blind, randomized, phase 3, on 120 patients, randomization using the sample function in R software.

Settings and conduct
This randomized clinical trial will be conducted in 4 parallel groups in 120 type 2 diabetic patients referred to the Endocrine and Metabolism Research Center of Isfahan University of Medical Sciences. This is a double-blind study in which the patients and the investigator that evaluates research outcomes do not know the group in which the individual is located.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Previously diagnosed T2DM • Age between 18 to 65 years • BMI between 25-35 kg/m2 Exclusion criteria: • History of chronic disease (other than T2DM) • Contraindication to tDCS

Intervention groups
1) real tDCS without any dietary recommendation; 2) real tDCS + hypocaloric diet; 3) sham tDCS without any dietary recommendation; 4) sham tDCS + hypocaloric diet.

Main outcome variables
The anthropometric measures; glycemic control; food craving status; and dietary intake

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220305054185N1**
Registration date: **2024-01-14, 1402/10/24**
Registration timing: **prospective**
Last update: **2024-01-14, 1402/10/24**
Update count: **0**

Registration date
2024-01-14, 1402/10/24

Registrant information

Name
Amirhossein Ramezani Ahmadi

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
2024-02-20, 1402/12/01

Expected recruitment end date
2024-06-09, 1403/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of transcranial direct current stimulation (tDCS) and a standard hypocaloric diet on food craving, appetite sensation, and glycemic control in patients with type 2 diabetes

Public title
Investigating the effect of transcranial direct current stimulation on appetite

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Previously diagnosed T2DM (HbA1C≥ 6.5% or FPG≥ 126 mg/dl or OGTT> 200 mg/dl) Age > 18 years and < 65 years BMI between 25-35 kg/m2 Food Craving Questionnaire-Trait (FCQ-T) > 30
Exclusion criteria:
Unwillingness or inability to complete any of the major aspects of the study protocol including food cue rating or behavioral assessments Previously diagnosed psychiatric disorders (i.e., depression, psychotic disorders, personality disorders, dementia-related disorders) Presence of eating disorders evaluated by Eating Disorder Examination Questionnaire History of cancer, stroke, and renal, cardiovascular, or liver diseases Use dietary supplements at the start of study or during last 3 months Using appetite increasing or suppressing drugs Any other condition the research team feel would put the subject at risk for entering the study Contraindication to tDCS (pacemaker, a metal embedded in the scalp or brain, skin lesions at the site of stimulation, history of head injury or neurosurgery, and seizures)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomization that will be used is block-randomization. The unit of randomization is individual participants. The randomization will be stratified according to gender. This means that the randomization process ensures an even distribution of male and female participants between the active tDCS and sham stimulation groups. The random sequence will be built in blocks of 8 numbers. Within each block, there will be a random allocation of participants to each of four groups while maintaining the stratification by gender. The randomization will be conducted using Random Allocation software version 2.0 . Allocation concealment (with an concealed envelope) is carried out to hiding the allocation sequence from those involved in enrolling participants and assigning them to different study groups. Only the clinician administering the tDCS will be aware of the randomization.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-05-21, 1402/02/31
Ethics committee reference number
IR.MUI.REC.1402.005

Health conditions studied

1

Description of health condition studied
type 2 diabetic patients
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
food craving
Timepoint
Before intervention, day 14, day 30, day 60, day 90 after intervention
Method of measurement
Food Craving Questionnaire

Secondary outcomes

1

Description
fasting plasma glucose
Timepoint
Before intervention, day 14, day 90 after intervention
Method of measurement
enzymatic UV-hexokinase

2

Description

glycated hemoglobin A1C

Timepoint

Before intervention, day 14, day 90 after intervention

Method of measurement

high-performance liquid chromatography

3

Description

Serum Insulin

Timepoint

Before intervention, day 14, day 90 after intervention

Method of measurement

chemiluminescence microparticle immunoassay

4

Description

weight

Timepoint

Before intervention, day 14, day 30, day 60, day 90 after intervention

Method of measurement

Scale

5

Description

Body composition

Timepoint

Before intervention, day 14, day 30, day 60, day 90 after intervention

Method of measurement

InBody 353 tetrapolar body composition analyzer

Intervention groups

1

Description

Intervention group: Transcranial direct stimulation for two weeks every other day with an intensity of 20 mA for 20 minutes in the F4 and F3 areas of the head without any dietary recommendation

Category

Treatment - Devices

2

Description

Intervention group: Transcranial direct stimulation for two weeks every other day with an intensity of 20 mA for 20 minutes in the F4 and F3 areas of the head along with calorie-restricted diet (500 kcal less than daily energy requirement calculated using Mifflin St. Joer equation and distribution of carbohydrate, protein, and fat will be 55, 15, and 30 percent of total energy intake)

Category

Treatment - Devices

3

Description

Intervention group: Sham stimulation of the head along with calorie-restricted diet (500 kcal less than daily energy requirement calculated using Mifflin St. Joer equation and distribution of carbohydrate, protein, and fat will be 55, 15, and 30 percent of total energy intake) for two weeks

Category

Treatment - Devices

4

Description

Control group: Sham stimulation of the head for two weeks without any dietary recommendation

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrine & Metabolism Research Center

Full name of responsible person

Amirhossein Ramezani Ahmadi

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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Amirhossein Ramezani Ahmadi
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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 collected deidentified IPD will be available.
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
only available for people working in academic institutions
Under which criteria data/document could be used
No other criteria are required.
From where data/document is obtainable
Applicants should contact Amirhossein Ramezani Ahmadi Tel: (+98)9120745664 Fax: (+98)31-33373733 Mailing

address: Isfahan Endocrine and Metabolism Research Center, Isfahan University of Medical Sciences, Isfahan, Iran. Email: amir.h.r.ahmadi@gmail.com

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

The applicant must first send his/her request by e-mail using his/her academic e-mail stating the reason and the data usage. After a maximum of 2 weeks, the answer will be given to the applicant.

Comments