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

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 fallow up (3), and point abstinence prevalence will be compared with drug therapy A at this time. The fallow 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 (QEEG)

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

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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 , witch designed by a team of analyzers of the research group. In order to allocation concealment sequentially numbered, sealed, opaque envelops 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
Street address
Shahroud University of Medical Sciences, Haftetir square
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3624773955
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
Befor intervention, weekly during intervention,end of the 6 months follow up.
Method of measurement
Tobacco craving questionnaire-short form

2

Description
Powerity of brain wave in Quantitative electroencephalogram
Timepoint
Befor 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 Bupropione 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 for30 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, Shahroud University of Medical Sci
Full name of responsible person
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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
Name of organization / entity
Shahroud University of Medical Sciences
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Position
MD
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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