Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 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

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Iran (Islamic Republic of)

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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

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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
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Full name of responsible person
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b.mostafaei@razi.ac.ir
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
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Position
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Person responsible for updating data

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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