

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of transcranial direct electrical stimulation of the brain (tDCS) with cognitive rehabilitation on selective attention, cognitive flexibility, response inhibition and craving in drug addicts undergoing maintenance treatment.

Protocol summary

Study aim

Comparison of the effectiveness of transcranial direct electrical stimulation of the brain (tDCS) with cognitive rehabilitation on selective attention, cognitive flexibility, response inhibition and craving in drug addicts undergoing maintenance treatment.

Design

A clinical trial with a control group with parallel groups, a blind strain, randomized on 45 patients, which was used for its randomization in the division of groups by lottery method.

Settings and conduct

In terms of data collection, it will be semi-experimental with a pre-test and post-test design with two experimental groups and one control group. The statistical population of the research includes all people suffering from substance abuse disorder who are being treated in the maintenance treatment centers with agonists in the city of Semnan in the first six months of 1402. A cluster sampling method will be used in the selection of subjects. Three centers will be selected from the centers of Semnan city and 15 people from each center will be randomly assigned to two test groups and one control group.

Participants/Inclusion and exclusion criteria

The criteria for entering the research include age between 18 and 60 years, at least two months have passed since the beginning of treatment, not receiving other psychological interventions, a negative test for drug use, not having or having a history of epilepsy, mental retardation, and having at least a high school diploma. .

Intervention groups

Experiment group A will receive ten sessions of transcranial electric current stimulation. The experimental group will receive ten sessions of cognitive

rehabilitation, the control group will continue their usual treatment program and will not receive any other intervention.

Main outcome variables

Selective attention, cognitive flexibility, response inhibition and craving

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230730058968N1**

Registration date: **2023-09-05, 1402/06/14**

Registration timing: **retrospective**

Last update: **2023-09-05, 1402/06/14**

Update count: **0**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name

Somayeh Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4231

Email address

researcher6411@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15
Expected recruitment end date
 2023-08-16, 1402/05/25
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison of the effectiveness of transcranial direct electrical stimulation of the brain (tDCS) with cognitive rehabilitation on selective attention, cognitive flexibility, response inhibition and craving in drug addicts undergoing maintenance treatment.

Public title
 Comparison of the effectiveness of transcranial direct electrical stimulation of the brain (tDCS) with cognitive rehabilitation in the treatment of drug addicts undergoing maintenance treatment.

Purpose
 Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 At least two months have passed since the start of treatment
 End of induction and stabilization period
 Negative drug test
 Having at least a high school diploma
 Written consent to enter the research
Exclusion criteria:
 Receiving other psychological interventions
 Having or having a history of epilepsy or other brain diseases and psychosis
 Mental retardation
 Taking drugs or anti-anxiety drugs

Age
 From **18 years** old to **60 years** old

Gender
 Male

Phase
 N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
 Target sample size: **45**

Randomization (investigator's opinion)
 Randomized

Randomization description
 To allocate people in the study groups, the dice throwing method was used so that the numbers 1 and 2 are for the placement of people in the tDCS treatment group, the numbers 3 and 4 are for the placement of people in the cognitive rehabilitation group and the numbers 5 and 6 are for the placement of people in the the control group was defined.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 In this study, the members of the medical centers from which the patients were selected, as well as the two

people who evaluated and completed the tools used in the research, were kept blind to the allocation of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Due to the fact that in this study, the participants receive one of cognitive rehabilitation interventions or direct transcranial electrical stimulation of the brain, it was not possible to blind the participants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University, Semnan branch

Street address

Islamic Azad University, Semnan Branch, Faculty of Humanities, Department of Psychology

City

Semnan

Province

Semnan

Postal code

3513137111

Approval date

2023-06-21, 1402/03/31

Ethics committee reference number

IR.IAU.SEMNAN.REC.1402.023

Health conditions studied

1

Description of health condition studied

Addicts undergoing maintenance treatment

ICD-10 code

F11.2

ICD-10 code description

Opioid dependence

Primary outcomes

1

Description

Selective attention

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

Stroop test

2

Description

Cognitive flexibility

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

Dennis and Vander Waal (2010) cognitive flexibility questionnaire (CFI)

3

Description

Response inhibition

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

go / no go test

4

Description

Craving

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

Craving intensity test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: experimental group A will receive ten sessions of transcranial electric current stimulation. Intervention with OASIS PRO WITH tDCS device from MIND ALIVE company was used. Subjects in this group participated in treatment sessions every other day for ten sessions. Anode electrode was placed in the posterolateral region of the left prefrontal cortex and cathode electrode was placed in the posterolateral region of the right prefrontal cortex, and in each session for 20 minutes, a current of 2 milliamps of direct electric current was passed through the skull of the subjects.

Category

Treatment - Devices

2

Description

Intervention group: The experimental group received ten sessions of cognitive rehabilitation, which used Nejati's cognitive rehabilitation computer program (2010), which includes strengthening working memory, strengthening selective attention, strengthening sustained attention, and strengthening transitional attention. It was

performed in 10 sessions of 30 minutes and 3 sessions per week

Category

Treatment - Other

3

Description

Control group: The control group will continue their usual treatment program and receive no other intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Clinic

Full name of responsible person

Hamid Eghbali

Street address

Ferdows Garden, above three roads of Valiasr

City

Semnan

Province

Semnan

Postal code

3519684713

Phone

+98 23 3334 1401

Email

esmaeili.afsaneh64@yahoo.com

2

Recruitment center

Name of recruitment center

Sadid Center

Full name of responsible person

Ali Asghar Jalali

Street address

Prophet Azam settlement, Noor Square, Fazilat Boulevard, Sadid center

City

Semnan

Province

Semnan

Postal code

7967499351

Phone

+98 23 3345 6895

Email

mjr.psychology@gmail.com

3

Recruitment center

Name of recruitment center

Noor Clinic

Full name of responsible person

Amir Masoud Tartib Godarzi

Street address

Noor Clinic, Shahada Square, 17 Shahrivar St., Imam Hossein St

City

Semnan

Province

Semnan

Postal code

351835646

Phone

+98 23 3342 3519

Email

esmaeili.afsaneh64@yahoo.com

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Islamic Azad University, Semnan Branch, Faculty of Humanities, Department of Psychology

City

Semnan

Province

Semnan

Postal code

3513137111

Phone

+98 23 3365 4231

Fax**Email**

researcher6411@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Arezoo Tahan

Street address

Kilometer 5 of Damghan Road, Islamic Azad University, Semnan branch

City

Semnan

Province

Semnan

Postal code

۳۷۱۱۳۵۱۳۱

Phone

+98 23 3165 6565

Email

info@semnaniau.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Somayeh Bagheri

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Somayeh Bagheri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Islamic Azad University, Semnan Branch, Faculty of Humanities, Department of Psychology

City

Semnan

Province

Semnan

Postal code

3513137111

Phone

+98 23 3365 4231

Fax**Email**

researcher6411@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Somayeh Bagheri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Islamic Azad University, Semnan Branch, Faculty of
Humanities, Department of Psychology

City

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Province

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Postal code

3513137111

Phone

+98 23 3365 4231

Fax

Email

researcher6411@gmail.com

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 can be shared after de-identifying individuals

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

The data will be available to researchers working in
scientific and academic institutions

Under which criteria data/document could be used

Data will be accessible for analyzes related to review
studies and meta-analysis

From where data/document is obtainable

To receive documents, you can contact
researcher6411@gmail.com

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

The authorized data file will be available to the
applicants as soon as they see the message in the e-
mail, within a week

Comments