Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Synergistic comparison of the effectiveness of cognitive-behavioral therapy (CBT) and cranial direct current stimulation therapy (tDCS) on the dorsal lateral prefrontal cortex (DLPFC) on reducing cravings and clinical signs and improving neuropsychological functions in amphetamin addicts .

Protocol summary

Study aim

Determining the synergistic role of cognitive behavioral therapy and treatment of the dorsolateral prefrontal cortex on reducing the basic and induced craving for amphetamine and clinical symptoms(anxiety and depression)and improving neuropsychological functions(cognitive inhibition)and behavioral) of amphetamine abusers.

Design

A clinical trial with three test groups and one control group, matched, single-blind, randomized, phase 2 on 40 patients. PASS software was used to estimate the sample size.

Settings and conduct

The statistical population of this research includes patients with clinical symptoms of substance abuse disorder who were referred to addiction treatment clinics in Mashhad,in the year 2023.Then at least 40 people who have the criteria to enter the research will be randomly replaced in4 groups(three experimental groups and one control group).In this research, a blind intervention study method will be used.

Participants/Inclusion and exclusion criteria

Inter:the main diagnosis of(amphetamine)abuse, the consent of the subjects to participate in the research,the absence of neurological diseases-Exit: Having a history of committing suicide and thoughts,having an injury in the head and neck area

Intervention groups

Before the intervention,a pre-test will be done in4 experimental groups by implementing questionnaires.Then group1:recipient of cognitive-behavioral therapy.Group2:recipient of stimulation therapy with direct current from the skull of the dorsolateral frontal region.Group3 both They will receive the treatment to check synergy.The control group will not receive any other intervention other than cognitive behavioral therapy.After the intervention,a post-test will be carried out from all4groups by implementing questionnaires.

Main outcome variables

Craving for basic and induced use of amphetamine, clinical signs, neuropsychological functions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230318057753N1**
Registration date: **2023-05-20, 1402/02/30**
Registration timing: **retrospective**

Last update: **2023-05-20, 1402/02/30**
Update count: **0**

Registration date

2023-05-20, 1402/02/30

Registrant information

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Name of organization / entity

Islamic Azad University, Bojnord branch

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-05, 1402/02/15
Expected recruitment end date
2023-05-20, 1402/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Synergistic comparison of the effectiveness of cognitive-behavioral therapy (CBT) and cranial direct current stimulation therapy (tDCS) on the dorsal lateral prefrontal cortex (DLPFC) on reducing cravings and clinical signs and improving neuropsychological functions in amphetamin addicts .

Public title
Synergistic comparison of the effectiveness of cognitive-behavioral therapy and cranial direct current stimulation therapy on the dorsal lateral prefrontal cortex on reducing cravings and clinical signs and improving neuropsychological functions in Stimulant substance abusers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primary diagnosis of amphetamine abuse based on clinical interview based on DSM-5 Age range 20-50 years He had at least middle school education Lack of diagnosis of any psychiatric disorder (except substance abuse) Not receiving any psychiatric medication for at least 6 months before entering the study Not receiving any other psychological intervention during the study Subjects' consent to participate in the research Not suffering from any specific physical disease Not suffering from neurological diseases (epilepsy, multiple sclerosis).
Exclusion criteria:
Having schizophrenia spectrum disorders and other psychotic disorders. Obsessive-compulsive disorder and related disorders. post-traumatic stress disorder and related disorders; Bipolar mood disorder and related disorders. Anxiety disorder caused by substances/drugs or caused by other medical conditions. Having a history of suicidal actions and thoughts. Having an injury in the head and neck area. history of consumption shorter than 6 months. History of implanting prosthesis in the head and neck area.
Age
From **20 years** old to **50 years** old
Gender
Male

Phase
1-2
Groups that have been masked
- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
According to the nature of the research, a quantitative and experimental approach is used. Quantitative approach is a research orientation that studies the studied phenomenon based on numerical and statistical indicators (Creswell, 2012). It should be noted that based on the purpose of the research, the current research is an applied research. Because its findings can help solve the problems ahead.Due to the availability of a sufficient sample for group research, the current research design is semi-experimental with a pre-test-post-test design with a control group. Considering the topic of the present research, PASS software will be used first to estimate the sample size with an alpha error coefficient of 0.05 and a beta error coefficient of 0.8 (Jabari Nougabi, 2009). After that, the people who meet the criteria for entering the research are randomly assigned to 4 groups (three experimental groups and one control group). Then by manipulating the independent variable, i.e. providing cognitive-behavioral therapy and tDCS stimulation therapy to the test groups, its effect on the dependent variables (reduction of basic and induced cravings, reduction of clinical symptoms of anxiety and depression, and The improvement of neuropsychological functions, i.e., cognitive inhibition and behavioral inhibition in the treatment of patients with glass (amphetamine) abuse disorder will be measured and analyzed. Before the intervention, a pre-test will be done from all four groups (three experimental groups and one control group) by implementing research questionnaires. Then, test group 1 received cognitive-behavioral therapy (CBT) and test group 2 received tDCS (DLPFC area) with the right anode-left cathode protocol and the third group received both treatments to check synergy. will do And the control group will not receive any intervention. After the implementation of the intervention, a post-test of all four groups will be conducted by implementing research questionnaires.
Blinding (investigator's opinion)
Single blinded
Blinding description
According to the designed diagram of the research plan, after placing the sample subjects into three test groups and one control group based on the specified treatment protocols, the pre-test will be done from all four groups. Then, the number of sessions and the days of the sessions will be coordinated with the patients, and after the end of the treatment sessions (sessions will be held weekly in two 45-minute sessions), a post-test will be done for all four groups. It should be mentioned that in order to control the intervening variables, people in 4 groups will first be replaced by a random method, which is the simplest method of controlling the intervening variables, and then based on the theoretical foundations of the research and the intervening variables, the people of the 4 groups will be matched until the variables Intervener to be controlled. Finally, a one-sided blind

intervention study method will be used in which the participants are not aware of which group they have been placed in and what treatment method has been prescribed for them. This research is in phase two. Because in this phase, the emphasis is on effectiveness. This stage is done with the aim of obtaining preliminary information about whether tDCS and CBT treatments work in the experimental group or not. To control the side effects of the intervention, ethical considerations will be observed in the research and all people will participate in the research with informed consent and the subjects will be properly informed of all the information that can be effective in making decisions. This information will include: the title and objectives of the research, the duration of the research and the method that is going to be used. Also, every subject can withdraw from the study at any time and will be informed and supported about the potential risks and losses caused by early withdrawal from the study. The researcher will also answer all the questions and concerns of the sample people patiently and accurately. These items are reflected in the informed consent. The researcher is responsible for observing the principle of confidentiality and keeping the subjects' secrets and taking appropriate measures to prevent their publication, and any kind of damage or loss caused by participating in the research will be compensated by the researcher. At the end of the research, any person from the sample, who wants to know about the results of the research, will be provided with the results.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Islamic Azad University - Bojnord Branch

Street address
Unit 2, No. 56, Daneshjo Blvd, Mashhad

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Approval date
2022-11-21, 1401/08/30

Ethics committee reference number
IR.IAU.BOJNOURD.REC.1401.024

Health conditions studied

1

Description of health condition studied
addiction

ICD-10 code
F15.1

ICD-10 code description
Mental and behavioural disorders due to use of other stimulants, including caffeine

Primary outcomes

1

Description
Craving for basic and induced amphetamines

Timepoint
Before the intervention, a pre-test will be done from all four groups (three experimental groups and one control group) by implementing research questionnaires. Then, test group 1 received cognitive-behavioral therapy (CBT) and test group 2 received tDCS (DLPFC area) with the right anode-left cathode protocol and the third group received both treatments to check synergy. will do And the control group will not receive any intervention.After the implementation of the intervention, a post-test of all four groups will be conducted by implementing research questionnaires.

Method of measurement
Questionnaire Amphetamine baseline craving questionnaire Video test to measure induced craving

2

Description
Clinical symptoms (anxiety and depression)

Timepoint
Before the intervention, a pre-test will be done from all four groups (three experimental groups and one control group) by implementing research questionnaires. Then, test group 1 received cognitive-behavioral therapy (CBT) and test group 2 received tDCS (DLPFC area) with the right anode-left cathode protocol and the third group received both treatments to check synergy. will do And the control group will not receive any intervention.After the implementation of the intervention, a post-test of all four groups will be conducted by implementing research questionnaires.

Method of measurement
questionnaire Beck depression questionnaire Beck's anxiety

3

Description
Functions of neuropsychology (cognitive and behavioral inhibition)

Timepoint
Before the intervention, a pre-test will be done from all four groups (three experimental groups and one control

group) by implementing research questionnaires. Then, test group 1 received cognitive-behavioral therapy (CBT) and test group 2 received tDCS (DLPFC area) with the right anode-left cathode protocol and the third group received both treatments to check synergy. will do And the control group will not receive any intervention.After the implementation of the intervention, a post-test of all four groups will be conducted by implementing research questionnaires.

Method of measurement

Neuropsychological Test of Behavioral Inhibition GO-NO GO-NO-GO (1984) Stroop cognitive inhibition neuropsychology test (1935)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: treatment only (CBT) In order to investigate the effectiveness of cognitive behavioral therapy on the dependent variables of the research (reduction of basic and induced cravings, reduction of clinical symptoms of anxiety and depression, and improvement of neuropsychological functions i.e. cognitive inhibition and behavioral inhibition) in the treatment of patients with (amphetamine) abuse disorder) The people receiving this intervention, who are 10 people, will only undergo cognitive behavioral therapy according to the designed protocol (10 sessions of 45 minutes).

Category

Behavior

2

Description

Intervention group: Treatment only (tDCS) Intervention group: only treatment (tDCS) in order to investigate the effectiveness of stimulation treatment with direct current from the skull on dependent variables (reduction of basic and induced cravings, reduction of clinical symptoms of anxiety and depression, and improvement of neuropsychological functions, i.e. cognitive inhibition and behavioral inhibition) In the treatment of patients suffering from (amphetamine) abuse disorder, the people receiving this intervention, who are 10 people, will only be treated with direct current stimulation from the skull with the right anode-left cathode protocol (10 sessions) of 20 minutes.

Category

Treatment - Devices

3

Description

Intervention group: therapy (CBT) and therapy (tDCS) Intervention group: treatment (CBT) and treatment (tDCS) in order to investigate the effectiveness of co-administration (combination) of cognitive behavioral therapy with stimulation therapy with direct current from the skull on the dependent variables (reduction of basic and induced cravings, reduction of clinical symptoms of anxiety and Depression, and improvement of neuropsychological functions, i.e., cognitive inhibition and behavioral inhibition in the treatment of patients with (amphetamine) abuse disorder. There are 10 participants after receiving cognitive behavioral therapy according to the designed protocol (10 sessions of 45 minutes). will be treated with direct current stimulation from the skull with right anode-left cathode protocol (10 sessions of 20 minutes).

Category

Treatment - Devices

4

Description

Control group: Failure to receive intervention In order to investigate and verify the combined effect of independent variables, i.e., cognitive behavioral therapy and stimulation therapy with direct current from the skull on dependent variables (reduction of basic and induced cravings, reduction of clinical symptoms of anxiety and depression, and improvement of functions Neuropsychology means cognitive inhibition and behavioral inhibition in the treatment of patients with glass (amphetamine) abuse disorder. The people receiving this intervention, who are 10 people, will not receive any other real intervention other than cognitive behavioral therapy. are placed in cognitive behavioral therapy, and in the therapeutic phase of stimulation with direct current from the skull in the dorsolateral prefrontal region, the stimulation in the skull region will be performed in a fake form, that is, the electrodes will be installed on their head, but the device is turned off and the current in the electrode There are no problems and practically no stimulation is done.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehravaran addiction treatment clinic

Full name of responsible person

Mahdi Helmzadeh

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd 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
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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 data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 1 year after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Psychologists, psychiatrists, psychology and psychiatry students and patients interested in research
From where data/document is obtainable
mahdi.helmzadeh@gmail.com
What processes are involved for a request to access data/document
After sending the request by email, within a maximum period of 1 month
Comments