Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the Effect of Transcranial Direct Current Stimulation (tDCS) With Cognitive-Behavioral therapy (CBT) Interventions on the stress and anxiety and depression and relapse in abstinent methamphetamine-dependent subjects in Farabi Hospital.

Protocol summary

Study aim

Comparative determination of the effect of direct transcranial electrical stimulation (tDCS) therapy with cognitive behavioral therapy (CBT) and the combination of these two interventions on stress and anxiety and depression responses and the possibility of recurrence and cortisol levels in methamphetamine users .

Design

In tDCS and sham groups, the anodal electrode is located in the right prefontal cortex (F3) and the cathode is in the left prefrontal cortex (F4) at 20 minutes and 1 mA during 10 sessions. CBT sessions are performed according to the matrix model, which will be 3 sessions of 45 minutes per week during 24 sessions. Anxiety, stress and depression and salivary cortisol levels and relapse before each intervention and also after tDCS and CBT sessions will be done using DASS-21 questionnaire and hormone test kit and also Persian version of AWAER questionnaire.

Settings and conduct

This study is a double-blind clinical trial in four groups (n = 20) in Farabi Hospital in the summer of 1401.

Participants/Inclusion and exclusion criteria

80 patients selected for treatment with methamphetamine addiction, male, right-handed, with at least a diploma and over 18 years of age, with a minimum history of 6 months of methamphetamine use during the period of abstinence from using this substance. The exclusion criteria, the desired drug interventions and the presence of metal in the head and neck. And history of seizures, the presence of pacemakers in the heart, psychiatric disorders, addiction, or the use of alcohol and sedatives.

Intervention groups

The electrical intervention group (tDCS), will apply electric current from the skull. Control group receive tDCS silently. The Cognitive Behavioral Therapy Group (CBT) and the combined group also receives both electrical and cognitive intervention simultaneously.

Main outcome variables

Salivary cortisol-Relapse-Stress-Anxiety-Depresion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120502009620N2**
Registration date: **2022-07-13, 1401/04/22**
Registration timing: **prospective**

Last update: **2022-07-13, 1401/04/22**
Update count: **0**

Registration date

2022-07-13, 1401/04/22

Registrant information

Name
Vahid Farnia

Name of organization / entity
Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Transcranial Direct Current Stimulation (tDCS) With Cognitive-Behavioral therapy (CBT) Interventions on the stress and anxiety and depression and relapse in abstinent methamphetamine-dependent subjects in Farabi Hospital.

Public title

Comparing the Effect of tDCS With CBT Interventions on the stress and anxiety and depression and relapse in abstinent methamphetamine-dependent subjects

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Male Right-hand Has a minimum education level of diploma Age over 18 years Has a minimum 6 months Methamphetamine use before treatment During Methamphetamine abstinence

Exclusion criteria:

Drug interventions Existence of metal in head and neck History of seizures The presence of a pacemaker in the heart Psychiatric disorders Addiction Alcohol consumption Consumption of sedatives

Age

From **18 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers are generated using R software and General Integer option, so that the largest and smallest desired number (1 and 10) with the specified sample size (80 people) is entered in the software and a random combination of 80 is created from numbers 1 to 10. The generated sample is then used to assign individuals to the samples. In this way, every ten random numbers generated in a block is a random combination of numbers from 1 to 10.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Etichs committees of kermanshah university of medical science

Street address

Shahid Beheshti Blvd. Building No. 2, Kermanshah University of Medical Sciences, Research and Technology Vice-Chancellor

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Postal code

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Approval date

2022-05-21, 1401/02/31

Ethics committee reference number

IR.KUMS..REC.1401.070

Health conditions studied

1

Description of health condition studied

Methamphetamine addiction

ICD-10 code

F15.2

ICD-10 code description

Other stimulant dependence

Primary outcomes

1

Description

Stress score in DASS test

Timepoint

Stress scores will be measured at the beginning of the study, ie one week before the intervention and after 10 sessions of direct current stimulation intervention and after 24 sessions of cognitive-behavioral therapy intervention. All tests will be repeated 4 months after the end of the study to follow the therapeutic effects.

Method of measurement

DASS-21 Stress, Anxiety and Depression Questionnaire

2

Description

Anxiety score in DASS test

Timepoint

Anxiety scores will be measured at the beginning of the study, ie one week before the intervention and after 10 sessions of direct current stimulation intervention and after 24 sessions of cognitive-behavioral therapy intervention. All tests will be repeated 4 months after the end of the study to follow the therapeutic effects.

Method of measurement

DASS-21 Stress, Anxiety and Depression Questionnaire

3

Description

Depression score in DASS test

Timepoint

Depression scores will be measured at the beginning of the study, ie one week before the intervention and after 10 sessions of direct current stimulation intervention and after 24 sessions of cognitive-behavioral therapy intervention. All tests will be repeated 4 months after the end of the study to follow the therapeutic effects.

Method of measurement

DASS-21 Stress, Anxiety and Depression Questionnaire

4

Description

Relapse score in the Persian version of the AWAER questionnaire

Timepoint

Relapse score will be measured at the beginning of the study, ie one week before the intervention and after 10 sessions of direct current stimulation intervention and after 24 sessions of cognitive-behavioral therapy intervention. All tests will be repeated 4 months after the end of the study to follow the therapeutic effects.

Method of measurement

Persian version of the AWAER questionnaire

5

Description

Salivary cortisol level

Timepoint

Salivary cortisol level will be measured at the beginning of the study, ie one week before the intervention and after 10 sessions of direct current stimulation intervention and after 24 sessions of cognitive-behavioral therapy intervention. All tests will be repeated 4 months after the end of the study to follow the therapeutic effects.

Method of measurement

Salivary cortisol test kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1- tDCS: Oasis Pro tDCS from Mind Alive Canada will be used to stimulate direct current stimulation. Anode or excitation electrode with dimensions of 25cm2 (5 * 5 cm) on the left prefrontal cortex (F3) and cathodal or inhibitory electrode with dimensions of 25cm2 (5 * 5 cm) on the right prefrontal cortex (F4), It will be set at 1 mA for 20 minutes, then rested for 15 minutes and then the second phase of electrical stimulation will be applied exactly according to the previous protocol and for a duration of 10 sessions of treatment . In order to eliminate the carry-over effect and also the possibility of patients' exposure to other environmental stimuli, sessions with a time interval of 48 hours have been considered.

Category

Rehabilitation

2

Description

Intervention group: 2- CBT: Cognitive-behavioral therapy (CBT) sessions based on the matrix model include a 2-month treatment period containing 24 treatment sessions of 3 sessions per week with 45-minute period, individually or in groups of 4 to 12 for individuals in cognitive - behavior therapy experimental groups will be performed, which is as follows. These therapy sessions will be performed using the psychotherapy of dependence on stimulants (glass) with the matrix pattern. Title of treatment sessions includes, Session 1: Individual motivational feedback and evaluation of the benefits of quitting drugs for the individual. Session 2: Introducing High-Risk Situations and Triggers. Session 3: Introducing the recovery path and roadmap. Session 4 and 5: Introduction and diagnosis of external and internal starters. Sessions 6, 7 and 8: Identify major problems on the path to recovery, including: family distrust, reduced energy and power, misuse of drugs and other substances as alternatives. Sessions 9, 10 and 11: Dealing with the desire to use drugs (dealing with temptation) and the wrong ways to deal with temptation. Session 12: Dealing with negative thinking and identifying thoughts, feelings and precursor behaviors of consumption. Session 13: Identify the feelings and physical symptoms of depression and boredom. Session 14: Training on relapse prevention activities. Session 15: Introduction to relapse predisposing activities. Session 16: Examining employment and its role in the process of recovery. Session 17: Familiarity with feelings of shame and guilt and how to manage them. Session 18: The role of enjoyable and exciting activities in the daily routine. Session 19: How do we shape our motivation for recovery? Session 20: Introduction to truthfulness skills during recovery. Session 21: Learning problem-solving skills without the use of any drugs (complete purity). Session 22: Familiarity with the process of addictive sexual relations and its complications. Sessions 23 and 24: Identify behaviors related to recurrence and prevent them.

Category

Rehabilitation

3

Description
Intervention group: Combined group CBT and tDCS: Electrical stimulation intervention and cognitive-behavioral therapy will be applied simultaneously to individuals in this group as mentioned in interventions 1 and 2.

Category
Rehabilitation

4

Description
Control group: The control group will consist of 20 participants who will not receive any electrical intervention or cognitive behavioral therapy and all questionnaire and laboratory tests will be taken from them. Since this group is also an sham electrical intervention group, the tDCS device will be placed on their head with exactly the same conditions as the electrical intervention group, but no electric current will be applied to their skulls and the device will only be turned on and off once for them.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Farabi Hospital

Full name of responsible person
Vahid Farnia

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Farabi Hospital, at the beginning of Dolatabad Boulevard, Isar Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Tahereh Sadat Javadifar

Position
Post doc researcher

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

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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
Yes - There is a plan to make this available
Title and more details about the data/document
All personal data and consent and treatment protocol and statistical analysis map and clinical study report can be shared after unrecognizable individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
For all researchers interested in the subject of this study
Under which criteria data/document could be used
With the aim of continuing research and related research work
From where data/document is obtainable
Contact the Substance Abuse Research Center located in Farabi Hospital of Kermanshah University of Medical Sciences.
What processes are involved for a request to access data/document
First, contact the Substance Abuse Research Center located in Farabi Hospital of Kermanshah University of Medical Sciences, and then the person in charge of responding to this research will provide them with information.
Comments