

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the Effect of Transcranial Direct Current Stimulation and Circuit Training on Drug Craving, Impulsivity, and Risky Decision-Making in Females with Drug Dependency during Rehabilitation Period

Protocol summary

Study aim

Evaluating the Effect of Exercise Training and Transcranial Direct Current Stimulation on Drug Craving, Impulsivity, Risky Decision-making, Pleasure Sensation, and Arousal in Females with Drug Dependency

Design

A within-subject, counterbalanced by the use of Latin Square, and double-blind study. 16 subjects will be exposed to 4 different conditions.

Settings and conduct

This study will be conducted at Razi University, Kermanshah. After selecting the subjects and familiarization, each subject will be exposed to 4 different conditions of the combination of exercise training and brain stimulation in a random order. Study variables will be measured before and after training and brain stimulation.

Participants/Inclusion and exclusion criteria

Inclusion: Aged between 18 to 50 years Resident of Kermanshah Not taking drugs for 2 to 12 months Being right handed History of drug abuse and being in the phase of rehabilitation Absence of physical drug dependency (participating in detoxification) Getting the certification of no prohibition of participating in the exercise training program from a specialist Exclusion: History of seizures, epilepsy, or other neurological diseases Existence of implantable devices or pacemakers in the body Tobacco and alcohol consumption Existence of ant musculoskeletal disorders Participation in regular exercise training program in last 6 months

Intervention groups

In this within-subject and counterbalanced study, participants will be exposed to 4 different conditions including 1) exercise+anodal brain stimulation, 2) exercise+ sham stimulation, 3) anodal brain stimulation, and 4) sham stimulation for 20 minutes and 2 milliamperes intensity.

Main outcome variables

Changes in drug craving, impulsivity, risky decision-making, pleasure sensation, and arousal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210617051606N8**

Registration date: **2023-02-09, 1401/11/20**

Registration timing: **prospective**

Last update: **2023-02-09, 1401/11/20**

Update count: **0**

Registration date

2023-02-09, 1401/11/20

Registrant information

Name

Ehsan Amiri

Name of organization / entity

Razi University

Country

Iran (Islamic Republic of)

Phone

+98 83 3845 8428

Email address

e.amiri@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-15, 1401/11/26

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Effect of Transcranial Direct Current Stimulation and Circuit Training on Drug Craving, Impulsivity, and Risky Decision-Making in Females with Drug Dependency during Rehabilitation Period

Public title
Effects of exercise training and brain stimulation on drug dependency

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Aged between 18 to 50 years Resident of Kermanshah
 Not taking the drug for 2 to 12 months Being right handed History of drug abuse and being in the phase of rehabilitation Absence of physical drug dependency (participating in detoxification) Getting the certification of no prohibition of participating in the exercise training program from a specialist
Exclusion criteria:
 History of seizures, epilepsy, or other neurological diseases Existence of implantable devices or pacemakers in the body Tobacco and alcohol consumption Existence of ant musculoskeletal disorders Participation in regular exercise training program in last 6 months

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the order of subjects' exposure to 4 different conditions will be randomized by the Latin Squares method. To do so, first, using the www.random.org website, a number between 1 and 16 will be randomly allocated to each subject as an identification code. Then, the English letters A, B, C, and D will be assigned to the four intervention conditions and a Latin Square will be created. In this case, a Latin square with four rows and four columns is created. Finally, participants number 1 to 4 will be placed in the sequence of the first row, participants number 5 to 8 will be placed in the sequence of the second row, participants number 9 to 12 will be placed in the sequence of the third row and, participants number 13 to 16 will be placed in the sequence of the fourth row.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind study, the investigator and the participants will be blinded to the type of transcranial electrical stimulation used in the four experimental conditions. In the current study, the Neurostim stimulation device will be used to induce direct current electrical stimulation in two types including 1) anodal and 2) sham in four experimental conditions. For this purpose, an individual outside the research team who is thoroughly familiar with using the brain stimulation device will be responsible for applying the stimulation in experimental sessions. In order to blind the participants, after they sit on a special chair, the stimulating device is hidden from their view and is completely covered by a cover, and the electrodes are placed on the desired areas by the examiner. In order to blind the researcher, the induction of brain stimulation will be done without the presence of the researcher and the relevant information will be available to the same person outside the research team. Also, in the sham stimulation mode, according to standard protocols, the active current is induced on the head for 30 seconds to induce the same sensation as the active stimulation mode. Then the current is cut off and the stimulation is deactivated, but the electrodes will remain on the head until the end of the same time as the anodal stimulation.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Research Ethics Committees of Kermanshah Razi University
Street address
 Room. 73, Faculty of Sport Sciences, Razi University, University Str, Taq-e-bostan, Kermanshah, Iran
City
 Kermanshah
Province
 Kermanshah
Postal code
 6714414971
Approval date
 2022-04-27, 1401/02/07
Ethics committee reference number
 IR.RAZI.REC.1401.015

Health conditions studied

1

Description of health condition studied

Drug abuse

ICD-10 code

Z71.5

ICD-10 code description

Drug abuse counseling and surveillance

Primary outcomes

1

Description

Changes in drug craving

Timepoint

Before and after interventions

Method of measurement

Drug craving standard questionnaire

2

Description

Changes in impulsivity

Timepoint

Before and after interventions

Method of measurement

Go/ No Go cognitive test software

3

Description

Risky decision-making

Timepoint

Before and after interventions

Method of measurement

IOWA gambling cognitive test software (This name is not an abbreviation and is the original name of the test)

Secondary outcomes

1

Description

Changes in pleasure sensation

Timepoint

Before and after interventions

Method of measurement

11-point pleasure sensation scale

2

Description

Changes in arousal

Timepoint

Before and after interventions

Method of measurement

6-point felt arousal scale

Intervention groups

1

Description

Intervention group: In this study, all the subjects were exposed to three intervention conditions with an interval of at least one week in between. These conditions include 1) circuit training+ anodal stimulation of the dorsolateral prefrontal cortex, 2) circuit training+ sham stimulation, and 3) anodal stimulation of the dorsolateral prefrontal cortex. Circuit training will consist of a standard 5-7 minute warm-up followed by 4 sets of circuit training. Each set consists 8 stations including bodyweight squats, crawls, bench dips, frog jumps, sit-ups, push-ups, moving lunges, and back hyperextensions. Subjects will perform the prescribed exercise for 40 seconds at each station. Subjects will be asked to do their best in 40 seconds to perform the prescribed exercise correctly and as much as possible. There will be a 20 second rest between each station. 20 minutes with 2 milliamperes will be used to stimulate the target area in the brain. For this purpose, the Neurostim stimulation device manufactured by Medina Teb Company will be used. The target area in the brain is identified using the international brain mapping system 10-20 and the target area is stimulated using two special stimulation electrodes and a special electroencephalogram cap. In intervention conditions, the study variables will be measured before interventions, and then the subjects will receive brain stimulation and then perform the prescribed exercise. After the end of the exercise, the study variables are measured again.

Category

Treatment - Devices

2

Description

Control group: In this study, in addition to three intervention sessions, all subjects were exposed to a control session including sham electrical brain stimulation (placebo effect). All details of the control session will be similar to the intervention sessions, except that in the control session, the brain is not electrically stimulated and the electrical current of the stimulator device will be deactivated after 30 seconds. The duration of control conditions will also be 20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Sport Sciences of Razi University

Full name of responsible person

Ali Heirani

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Razi University

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

Razi University

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**

Razi University

Full name of responsible person

Ehsan Amiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No. 73, Faculty of Sport Sciences, Razi University,
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Razi University

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

All data are shared after the de-identification of the
participants

**When the data will become available and for how
long**

3 months after publication

To whom data/document is available

All individuals upon formal request

Under which criteria data/document could be used

Data sharing requests are accepted for any purposes

From where data/document is obtainable

To obtain any data/documents, please send an e-mail to
Ehsan Amiri, a faculty member at Razi University,
through the following e-mail address: e.amiri@razi.ac.ir

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

Upon formal request, mentioning due reasons, and
providing full personality details, data will be sent after
72 h via e-mail

Comments