

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the trans-cranial Direct Current Stimulation (tDCS) and Bupropion on treatment of nicotine-dependent smokers.

Protocol summary

(QEEG)

Study aim

compare the efficacy of transcranial Direct Current Stimulation with bupropion in the treatment of nicotine addicts

Design

Five arm parallel group randomized sham-controlled trial with blinded participants and outcome assessors.

Settings and conduct

Bupropion treatment starts at 150 mg for one week, then 300 mg for 8 weeks, and stopping cigarettes will begin in the second week of intervention started. the position of the anode and the cathode in accordance with the standard location of the 20/20, anode is F3, and cathode is F4. The stimulation intensity in the active stimulation group is 2 mA for 20 minutes and in the sham groups is only 30 seconds. The electrodes used in these groups were made of carbon and inside the salt-impregnated sponge with an anode size of 35 and a cathode of 100 centimeters. The outcomes will be measured at the baseline (1), end of interventions (2) and the end of six months of follow up (3), and point abstinence prevalence will be compared with drug therapy A at this time. The follow up period is the same for all groups and is 6 months from the start of the intervention.

Participants/Inclusion and exclusion criteria

participants of this study select with the public invitation from right-handed 15 - 65 years old smokers, that nicotine addicted according to DSM 5.

Intervention groups

These study interventions included 5 groups: 1) Bupropion medication, 2) Active tDCS (20 sessions/4 weeks), 3) Sham tDCS (20 sessions/4 weeks), 4) Active tDCS (20 sessions/12 weeks) and 5) Sham tDCS (20 sessions/12 weeks).

Main outcome variables

the outcomes of this study consist of Salivary Cotinine, Fagerstrom Test of Nicotine Dependence (FTND), Cigarette Per Day (CPD), Tobacco Craving Questionnaire-Short Form and Quantitative Electroencephalogram

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072629093N1**

Registration date: **2016-12-25, 1395/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-18, 1397/03/28**

Update count: **1**

Registration date

2016-12-25, 1395/10/05

Registrant information

Name

Shahram Ghorbani Behnam

Name of organization / entity

Shahroud University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shahrud University of Medical Sciences

Expected recruitment start date

2016-11-22, 1395/09/02

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

2016-12-05, 1395/09/15

Actual recruitment end date

2017-12-08, 1396/09/17

Trial completion date

empty

Scientific title

Comparison of the trans-cranial Direct Current Stimulation (tDCS) and Bupropion on treatment of nicotine-dependent smokers.

Public title

Effect of transcranial Direct Current Stimulation (tDCS) in cigarette smokers treatment.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Right-handed, 15 to 65 years old smokers who are nicotine addicted according to DSM-5

Exclusion criteria:

Other substances use (heroin, amphetamines, cannabis) psychiatric diseases (Depression, Bipolar Mood Disorders, ...) physical disease (brain tumors, seizure attacks, ...) drug use containing calcium, sodium, potassium Other tobacco use, such as chops and hookahs

Age

From **15 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **175**

Actual sample size reached: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, for random sequencing generation, random allocation rule from restricted randomization with similar spheres was done, which was designed by a team of analyzers of the research group. In order to allocation concealment sequentially numbered, sealed, opaque envelopes were used that were kept by our research center reception and were implemented by them, and thus, participants were assigned in their groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The method of the blindness of this study was that all interventions were performed by the researcher and carried out tests, recorded results and analyzed by other research partners. So that the intervener was unaware of the outcome of the interventions, and other research partners were unaware of the types of interventions of each group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahrud Medical University

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Shahroud University of Medical Sciences, Haftetir square

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Approval date

2016-07-26, 1395/05/05

Ethics committee reference number

ir.shmu.rec.1395.75

Health conditions studied**1****Description of health condition studied**

Nicotine dependence in cigarette smokers

ICD-10 code

F17.21

ICD-10 code description

Nicotine dependence, cigarettes

Primary outcomes**1****Description**

Salivary Cotinine

Timepoint

before intervention, end of intervention, after 6 months

Method of measurement

Salivary Cotinine ELISA Kit - Salimetrics

2**Description**

Fagerstrom Test for Nicotine Dependence

Timepoint

before intervention, weekly during intervention, monthly until 6 months follow up

Method of measurement

Fagerstrom Questionnaire Completion - Self Declaration

Secondary outcomes

1

Description

Craving

Timepoint

Before intervention, weekly during intervention, end of the 6 months follow up.

Method of measurement

Tobacco craving questionnaire-short form

2

Description

Power of brain wave in Quantitative electroencephalogram

Timepoint

Before intervention, weekly during intervention, end of 6 month follow up.

Method of measurement

Quantitative electroencephalogram

Intervention groups

1

Description

Nicotine Replacement Therapy with 300 mg Bupropion tablet, daily, for 8 weeks.

Category

Treatment - Drugs

2

Description

Active stimulation (transcranial Direct Current Stimulation with 2 mA amplitudes for 20 minutes, anode will be attached on left DLPFC (dorsolateral prefrontal cortex) and cathode will be attached on right DLPFC) for 20 sessions consisted of 5 sessions per week for 4 weeks

Category

Treatment - Other

3

Description

Twenty sessions sham transcranial Direct Current Stimulation (in which electrodes attachments and stimulation intensity are similar to active stimulation groups except electrical flow will be cut after 30 seconds) with 2 mA for 30 seconds, anode on left and cathode on right DLPFC (5 sessions per week for 4 weeks).

Category

Other

4

Description

Active stimulation (transcranial Direct Current Stimulation with 2 mA amplitudes for 20 minutes, anode will be attached on left DLPFC (dorsolateral prefrontal cortex) and cathode will be attached on right DLPFC)

which will be done in 5 sessions per week for 2 weeks, and then 1 session per week for 10 weeks

Category

Treatment - Other

5

Description

Twenty sessions sham transcranial Direct Current Stimulation (in which electrodes attachments and stimulation intensity are similar to active stimulation groups except electrical flow will be cut after 30 seconds) with 2 mA for 30 seconds, anode on left and cathode on right DLPFC (5 sessions per week for 2 weeks, and then 1 session per week for 10 weeks).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of health related social and Behavioural science research, Shahrood University of Medical Sciences

Full name of responsible person

Seyed Mohammad Mirrezaie

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Sponsors / Funding sources

1

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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
Shahroud 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

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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