Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of direct electrical stimulation of the brain (TDCS) and cognitive-behavioral therapy (CBT) in reducing cravings, mood and smoking dependence

Protocol summary

Study aim
Comparison of the effectiveness of direct electrical stimulation of the brain (TDCS) and cognitive-behavioral therapy (CBT) in reducing cravings, mood, and smoking dependence

Design
A controlled clinical trial with parallel, randomized, phase 2 groups on 12 patients. Excel software rand function was used for randomization.

Settings and conduct
Three treatment centers in Mashhad are randomly connected to the intervention and control groups and to the intervention group of the TDSM device and to the control group of cognitive-behavioral therapy (CBT).

Participants/Inclusion and exclusion criteria
Admission requirements: Men who are heavily dependent on smokers and have been referred to a medical center Conditions of non-entry: History of using psychiatric drugs

Intervention groups
Intervention group: Direct current cranial wall stimulation (tDCS): Each session is for 20 sessions of 30 to 30 minutes according to the treatment protocol and after attaching the cathode and Andy to the test head, stimulate the lateral dorsal region of the prefrontal lobe. we do. 2 mA current Cognitive-Behavioral Therapy Control Group (CBT): Each session will receive cognitive-behavioral therapy for 9 sessions of 1 to 1.5 hours, depending on the treatment process.

Main outcome variables
Cigarette cravings Nicotine addiction test (FTND) and positive and negative emotion scale test (PNAS) are taken before and after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101130005280N51**
Registration date: **2022-04-08, 1401/01/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-08, 1401/01/19**
Update count: **0**

Registration date
2022-04-08, 1401/01/19

Registrant information

Name
Raheleh Nejati

Name of organization / entity
Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country
Iran (Islamic Republic of)

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+98 51 3711 2540

Email address
nejatir2@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-25, 1401/01/05

Expected recruitment end date
2022-08-27, 1401/06/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of direct electrical stimulation of the brain (TDCS) and cognitive-behavioral therapy (CBT) in reducing cravings, mood and smoking dependence

Public title
Comparison of the effectiveness of direct electrical electrical stimulation (TDCS)
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
People addicted to cigarettes male gender
Exclusion criteria:
History of mental illness and use of psychiatric drugs
Age
From **18 years** old to **40 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **12**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done in a simple way using a random number table using the site www.randomization.com. The numbers will be placed in sealed envelopes and when the participants enter, each envelope will be assigned to one of the two groups. The people in even pairs are the control group and the people
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ferdowsi University of Mashhad
Street address
Ferdowsi University of Mashhad, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948974
Approval date
2022-01-30, 1400/11/10
Ethics committee reference number
IR.UM.REC.1400.358

Health conditions studied

1

Description of health condition studied
direct electrical stimulation of the brain (TDCS) and cognitive-behavioral therapy (CBT) in reducing cravings, mood and smoking dependence
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Tendency to smoke
Timepoint
Before and after the treatment program
Method of measurement
Fagstrom Nicotine Dependence Test (FTND), Positive and Negative Emotion Scale (PNAS) and Smoking Tendency Questionnaire (UTS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 6 patients in TDCS treatment of direct current cranial wall stimulation (tDCS): each session according to the treatment protocol is for 10 sessions of 20 to 30 minutes and after connecting the cathode and Andy to the test head of the lateral dorsal region We stimulate the prefrontal lobe. Device name: TDS current intensity 2 mAh. All subjects will respond to the Fagstrom Nicotine Dependence Test (FTND), the Positive and Negative Emotion Scale (PNAS), and the Smoking Attitude Questionnaire (UTS) before and after treatment.
Category
Treatment - Other

2

Description
Control group: 6 people in Cognitive-Behavioral Therapy (CBT): Each session will receive 1 to 1.5 hours of cognitive-behavioral therapy for 9 sessions according to the treatment process, so that the subject of session 1 is to create and maintain motivation for change. Session 2: Identifying and coping with motivating situations,

Session 3: Tackling temptation, Session 4: Refusal skills, social situation management and courage ..., Session 5: Making wise decisions when choosing, Session 6: Problem solving, Session 7 is lifestyle modification and coping with boredom, the topic of Session 8 is the management of boredom and boredom and the topic of Session 9 is prevention of recurrence, maintaining stability and termination of treatment. PNAS and Smoking Questionnaire (UTS) will answer before and after treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers in Mashhad

Full name of responsible person

Hossein Share

Street address

Mashhad University Street

City

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Razavi Khorasan

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345 -91357

Phone

+98 51 3711 2701

Email

raikaravan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Province

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GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Share

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

Full name of responsible person

Hossein Share

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hossein Share
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available