

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the effectiveness of direct electrical brain movement and cognitive-behavioral therapy in executive function and consumption in individuals with substance abuse

#### Protocol summary

##### Study aim

The aim of this study was to compare the effectiveness of motor, brain and cognitive-behavioral therapy in executive functions and consumption in individuals with substance abuse.

##### Design

A clinical trial with two control groups and one control group, with parallel, randomized groups, on 45 patients. To do this, a random block sequencing website is used.

##### Settings and conduct

Statistical population: All men who abuse drugs in the 15th district of Tehran in 1400 who referred to addiction treatment and rehabilitation centers in 1399-1400. The sample of the present study was selected from the statistical population using the available sampling method and considering the criteria for entering and leaving the research. The sampling method was non-random and purposeful. 45 men who met the entry criteria for the study were identified and divided into three groups of 15, namely two experimental groups and a control group by random assignment.

##### Participants/Inclusion and exclusion criteria

Entry criteria: Completion of informed consent form, age range 20 to 40 years, opioid dependence, constant amount of medication (methadone, buprenorphine, etc.) until the end of the project, having an up-cycle education, being right-handed  
Exit criteria: History of subcortical direct electrical stimulation of the brain for any disorder, acute or chronic physical and psychological disorders other than addiction, non-opioid dependence, history of seizures or head trauma, having a tummy tuck or implant with a skull, left hand on hand

##### Intervention groups

Direct brain electrical stimulation intervention was performed on one of the experimental groups and cognitive-behavioral intervention was performed on the other experimental group. The intervention was not

performed on the control group and pre-test and post-test were taken.

##### Main outcome variables

Executive functions; Craving consumption

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220518054902N1**

Registration date: **2022-05-28, 1401/03/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-28, 1401/03/07**

Update count: **0**

##### Registration date

2022-05-28, 1401/03/07

##### Registrant information

##### Name

Mohammad Entezamimehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3392 7727

##### Email address

email4m.mehr@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-22, 1401/03/01

##### Expected recruitment end date

2022-08-23, 1401/06/01

##### Actual recruitment start date

2022-05-22, 1401/03/01  
**Actual recruitment end date**  
2022-08-23, 1401/06/01  
**Trial completion date**  
2022-08-23, 1401/06/01

**Scientific title**  
Comparison of the effectiveness of direct electrical brain movement and cognitive-behavioral therapy in executive function and consumption in individuals with substance abuse

**Public title**  
Comparison of the effectiveness of direct electrical brain movement and cognitive-behavioral therapy in executive function and consumption in individuals with substance abuse

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Completion of informed consent form, age range 20 to 40 years, opioid dependence, constant amount of medication (methadone, buprenorphine, etc.) until the end of the project, having an up-cycle education, being right-handed  
**Exclusion criteria:**

**Age**  
From **20 years** old to **40 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **45**  
Actual sample size reached: **45**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
A clinical trial consisting of two control groups and a control group, with parallel, randomized groups, on 45 patients. For random allocation, the block-making method (quadruple blocks) is used. A list of blocks is written and numbers are assigned to them, and finally the treatment allocation list is determined based on random numbers. To do this, a random block sequencing website is used. Random block sequencing is provided to a specific person outside the research team who is responsible for random allocation.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Both experimental groups for blinding in 10 sessions, one group participates in cognitive-behavioral therapy sessions and the other group participates in sessions of electrical stimulation of the brain, and the control group does not receive any intervention. Attempts are made to schedule the meetings in such a way that the members of the control and intervention group do not collide with

each other and are not informed about the content of each other's meetings. Also, the participant is not aware of the result.

**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Islamic Azad University- Arak Branch

##### Street address

No. 47, Eighth floor, Industry building, Zahiralaslam St., Jomhory St, Tehran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1146835785

#### Approval date

2022-05-21, 1401/02/31

#### Ethics committee reference number

IR.IAU.ARAK.REC.1401.027

## Health conditions studied

### 1

#### Description of health condition studied

People with a history of substance abuse

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Direct electrical stimulation of the brain, Cognitive-behavioral therapy

#### Timepoint

3 month

#### Method of measurement

Therapeutic intervention of electrical stimulation of the brain, cognitive-behavioral therapy protocol

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Direct electrical stimulation period of the brain: twice a week on Sundays and Thursdays for 5 consecutive weeks as follows. How to hold meetings. The treatment plan will be the same in all 10 sessions of intervention in terms of type, severity and duration of stimulation. During the treatment sessions, the subject will sit on a comfortable chair, then according to the standard system of 10 to 20 electroencephalography reported by Jasper, points will be identified on the subject's head and the anode electrode on the lateral dorsal lateral cortex and the cathode electrode on the lateral dorsal cortex. His right forehead will be placed and applied with a pair of sponge electrodes measuring 3.5 cm of direct current generated by a current of 2 mA with 30 seconds of up and down for 20 minutes. During the stimulation, the subject sits on a chair and does not perform a specific task.

#### Category

Treatment - Other

### 2

#### Description

Group cognitive-behavioral therapy will be based on Beck theory's cognitive-behavioral therapy. This intervention will be taught in 10 sessions as follows: Session 1: initial acquaintance and establishing a therapeutic relationship, raising the main complaints of women, brief introduction of the type of treatment, collaborating with the research sample in determining the goals of the treatment protocol, determining the relationship between cognition, Emotion and behavior, choosing goals and identifying goals and agreeing on homework, recording life events. Session 2: Formulation of general problems of addicts in the form of cognitive-behavioral model, integration of cognitive triangle in treatment strategies, use of standard behavioral activation techniques , Redesigning negative spontaneous thoughts and presenting dysfunctional thoughts record sheet. Session 3: Continuing to work with spontaneous thoughts, examining patients' dysfunctional thoughts record sheets, challenging spontaneous thoughts by Socrates method. Session 4: Recognizing underlying beliefs and how to activate them in situations Specifically, the use of downward arrow technique, review of some of the patients' target issues. Session 5: Developing awareness of underlying beliefs, strengthening positive self-talk, using behavioral techniques to replace positive thoughts instead of negative thoughts. Session 6: Use of cognitive-behavioral techniques about daring, Problem Solving and Teaching Social Skills to Addicts Session 7: Identify more unconditional and nuclear beliefs, weaken unconditional beliefs by questioning them in a Socratic manner, and rate negative beliefs on a scale of 0 to 100. Session 8: Continued Generating and developing alternative positive beliefs through the development of social and communication skills, developing problem-solving skills

and courageous behaviors, grading alternative thoughts, preparing to apply the methods learned in future life situations. Session 9: Skills training Communication, group discussion, supplementary activities, teaching effective verbal response style and active listening skills. Session 10: Teaching self-control and alertness skills, group discussion, providing complementary activities and post-test.

#### Category

Treatment - Other

### 3

#### Description

Control group:

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Addiction Treatment and Rehabilitation Centers, District 15, Tehran

##### Full name of responsible person

Mohammad Entezamimehr

##### Street address

No. 47, Eighth floor, Industry building, Zahiralaslam St., Jomhory St, Tehran.

##### City

Tehran

##### Province

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##### Postal code

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##### Phone

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##### Email

Email4m.mehr@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic azad university, arak branch

##### Full name of responsible person

Mohammad Entezamimehr

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No. 47, Eighth floor, Industry building, Zahiralaslam St., Jomhory St, Tehran.

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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**

Islamic azad university, Arak branch

**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**

Islamic azad university, arak branch

**Full name of responsible person**

Mohammad Entezamimehr

**Position**

M.A. student in clinical psychology

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic azad university, arak branch

**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic azad univrsty, arak branch

**Full name of responsible person**

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**Position**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Because of moral issues

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available