

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of effectiveness of Mindfulness-Based Substance Abuse Treatment for Adolescents (MBSAT) With and without Transcranial direct current stimulation (TDCS) on improve executive functions, emotional dysregulation, craving and attention bias in relation to the stimuli in adolescent with Substance use disorder

Protocol summary

Study aim

Determine the comparison of effectiveness of Mindfulness-Based Substance Abuse Treatment for Adolescents (MBSAT) With and without Transcranial direct current stimulation (TDCS) on improve executive functions, emotional dysregulation, craving and attention bias in relation to the stimuli in adolescent with Substance use disorder

Design

The method of this study is a clinical trial with pretest-post test and follow-up with the control group.

Settings and conduct

After coordination with the well-being of Ardabil province, the plan begins.

Participants/Inclusion and exclusion criteria

Include criteria (age range of 18 to 21 years; diagnosis of substance use disorder based on DSM5 criteria; being male); and Exclude criteria (use of psychiatric medications ; diagnosis bipolar mood disorder or psychotic disorder Based on DSM5 criteria, intracranial implants and epileptic seizures.

Intervention groups

Three experimental groups (therapeutic groups) and one control group.

Main outcome variables

Executive Functions, Emotional Dysregulation, Craving and Attention Bias in relation to the stimuli

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181013041327N1**

Registration date: **2019-09-01, 1398/06/10**

Registration timing: **retrospective**

Last update: **2019-09-01, 1398/06/10**

Update count: **0**

Registration date

2019-09-01, 1398/06/10

Registrant information

Name

jaber Alizadehgoradel

Name of organization / entity

The University of shahid beheshti

Country

Iran (Islamic Republic of)

Phone

+98 45 3325 0055

Email address

j.alizadeh45@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of Mindfulness-Based Substance Abuse Treatment for Adolescents (MBSAT) With and without Transcranial direct current stimulation (TDCS) on improve executive functions, emotional dysregulation, craving and attention bias in relation to the stimuli in adolescent with Substance use disorder		Ethics committee of Shahid Beheshti University	
Public title		Street address	
Study the effect of tdcS and treatment of mindfulness in substance abuse disorder		Institute of Cognitive and Brain Sciences , Shahid Beheshti University, Shahid Shahriari Square, Shahid Chamran Highway, Tehran	
Purpose		City	
Treatment		Tehran	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Tehran	
Age range 18 to 21 years Detection of substance abuse disorder based on DSM5 criteria Be a boy		Postal code	
Exclusion criteria:		1983969411	
Taking psychiatric medications Diagnosis of bipolar mood disorder or psychotic disorder based on DSM5 criteria Intracranial implants History of epilepsy and seizure		Approval date	
Age		2018-12-01, 1397/09/10	
From 18 years old to 21 years old		Ethics committee reference number	
Gender		97/1036.IR.SBU.ICBS	
Male		Health conditions studied	
Phase		1	
N/A		Description of health condition studied	
Groups that have been masked		Substance use disorder	
No information		ICD-10 code	
Sample size		F19	
Target sample size: 80		ICD-10 code description	
Randomization (investigator's opinion)		Other psychoactive substance related disorders	
Randomized		Primary outcomes	
Randomization description		1	
For small study, you can use random digits table to sort people in groups.to use the random digits table, the participants in the study will be given a code or machine gun number, respectively. As many as 80 people will be selected. So the assigned codes and numbers will be two digits. To select sample individuals from the table, it will randomly start from a table point in the row or column direction. also,Individuals are randomly assigned to one of four study groups with the help of a random number table and receive the intervention of the same group.		Description	
Blinding (investigator's opinion)		Executive Functions	
Not blinded		Timepoint	
Blinding description		Before the intervention, after the intervention and three weeks after the intervention	
Placebo		Method of measurement	
Not used		Wisconsin card sorting test, N-Back Test, Go/ No Go Task, Balloon Analogue Risk Taking Task	
Assignment		2	
Parallel		Description	
Other design features		Emotional Dysregulation	
		Timepoint	
		Before the intervention, after the intervention and three weeks after the intervention	
		Method of measurement	
		DERS	
Secondary Ids		3	
empty		Description	
		Craving	
Ethics committees		Timepoint	
1		Before the intervention, after the intervention and three weeks after the intervention	
Ethics committee		Method of measurement	
Name of ethics committee		Craving Questionnaire(Franken & etal)	

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Description

Attention Bias in relation to the stimuli

Timepoint

Before the intervention, after the intervention and three weeks after the intervention

Method of measurement

Dot-Probe Task

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindfulness-Based Substance Abuse Treatment for Adolescents (MBSAT) With Transcranial direct current stimulation (TDCS):The Package of Mindfulness Therapy (Hamletstein & Saul, 2016) will be done in 12 sessions. Also, in the treatment of dTDCS, the dlpc region will be stimulated by an active dose of 1/5 MA.

Category

Rehabilitation

2

Description

Intervention group: Mindfulness-Based Substance Abuse Treatment for Adolescents (MBSAT) Without Transcranial direct current stimulation (TDCS): This group will only have a healing mindfulness package (Hamletstein & Saul, 2016) during 12 sessions of therapy.

Category

Rehabilitation

3

Description

Intervention group: Transcranial direct current stimulation (TDCS): This group will receive only tdc stimulation therapy.

Category

Rehabilitation

4

Description

sham group: receiving sham tdc

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Welfare Aedebil province

Full name of responsible person

Behzad Sattari

Street address

Street of Shahid Vadood sad sale, Hafez Township

City

Ardabil

Province

Ardabil

Postal code

5615711116

Phone

+98 45 3371 2851

Email

b_sattari@sbu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cognitive Science and Technologies Council

Full name of responsible person

Mohammad Rostami

Street address

No 35, West Alvand, Argantin Square

City

Tehran

Province

Tehran

Postal code

15948

Phone

+98 21 8819 4956

Email

info@cogc.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Cognitive Science and Technologies Council

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

The University of Shahid Beheshti

Full name of responsible person

Jaber Alizadeh Goradel

Position

PHD Student Of Clinical Psychology

Latest degree

Master

Other areas of specialty/work

Addiction

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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

A behavioral data file, a study protocol, a informed consent form, and a clinical study report after unidentifiable individuals can be shared.

When the data will become available and for how long

The beginning of the access period is 1 year after the publication of the results.

To whom data/document is available

The behavioral data of this research will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use of data is permitted only for articles related to the field of addiction.

From where data/document is obtainable

Jaber Alizadeh Goradel, j.alizadeh45@gmail.com

What processes are involved for a request to access data/document

Researchers who want to access the data should receive a letter from the university at their place of work and send it to the responsible person's email address, in which case the data will be available to them in less than one month.

Comments