

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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)

Phone

+98 51 3711 2540

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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 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

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Mashhad University Street

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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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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****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

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

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Hossein Share

Position

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Phone**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