Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of electrical extracranial stimulation of the brain (TDCS) combined with matrix psychotherapy in comparison with matrix psychotherapy alone in reducing cravings and improving cognitive functions in the methamphetamine withdrawal phase

Protocol summary

Study aim

This therapeutic method- that is used along with other common psychotherapies in stimulants addiction to evaluate the effectiveness of electrical stimulation of brain in controlling and reducing drug craving among methamphetamine addicts- can be considered as an effective method in methamphetamine addiction treatment. Accordingly, this study was conducted to examine effectiveness of brain electrical stimulation along with psychotherapy in reducing methamphetamine craving compared to the psychotherapy used alone.

Design

The clinical trial consists of three groups of 11, 8, and 9 individuals, not blinded, randomized.

Settings and conduct

Iranian Family Rehabilitation Center in Karaj

Participants/Inclusion and exclusion criteria

Inclusion criteria were as follows: patients who had referred to the common accommodation a, having at least 12-month experience of methamphetamine addiction based on the DSM-5 criteria, avoiding any drug or stimulant abuse except for cigarette, drug abuse in 6 days a week, consent signing of ethical form. Exclusion criteria included having any psychiatric disorder except for drug-related disorders, traumatic brain injuries، having metal implants inside the skull, mental retardation, organic brain disorder, having serious suicidal thoughts, receiving another medical or psychological intervention at the same time.

Intervention groups

11 patients of group 1 received tDCS with craving therapy protocol during 15 sessions; and 24 sessions of psychological therapy 8 patients in group received 15 sessions tDCS with craving treatment protocol through shame method and without effectiveness; they also received 24 sessions of psychological therapy 9 patients in group 3 just received 24 sessions of psychological therapy

Main outcome variables

Craving (outcome); Cognitive functions (outcome)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161026030510N3**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **retrospective**

Last update: **2020-09-29, 1399/07/08**
Update count: **0**

Registration date

2020-09-29, 1399/07/08

Registrant information

Name

Reza Arezoomandan

Name of organization / entity

Addiction Department, School of Behavioral Sciences and Mental Health (Institute of Tehran Psychiatr

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

2019-11-11, 1398/08/20

Actual recruitment end date

2020-03-20, 1399/01/01

Trial completion date

2020-05-10, 1399/02/21

Scientific title

Evaluation of the effectiveness of electrical extracranial stimulation of the brain (TDCS) combined with matrix psychotherapy in comparison with matrix psychotherapy alone in reducing cravings and improving cognitive functions in the methamphetamine withdrawal phase

Public title

Evaluation of the effectiveness of electrical extracranial stimulation of the brain (TDCS) combined with matrix psychotherapy in comparison with matrix psychotherapy alone in reducing cravings and improving cognitive functions in the methamphetamine withdrawal phase

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who had referred to the common accommodation and outpatient treatment center in order to quite methamphetamine addiction Having at least 12-month experience of methamphetamine addiction based on the DSM-5 criteria Drug abuse in 6 days a week, Avoiding any drug or stimulant abuse except for cigarette Age: 18-50, Consent signing of ethical form.

Exclusion criteria:

Having any psychiatric disorder except for drug-related disorders, Traumatic brain injuries (medium to severe) along with neurologic deficits or suffering from acute and unstable medical conditions that may put the patient at risk, Having metal implants inside the skull, mental retardation, organic brain disorder, having serious suicidal thoughts, Receiving another medical or psychological intervention at the same time.

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization performed with simple method and random numbers generated by computer software (Stat Trek) which choose the random numbers.Then, we consider the specific numbers for both groups for example: the even numbers are for experimental group and odd numbers are for 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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences,Shahid Hemmat Highway; Next to Milad Tower

City

Tehran

Province

Tehran

Postal code

14665-354

Approval date

2019-11-11, 1398/08/20

Ethics committee reference number

IR.IUMS.REC.1397.139

Health conditions studied

1

Description of health condition studied

Methamphetamine abusers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Craving Score in Craving questionnaire

Timepoint

Before and after the intervention

Method of measurement

Craving questionnaire or OCDUS - Obsessive Compulsive Drug Use Scale

2

Description

Working memory score in Wechsler subscale

Timepoint

Before and after the intervention

Method of measurement

The digit span subscale of Wechsler Intelligence Scale

3

Description

Cognitive function score in Wisconsin Scale

Timepoint

Before and after the intervention

Method of measurement

Wisconsin Test

Secondary outcomes

empty

Intervention groups

1

Description

Rreal tDCS: 11 patients in this group received tDCS with craving therapy protocol during 15 sessions; they also received 24 sessions of psychological therapy based on the matrix protocol. Therapeutic protocol of intervention group (real TDCS) included 2MA current for 20 minutes in form of DC current. In this research, the direct electrical current was received from an electric current generator that works with batteries then transferred to a pair of electrodes 5×7 (35 cm2). Carbon electrodes were placed inside the sponge coating impregnated with serum.The matrix protocol includes: a variety of psychological therapies for patients

Category

Rehabilitation

2

Description

Sham tDCS: 8 patients in group received 15 sessions tDCS with craving treatment protocol through shame method and without effectiveness (without informing the patient); they also received 24 sessions of psychological therapy based on the matrix protocol. The matrix protocol includes: a variety of psychological therapies for patients

Category

Rehabilitation

3

Description

Control group: 9 patients in group 3- as a control group- just received 24 sessions of psychological therapy based on the matrix protocol. The matrix protocol includes: a variety of psychological therapies for patients

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Family Rehabilitation Center

Full name of responsible person

Reza arezoomandan

Street address

North Taleghani Street

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Karaj

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Alborz

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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?

No

Title of funding source

.

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
Iran University of Medical Sciences

Full name of responsible person
Dr. Reza Arezoomandan

Position
Assistant Professor

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
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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Clinical and cognitive outcomes of patients after the intervention

When the data will become available and for how long
2020

To whom data/document is available
Researchers

Under which criteria data/document could be used
Researchers from all scientific centers

From where data/document is obtainable
Email

What processes are involved for a request to access data/document
Email - 3 Weeks

Comments