Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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
Type of organization providing the funding
Academic

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
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Person responsible for updating data

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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