

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation the effectiveness of direct electrical brain stimulation (tDCS) on cognitive functions and cravings in drug addicts undergoing maintenance treatment

#### Protocol summary

##### Study aim

The effectiveness of direct electrical brain stimulation (tDCS) on cognitive functions and cravings in drug addicts undergoing maintenance treatment

##### Design

Clinical trial with control group, with parallel groups, non blind, randomized, on 30 patients

##### Settings and conduct

Place of study: Navid drug addiction treatment clinic located in Semnan city; Study population: all substance dependent people treated with methadone maintenance drug in Semnan city; Type of blinding: Blinding was not done in this study

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent, having at least elementary education, not using drugs (narcotics), using maintenance treatment method. Exclusion criteris: using methods other than maintenance methods to treat addiction, female gender, illiteracy.

##### Intervention groups

Intervention group: direct electrical brain stimulation (tDCS). Control group: usual treatment program without any intervention or change.

##### Main outcome variables

Cognitive function, cravings

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230816059170N1**

Registration date: **2023-12-20, 1402/09/29**

Registration timing: **retrospective**

Last update: **2023-12-20, 1402/09/29**

Update count: **0**

##### Registration date

2023-12-20, 1402/09/29

##### Registrant information

###### Name

mostafa nikfard

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3336 0529

###### Email address

nikfardmostafa@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-03, 1402/04/12

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

2023-07-03, 1402/04/12

##### Actual recruitment end date

2023-09-11, 1402/06/20

##### Trial completion date

2023-09-21, 1402/06/30

##### Scientific title

Evaluation the effectiveness of direct electrical brain stimulation (tDCS) on cognitive functions and cravings in drug addicts undergoing maintenance treatment

##### Public title

The effectiveness of direct electrical stimulation of the brain on cognitive functions and craving

##### Purpose

Other

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Having informed consent to participate in the research  
Having at least primary education  
No drug use  
Use of maintenance treatment method

**Exclusion criteria:**

Using a method other than conservative treatment  
methods  
female gender  
Illiteracy

**Age**

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **30**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To allocate people in the study groups, the dice throwing method was used so that the numbers 1, 2, and 3 were defined for the placement of people in the tDCS treatment group, and the numbers 4, 5, and 6 were defined for the placement of people in the control group.

**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 Semnan Azad University

**Street address**

No 44; Yas building; Sizdahom Gharbi street; Taavon town

**City**

Semnan

**Province**

Semnan

**Postal code**

3514753367

**Approval date**

2023-07-18, 1402/04/27

**Ethics committee reference number**

IR.IAU.SEMNAN.REC.1402.052

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

Addiction

**ICD-10 code**

F11

**ICD-10 code description**

Opioid related disorders

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

Craving

**Timepoint**

Before starting the intervention and after 10 treatment sessions

**Method of measurement**

Craving questionnaire

**2****Description**

Cognitive function

**Timepoint**

Before starting the intervention and after 10 treatment sessions

**Method of measurement**

Working memory performance questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The intervention group received ten sessions of transcranial electric current stimulation. Intervention with OASIS PRO WITH tDCS device from MIND ALIVE company was used. Subjects in this group participated in treatment sessions every other day for ten sessions. Anode electrode was placed in the posterolateral region of the left prefrontal cortex and cathode electrode was placed in the posterolateral region of the right prefrontal cortex, and in each session for 20 minutes, a current of 2 milliamps of direct electric current was passed through the skull of the subjects.

**Category**

Treatment - Devices

**2****Description**

Control group: The control group continued their usual treatment program and did not receive any other intervention

**Category**

N/A

**Type of organization providing the funding**

Academic

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

Navid addiction treatment clinic

**Full name of responsible person**

Dr. Hajar Kasaian

**Street address**

3rd floor; Aftab building; Ghaem Blvd.

**City**

Semnan

**Province**

Semnan

**Postal code**

3519667961

**Phone**

+98 23 3334 6672

**Email**

dr.hkasaian@gmail.com

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

Islamic Azad University

**Full name of responsible person**

Arezu Tahan

**Street address**

Semnan Azad University; Sokan Park

**City**

Semnan

**Province**

Semnan

**Postal code**

۳۷۱۱۱-۳۵۱۳۱

**Phone**

+98 23 3165 6565

**Email**

info@semnaniau.ac.ir

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

No

**Title of funding source**

Islamic Azad University, Semnan branch

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

Islamic Azad University

**Full name of responsible person**

Mostafa Nikfard

**Position**

Psychologist

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

No 44; Yas building; Sizdahom Gharbi street; Taavon town

**City**

Semnan

**Province**

Semnan

**Postal code**

3514753367

**Phone**

+98 23 3336 0529

**Fax****Email**

nikfardmostafa@gmail.com

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

Islamic Azad University

**Full name of responsible person**

Mostafa Nikfard

**Position**

Psychologist

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**Phone**

+98 23 3336 0529

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nikfardmostafa@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mostafa Nikfard

**Position**

Psychologist

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**City**

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**Postal code**

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**Fax****Email**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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**

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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

All data can be shared

**When the data will become available and for how long**

Late 2023

**To whom data/document is available**

It can be made available to the public

**Under which criteria data/document could be used**

Permission is granted

**From where data/document is obtainable**

nikfardmostafa@gmail.com

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

After submitting the application and checking the documents

**Comments**