Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effectiveness of transcranial direct current stimulation (tDCS) on the level of craving and quality of life of patients with substance-use disorders

Protocol summary

Study aim
Determination of the effectiveness of tDCS on the level of craving and quality of life of patients with substance-use disorders

Design
The study is a clinical trial with a control group, with crossover groups, randomized, phase 3 on 60 patients. Participants will be divided into three groups of 20 people using the block randomization method with a size of 6. First and second groups will be crossover on tDCS treatment and Sham control.Third group will only be subject to standard treatment.Sequence generation will be obtained through the sealed envelope site and allocation concealment through a sealed envelope.

Settings and conduct
Patients from the substance abuse treatment center of Shafa Hospital in Rasht in 2023 through available sampling entered into the study.Blinding is not done in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with substance use disorders Non-Inclusion criteria: Taking anticonvulsant drugs in the last 6 months neurological diseases Exclusion criteria: Any complication due to treatment and the patient's unwillingness to participate in the study

Intervention groups
In the intervention group, brain stimulation is done in daily sessions each session for 30 minutes for fifteen days according to the tDCS protocol of cathedral type, using films and music during the 30 minutes to calm patients. The control group is controlled by Sham. Probes are connected to their heads, but electricity does not flow.After 5 days of rest for both groups, in the next 15 sessions, the places of the two groups will be changed.Third group will only be treated with the standard ,no tDCS. Then, for 6 months, three groups receive standard matrix psychotherapy and 6 sessions of relaxation training.

Main outcome variables
craving and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230430058029N1**
Registration date: **2023-05-29, 1402/03/08**
Registration timing: **prospective**

Last update: **2023-05-29, 1402/03/08**
Update count: **0**

Registration date
2023-05-29, 1402/03/08

Registrant information

Name
Kiomars Najafi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-19, 1402/03/29

Expected recruitment end date
2024-06-18, 1403/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of transcranial direct current stimulation (tDCS) on the level of craving and quality of life of patients with substance-use disorders

Public title
Evaluation of the effectiveness of transcranial direct current stimulation (tDCS) in patients with substance abuse
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with opioid or methamphetamine substance use disorders (based on DSM-5 criteria).
Exclusion criteria:
Taking anticonvulsiant drugs in the last 6 months Having neurological diseases Pregnancy Mental retardation Presence of a complication in the skull Presence of any metal in the skull or brain
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **60**
Patients with substance abuse disorder were selected by easy and available selection method from those referred to the substance abuse treatment center of Shafa Hospital in Rasht in 2023.Patients range in age from 18 to 65 years.First, by taking a urine sample and conducting a diagnostic interview, the type of consumption disorder is determined separately by the type of substance.At the beginning of treatment, the subject is allowed to reduce the substance over a period of ten days, and if they have withdrawal symptoms, medications are used to reduce the subject's symptoms. Retrieval symptoms are measured by sows and oows in subjects.If in the initial evaluation of any of the clients according to DSM-5 criteria, they suffer from anxiety disorder or depression, anti-depressant and anti-anxiety drugs are used in the patients.
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into three groups of 20 people using the block randomization method with a size of 6. The randomization unit is individual and generates sequences through the site "sealed envelope (https://www.sealedenvelope.com/simple-randomiser/v1/lists)" Will be achieved. Allocation concealment will be done through a sealed envelope.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features
Due to the chronicity of substance dependence, the high cost of tDCS treatment and also the benefit of more participants from this treatment, a cross-sectional design will be used in this study. Participants in this project will be divided into three groups of 20 people using block randomization method. The first and second groups will be cross-checked on tDCS treatment and Sham control. In the first 15 sessions, the first group is treated daily by cathodic tDCS and the second group is controlled by Sham. In the next 15 sessions, the two groups will be replaced. The third group will only be subject to standard treatment.Active treatment of brain stimulation according to the tDCS protocol of cathedral type is done in daily sessions, each session for 30 minutes for fifteen days. Each time a tDCS is performed (before and after each session), the patient is evaluated for any side effects. Assessment of side effects in it is performed based on a self-made questionnaire (made by the research center and supervised by 5 collaborating specialists). After the initial treatment, for three months on a weekly basis, all three groups receive standard matrix psychotherapy and 6 sessions of relaxation training. During the follow-up period, patients will be evaluated for substance use in three stages of 1 month, 3 months and 6 months. Examining substance use in matrix treatment sessions will be random.Brain stimulation through electrical current is a widespread applied technology for cerebral diseases.In the present study, for brain stimulation, we used TDCS device that was devised by Paym-e Gilan Mehr (knowledge-based company in Iran). The source of current is 18 V alkaline batteries with dimention about 32 cm × 21 cm × 11 cm; its weight is 5.1 kg In this study, 3 cathode leads and 3 anode leads are used. Each probe has two poles, positive and negative(3 cathode probes and 3 anode probes) has a cross-sectional area of 4 cm and a coating of rubber material is drawn on it, which easily transfers the current to the surface of the skull by the gel. The probes are placed side by side.Find that the cathodal leads are connected to each other without connecting to each other and in a triangular manner with the base downwards in the supraorbital regions of the right and fp2 in the EEG 10-20 system and the anodal leads in the left temporal-occipital region.(P1-C3- T7) is placed in the form of a triangle whose vertex is upwards and the base is outwards and downwards. The anode probes are placed slightly below the said level (limbic area of the brain).The electrodes are non-metallic and conductive and, after being impregnated with normal saline, are held in place by an elastic band in the scalp to facilitate transmission and reduce irritation in the skin area. After ensuring the placement of the electrodes, the tDCS device, which can be charged with an 18-volt battery,

supplies direct and uniform direct current (up to 2 mA to each of the 3 electrodes) through the electrodes to the cortex below the electrode for a maximum of 30 minutes. Sends. Films and music are also used during the 30 minutes of treatment to help calm patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Guilan University of Medical Sciences

Street address
University Research and Technology Vice-Chancellor,in front of 17 Shahrivar Hospital, Shahid Siyadati St, Namjo St, Rasht

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Approval date
2023-04-18, 1402/01/29

Ethics committee reference number
IR.GUMS.REC.1402.047

Health conditions studied

1

Description of health condition studied
substance use disorder

ICD-10 code
F11.2

ICD-10 code description
Opioid dependence

2

Description of health condition studied
Other stimulant dependence

ICD-10 code
F15.2

ICD-10 code description
Other stimulant dependence

Primary outcomes

1

Description
The amount of craving

Timepoint
6 months.During the follow-up period, patients will be evaluated for substance use in three stages of 1 month, 3 months and 6 months.

Method of measurement
Addiction Craving Scale (ACS) questionnaire

Secondary outcomes

1

Description
Quality of life

Timepoint
Before the intervention and in the follow-up period of 1 month, 3 months and 6 months

Method of measurement
SF-36 questionnaire score

2

Description
Data of EEG

Timepoint
Before the intervention and in the follow-up period of 1 month, 3 months and 6 months

Method of measurement
Brain signal processing

Intervention groups

1

Description
The first intervention group is treated daily with cathodic TDCS method in the first 15 sessions, and after 5 days of rest, they are treated with Sham in the next 15 sessions.Active treatment of brain stimulation according to the tDCS protocol of cathedral type is done in daily sessions, each session for 30 minutes for fifteen days. Each time a tDCS is performed (before and after each session), the patient is evaluated for any side effects.Sham treatment is in such a way that the probes are placed on the head of the patients, but the electric current is not connected to it. Films and music are also used during the 30 minutes of tDCS and Sham treatment to help calm patients. After initial treatment, for 6 months, all three groups receive standard matrix psychotherapy and 6 sessions of relaxation training weekly. In the present study, for brain stimulation, we used TDCS device that was devised by Paym-e Gilan Mehr (knowledge-based company in Iran). The source of current is 18 V alkaline batteries with dimention about 32 cm × 21 cm × 11 cm; its weight is 5.1 kg In this study, 3 cathode leads and 3 anode leads are used. Each probe has two poles, positive and negative(3 cathode probes and 3 anode probes) has a cross-sectional area of 4 cm and a coating of rubber material is drawn on it, which easily transfers the current to the surface of the skull by the gel. The probes are placed side by side.Find that the cathodal leads are connected to each other without connecting to each other and in a triangular manner with the base downwards in the supraorbital regions of the right and fp2 in the EEG 10-20 system and the anodal leads in the left temporal-occipital region.(P1-C3- T7) is

placed in the form of a triangle whose vertex is upwards and the base is outwards and downwards. The anode probes are placed slightly below the said level (limbic area of the brain).The electrodes are non-metallic and conductive and, after being impregnated with normal saline, are held in place by an elastic band in the scalp to facilitate transmission and reduce irritation in the skin area. After ensuring the placement of the electrodes, the tDCS device, which can be charged with an 18-volt battery, supplies direct and uniform direct current (up to 2 mA to each of the 3 electrodes) through the electrodes to the cortex below the electrode for a maximum of 30 minutes.

Category

Treatment - Other

2

Description

The second intervention group will be sham treatment during the first 15 sessions and after 5 days of rest, they will be treated with active TDCS method during 15 sessions. Active treatment of brain stimulation according to the tDCS protocol of cathedral type is done in daily sessions, each session for 30 minutes for fifteen days. Sham treatment is in such a way that the probes are placed on the head of the patients, but the electric current is not connected to it. Films and music are also used during the 30 minutes of tDCS and Sham treatment to help calm patients. After initial treatment, for 6 months, all three groups receive standard matrix psychotherapy and 6 sessions of relaxation training weekly.

Category

Treatment - Other

3

Description

The control group receives common treatment. In this way, for the treatment of opium (opium, etc.), The National Protocol f Agonist treatment will be used and for the treatment of methamphetamines, The Standard Matrix treatment will be used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Medical Education Center

Full name of responsible person

Kiomars Najafi

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Shafa Medical Education Cente,15 Khordad Str, Mosalla Square, Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Kiomars Najafi

Street address

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Grant name

Grant code / Reference number

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

No

Title of funding source

Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Rasht University of Medical Sciences

Full name of responsible person

Kiomars Najafi

Position

Associate Professor of Psychiatry Department of Psychiatry, School of Medicine Shafa Hospital Guilan

Latest degree

Specialist

Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Kiomars Najafi
Position
Associate Professor of Psychiatry Department of Psychiatry, School of Medicine Shafa Hospital Guilan
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Kiomars Najafi
Position
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Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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City
Rasht
Province
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Postal code
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Email
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable