Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Investigating of the effects of electrical stimulation on the DLPFC region on risky decision making behavior and brain waves pattern following craving induction in smokers: A cognitive and computational approach

Protocol summary

Study aim

the effects of electrical stimulation on the DLPFC area on risky decision-making behavior and brain wave pattern following craving induction in smokers

Design

The clinical trial has 3 groups of 21 people, randomized, blinded

Settings and conduct

Mazandaran University of Medical Sciences

Participants/Inclusion and exclusion criteria

The inclusion criteria are: having informed consent, age 18-60 years, smoking at least 10 cigarettes a day, knowing Persian, smoking for at least 2 years, not having a psychiatric diagnosis, not having a head injury or any brain damage. and neurological problems, absence of any visual defect, absence of metal object implantation in the head, absence of simultaneous participation in another study Exclusion criteria: occurrence of any physical and uncomfortable symptoms during the test, history of any physical illness and acute infection, history of any psychiatric illness, history of seizures for any reason, psychiatric and anticonvulsant medications during has consumed in the last 3 months, history of drug and alcohol consumption, history of accidents and head trauma, deprivation of sleep the night before the visit

Intervention groups

21 smokers in the first group, during 10 sessions, received tdcs in the right DLPFC area, and the anode electrode was placed on the right side. 21 smokers in the first group, during 10 sessions, received tdcs in the left DLPFC region and also the cathode electrode was placed in the right part. 21 smokers in the first group, during 10 sessions, are located in the DLPFC area. (sham group)

Main outcome variables

Dependent variables: relative power of alpha waves; relative power of beta waves; relative power of theta waves; relative power of delta waves; spectral power of alpha waves; spectral power of beta waves Independent variables: Nicotine use disorder; Fagerstrom Nicotine Addiction Scale score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230806059051N1**
Registration date: **2023-11-14, 1402/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-14, 1402/08/23**
Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

Name

Hamed Ghazvini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating of the effects of electrical stimulation on the DLPFC region on risky decision making behavior and brain waves pattern following craving induction in smokers: A cognitive and computational approach

Public title

Investigating of the effects of electrical stimulation on the DLPFC region on risky decision making behavior and brain waves pattern following craving induction in smokers: A cognitive and computational approach

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent Age 18 to 60 years Smoking at least 10 cigarettes a day Knowing the Persian language (Persian or Mazandarani dialect) Being a smoker for at least 2 years Not having a psychiatric diagnosis (schizophrenia-mania-bipolar disorders-major depression) Absence of head injury or any brain damage and neurological problems, for example, having a history of epilepsy, seizures, stroke, and brain or spinal cord tumors. Absence of any visual impairment Not implanting a metal object in the head Lack of simultaneous participation in another study

Exclusion criteria:

Occurrence of any uncomfortable physical symptoms during the test History of suffering from any type of physical disease such as multiple sclerosis, diabetes, heart, lung, liver, kidney diseases and suffering from any acute infection. History of any type of psychiatric illness History of seizures for any reason Has taken psychiatric and anticonvulsant drugs in the last 3 months History of drug and alcohol use History of accidents and head trauma Sleep deprivation the night before the visit Drink tea and caffeine at least 3 hours before the cognitive test

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the eligible people, randomly and using the minimization method, are allocated in one of the four groups receiving multi-site electrical stimulation. QMinim program (web version of MinimPy software) is used to carry out the process of random allocation using the minimization method. In the minimization method, the first person randomly enters one of the four groups with equal probability. From the second person onwards, participants enter groups with unequal probability (in favor of the group that has the least balance with other groups in terms of the desired variables). This process is done in such a way, that by allocating each participant, the most possible balance is achieved in the distribution of the desired variables among the groups, and at the same time, the number of people in each group is as equal as possible. In this study, the basic probability of each person being in a group with the least balance (compared to other groups) is 85%.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants are blind on the one hand, that is, they do not know about the type and process of stimulation, and the analyst also does not know about the type and process of stimulation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Faculty of Modern Medical Technologies, Mazandaran University of Medical Sciences, Km 18 Khazarabad Road, Sari, Mazandaran, Iran

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Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.MAZUMS..REC.1402.17548

Health conditions studied

1

Description of health condition studied

People who smoke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Craving scale
Timepoint
Before the start of the intervention and after the start of the intervention
Method of measurement
Nicotine craving scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, smokers received 20-minute TDCS electrical stimulation with an intensity of 2 mA in the left DLPFC region, and the cathode electrode was placed in the right part.
Category
Treatment - Devices

2

Description
Intervention group: In this group, smokers received 20-minute TDCS electrical stimulation with an intensity of 2 mA in the right DLPFC area, and the anode electrode was placed on the right side.
Category
Treatment - Devices

3

Description
Control group: A group of smokers who only had stimulation electrodes placed in the DLPFC region for 30 seconds. (sham group)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
دانشگاه علم پزشکی مازندران
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Hamed ghazvini
Position
Assistant professor
Latest degree

Ph.D.

Other areas of specialty/work
Neuroscience

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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