

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the effectiveness of direct electrical stimulation of the brain (TDCS) and cognitive-behavioral therapy (CBT) in reducing cravings, mood and smoking dependence

#### Protocol summary

##### Study aim

Comparison of the effectiveness of direct electrical stimulation of the brain (TDCS) and cognitive-behavioral therapy (CBT) in reducing cravings, mood, and smoking dependence

##### Design

A controlled clinical trial with parallel, randomized, phase 2 groups on 12 patients. Excel software rand function was used for randomization.

##### Settings and conduct

Three treatment centers in Mashhad are randomly connected to the intervention and control groups and to the intervention group of the TDSM device and to the control group of cognitive-behavioral therapy (CBT).

##### Participants/Inclusion and exclusion criteria

Admission requirements: Men who are heavily dependent on smokers and have been referred to a medical center  
Conditions of non-entry: History of using psychiatric drugs

##### Intervention groups

Intervention group: Direct current cranial wall stimulation (tDCS): Each session is for 20 sessions of 30 to 30 minutes according to the treatment protocol and after attaching the cathode and Andy to the test head, stimulate the lateral dorsal region of the prefrontal lobe. we do. 2 mA current Cognitive-Behavioral Therapy Control Group (CBT): Each session will receive cognitive-behavioral therapy for 9 sessions of 1 to 1.5 hours, depending on the treatment process.

##### Main outcome variables

Cigarette cravings Nicotine addiction test (FTND) and positive and negative emotion scale test (PNAS) are taken before and after the intervention

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N51**

Registration date: **2022-04-08, 1401/01/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-08, 1401/01/19**

Update count: **0**

##### Registration date

2022-04-08, 1401/01/19

##### Registrant information

###### Name

Raheleh Nejati

###### Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3711 2540

###### Email address

nejatir2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-25, 1401/01/05

##### Expected recruitment end date

2022-08-27, 1401/06/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effectiveness of direct electrical stimulation of the brain (TDCS) and cognitive-behavioral therapy (CBT) in reducing cravings, mood and smoking dependence

## Public title

Comparison of the effectiveness of direct electrical stimulation (TDCS)

## Purpose

Diagnostic

## Inclusion/Exclusion criteria

### Inclusion criteria:

People addicted to cigarettes male gender

### Exclusion criteria:

History of mental illness and use of psychiatric drugs

## Age

From **18 years** old to **40 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **12**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization is done in a simple way using a random number table using the site [www.randomization.com](http://www.randomization.com). The numbers will be placed in sealed envelopes and when the participants enter, each envelope will be assigned to one of the two groups. The people in even pairs are the control group and the people

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ferdowsi University of Mashhad

##### Street address

Ferdowsi University of Mashhad, Azadi Square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948974

## Approval date

2022-01-30, 1400/11/10

## Ethics committee reference number

IR.UM.REC.1400.358

## Health conditions studied

### 1

#### Description of health condition studied

direct electrical stimulation of the brain (TDCS) and cognitive-behavioral therapy (CBT) in reducing cravings, mood and smoking dependence

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Tendency to smoke

#### Timepoint

Before and after the treatment program

#### Method of measurement

Fagstrom Nicotine Dependence Test (FTND), Positive and Negative Emotion Scale (PNAS) and Smoking Tendency Questionnaire (UTS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 6 patients in TDCS treatment of direct current cranial wall stimulation (tDCS): each session according to the treatment protocol is for 10 sessions of 20 to 30 minutes and after connecting the cathode and Andy to the test head of the lateral dorsal region We stimulate the prefrontal lobe. Device name: TDS current intensity 2 mAh. All subjects will respond to the Fagstrom Nicotine Dependence Test (FTND), the Positive and Negative Emotion Scale (PNAS), and the Smoking Attitude Questionnaire (UTS) before and after treatment.

#### Category

Treatment - Other

### 2

#### Description

Control group: 6 people in Cognitive-Behavioral Therapy (CBT): Each session will receive 1 to 1.5 hours of cognitive-behavioral therapy for 9 sessions according to the treatment process, so that the subject of session 1 is to create and maintain motivation for change. Session 2: Identifying and coping with motivating situations,

Session 3: Tackling temptation, Session 4: Refusal skills, social situation management and courage ..., Session 5: Making wise decisions when choosing, Session 6: Problem solving, Session 7 is lifestyle modification and coping with boredom, the topic of Session 8 is the management of boredom and boredom and the topic of Session 9 is prevention of recurrence, maintaining stability and termination of treatment. PNAS and Smoking Questionnaire (UTS) will answer before and after treatment.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Medical centers in Mashhad

**Full name of responsible person**

Hossein Share

**Street address**

Mashhad University Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

345 -91357

**Phone**

+98 51 3711 2701

**Email**

raikaravan@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayour

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

**City**

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**Postal code**

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**Phone**

+98 51 3841 2081

**Email**

GhayourM@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Share

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychology

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hoshareh@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Share

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychology

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Share

**Position**

Associate professor

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**Other areas of specialty/work**

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**Phone****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