Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Assessing Executive Function and Drug Craving Modulatory Effects of Transcranial Direct Current Stimulation (tDCS) among Opioid Dependents

Protocol summary

Study aim

Quantitative determination of opium cravings in opioid addicts and the effect of tDCS on it. Quantitative determination of executive dysfunction (decision making, response control and working memory) in opioid addicts and evaluation of the effect of tDCS on it. Determination of changes in serum BDNF levels as a result of treatment with tDCS. Determining the effectiveness of a treatment protocol.

Design

In this study, 72 people are randomly divided into two groups: Real and Sham. The rand function in c++ was used to obtain random numbers and randomization.

Settings and conduct

This study is performed in MMT centers in Tehran. Executive function tests, craving assessment, and serum level BDNF evaluation are performed before and immediately after the intervention, and the tests are repeated 8 weeks later (except BDNF). Participants and statistics analysts are blind, and the method of opaque, sealed envelopes was used.

Participants/Inclusion and exclusion criteria

Opioid users over the age of 18 will be the most benefited from this treatment so they will be included in the study, and those who have contraindications to tDCS, including those with any type of metal plate in the head and brain injury, chronic skin disorders, severe reactions to tDCS in previous treatments, and a history of seizures, will be the most harmed so they will be excluded from the study.

Intervention groups

tDCS is performed for 2 sessions every day for 5 consecutive days. In the Real group, stimulation is performed twice for 13 minutes and at a distance of 10 minutes, 2 mA. In the sham group, the applied electric current will be disconnected after 30 seconds.

Main outcome variables

Craving; Serum level BDNF; Response Inhibition; Working Memory; Decision Making and Risk-Taking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048850N1**
Registration date: **2020-10-10, 1399/07/19**
Registration timing: **prospective**

Last update: **2020-10-10, 1399/07/19**
Update count: **0**

Registration date

2020-10-10, 1399/07/19

Registrant information

Name

Roghieh Bahareh Borzooee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing Executive Function and Drug Craving Modulatory Effects of Transcranial Direct Current Stimulation (tDCS) among Opioid Dependents

Public title
Assessing the effect of tDCS on opioid addicts and their brain function
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Subjects have to be male Subject who is right-handed Subject whose age is between 18 to 55 years At least the fifth elementary education Have opioid dependence criteria based on DSM-5 criteria Have no other psychiatric or neurological illness The main substance consumption have to be opium Do not consume other substances during the project Subject consents to participation in the study and provides a signed informed consent form
Exclusion criteria:
Contraindications to tDCS include the presence of any type of cerebral injury in the brain and metal plates on the head, chronic skin problems, severe reactions to tDCS in previous treatments, history of seizures
Age
From **18 years** old to **55 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The blocking method is used for randomization in this study. In this method, at first, the block size is determined. Considering the possible loss to follow-up, the sample size is considered to be 72, and considering that we have two groups (R (Real) and (S) Sham, the block size is considered to be 4, and then the list of blocks is written (SRRS). , (SRSR), (SSRR), (RSSR), (RSRS), (RRSS). By writing a program in Č ++ language, we create random numbers (numbers between 0 and 51 are considered to be R and numbers between 51 and 100 are considered to be S) and finally we determined the blocks based on the assigned random numbers. We ask the participants to choose a number from 0 to 6. Because we have 6 blocks, we can have 12 people in each block.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, data analyst and participants are kept blind to the allocation of study groups. After randomization, the opaque sealed envelope method is used. Researchers and project implementers are not blind to the allocation of study groups.
Placebo
Used
Assignment
Parallel
Other design features
In this study, changes in serum BDNF levels are also evaluated.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahroud University of Medical Sciences
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Approval date
2019-03-11, 1397/12/20
Ethics committee reference number
IR.SHMU.REC.1397.222

Health conditions studied

1

Description of health condition studied
Drug use disorder
ICD-10 code
F11.188
ICD-10 code description
Opioid abuse with other opioid-induced disorder

Primary outcomes

1

Description
Rate of changes in baseline substance craving and cue-induced craving
Timepoint
Before the intervention and after the intervention (fifth day) and 2 months later
Method of measurement
Visual Analog Scale, Desire for Drug Questionnaire, Obsessive-Compulsive Drug Use Scale

2

Description

serum level changes of Brain-Derived Neurotrophic Factor

Timepoint

Before the intervention and after the intervention (fifth day)

Method of measurement

Enzyme-Linked Immunosorbent Assay(ELISA)

3

Description

Evaluation of changes in short-term memory and working memory

Timepoint

Before the intervention and after the intervention (fifth day) and 2 months later

Method of measurement

Forward & Backward Digit span Test

4

Description

Evaluation of changes in response inhibition and impulsivity

Timepoint

Before the intervention and after the intervention (fifth day) and 2 months later

Method of measurement

Go-No Go Test

5

Description

Evaluation of changes in decision making and risk-taking

Timepoint

Before the intervention and after the intervention (fifth day) and 2 months later

Method of measurement

Balloon Analog Risk Task (BART)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Transcranial Direct Current Stimulation (tDCS) is performed 2 times a day for 5 consecutive days. Stimulation is performed twice in the intervention group for 13 minutes and with 10 minutes interval, 2 mA.

Category

Treatment - Other

2

Description

Control group: In this group, Transcranial Direct Current Stimulation (tDCS) at 2 mA is cut off after 30 seconds. This protocol is performed for 5 consecutive days, 2 sessions every day and 13 minutes each session with 10 minutes interval.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Saye Clinic

Full name of responsible person

Milad Taksibi

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2

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Sponsors / Funding sources

1

Sponsor

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Grant name
Vice Chancellery of Research and Technology

Grant code / Reference number
97135

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Roghieh Bahareh Borzooee
Position
PhD Candidate
Latest degree
Medical doctor
Other areas of specialty/work
Addiction Studies
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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
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 personal data of the participants are shared without a name and personal information (unidentifiable).

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The use of all data or documents for researchers for use in scientific research with reference to the source is allowed.

From where data/document is obtainable
To the researcher of this study, Roghieh Bahareh Borzooee, refer to the email address b.borzooee@shmu.ac.ir

What processes are involved for a request to access data/document
By sending an email to b.borzooee@shmu.ac.ir, the files will be provided to the applicant within 15 days.

Comments