

# 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/m<sup>2</sup>  
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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3337 3733

###### Email address

amir.h.r.ahmadi@res.mui.ac.ir

##### 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 $\geq$  6.5% or FPG $\geq$  126 mg/dl or OGTT $>$  200 mg/dl) Age  $>$  18 years and  $<$  65 years BMI between 25-35 kg/m<sup>2</sup> 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

Isfahan

##### 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

**Street address**

Khorram street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8187698191

**Phone**

+98 31 3335 9933

**Email**

amir.h.r.ahmadi@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr Gholamreza Asgary

**Street address**

Hezar jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3668 8138

**Email**

research@mui.ac.ir

**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

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Khorram street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8187698191

**Phone**

+98 31 3335 9933

**Email**

amir.h.r.ahmadi@gmail.com

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Esfahan University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

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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**