Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing Effectiveness of Transcranial direct-current stimulation (tDCS) of Dorsa Lateral Prefrontal Cortex and Mindfulness-Based Cognitive Therapy (MBCT) On Frontal lobe performance and Psychological Profile in Patients with Epilepsy Disorder.

Protocol summary

Study aim

Comparing Effectiveness of Transcranial direct-current stimulation (tDCS) of Dorsa Lateral Prefrontal Cortex and Mindfulness-Based Cognitive Therapy (MBCT) On Frontal lobe performance and Psychological Profile in Patients with Epilepsy Disorder.

Design

The clinical trial included a sham group and two experimental groups, tDCS and MBCT (parallel). Initial selection was by convenience sampling and according to entry criteria but assignment to groups was randomly.

Settings and conduct

The population consisted of all patients with epilepsy who were referred to private clinic in Urmia (Dr. somayeh Hasani Kia). The sample consisted of 45 patients with temporal lobe epilepsy who were selected by convenience sampling and assigned to two experimental and one sham groups randomly. To gather the data, first, pretest was administered. Next, tDCS and MBCT interventions were implemented to experimental groups.The sham group will receive no stimulation despite the electrodes being placed and will not participate in the MBCT classes. finally post-test will perform.

Participants/Inclusion and exclusion criteria

The most important criterion for entry into intervention are having temporal epilepsy, Not being in menstruation period, not having prosthesis in skull , not having battery in the heart, and not being pregnant. The most important criterion for entry into intervention are receiving psychological and medical interventions and medications, and any possible sensitivity to the tDCS.

Intervention groups

First group: tDCS Second group: MBCT Third group: sham

Main outcome variables

Frontal lobe function includes memory, concentration, attention, information processing, and cognitive flexibility. Psychological profiles include depression, anxiety, and stress.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190803044417N1**
Registration date: **2019-09-06, 1398/06/15**
Registration timing: **retrospective**

Last update: **2019-09-06, 1398/06/15**
Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name
Shahin Azmoodeh
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Urmia University
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing Effectiveness of Transcranial direct-current stimulation (tDCS) of Dorsa Lateral Prefrontal Cortex and Mindfulness-Based Cognitive Therapy (MBCT) On Frontal lobe performance and Psychological Profile in Patients with Epilepsy Disorder.

Public title
Effect of Brain Stimulation and Mindfulness in treatment of Epilepsy.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Fill out the informed consent form Having temporal lobe epilepsy Age range between 15 to 50 At least be a middle school graduate Not being pregnant No prosthesis in the skull No battery in the heart Lack of psychological treatment in the past one year No other medical illnesses such as skin disease, superficial injury and fracture or infraction of skull in the stimulation area

Exclusion criteria:
Being pregnant Prior Information about Sensitivity to tDCS receiving psychological interventions and medications Receiving medical interventions for any other disorder

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Forty five patients with epilepsy who were selected by convenience sampling and assigned randomly (At first, a list of available patients was prepared randomly and then coded from 01 to 45. Using random digits table, 15 person was assigned to each group.) to two experimental and one sham groups. Each group contains of 15 patients. For random assignment we used a lottery system. In the sham group, electrodes were connected but no stimulation was applied and participants were not aware of no stimulation.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
No. 39, Entezar Ave., manzariye Street.

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Tabriz

Province
East Azarbaijan

Postal code
5174873871

Approval date
2019-06-19, 1398/03/29

Ethics committee reference number
IR.UMSU.REC.1398.140

Health conditions studied

1

Description of health condition studied
Temporal lobe Epilepsy

ICD-10 code
G40

ICD-10 code description
Epilepsy and recurrent seizures

Primary outcomes

1

Description
Working memory

Timepoint
tDCS group: before intervention (pre-test) and 15 days later (post-test) ,MBCT group: before intervention (pre-test) and 8 weeks later (post-test) and in the sham group, the interval between pre-test and post-test was 15 days

Method of measurement
Wechsler Scale

2

Description
Concentration

Timepoint
tDCS group: before intervention (pre-test) and 15 days later (post-test) ,MBCT group: before intervention (pre-

test) and 8 weeks later (post-test) and in the sham group, the interval between pre-test and post-test was 15 days

Method of measurement

Continuous Performance Test

3

Description

Attention

Timepoint

tDCS group: before intervention (pre-test) and 15 days later (post-test) ,MBCT group: before intervention (pre-test) and 8 weeks later (post-test) and in the sham group, the interval between pre-test and post-test was 15 days

Method of measurement

Stroop test

4

Description

Cognitive Flexibility

Timepoint

tDCS group: before intervention (pre-test) and 15 days later (post-test) ,MBCT group: before intervention (pre-test) and 8 weeks later (post-test) and in the sham group, the interval between pre-test and post-test was 15 days

Method of measurement

Cognitive Flexibility Inventory

5

Description

Psychological Profile

Timepoint

tDCS group: before intervention (pre-test) and 15 days later (post-test) ,MBCT group: before intervention (pre-test) and 8 weeks later (post-test) and in the sham group, the interval between pre-test and post-test was 15 days

Method of measurement

Depression Anxiety Stress Scales -21

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In first intervention group the tDCS applies for 20 min over the left Dorso-lateral prefrontal cortex (DLPFC), the intensity is 1.5 mA. This method was applies in the first experimental group for 10 sessions. The first 5 sessions are consecutive, and the next 5 sessions are every other day. Based on the International 10–20 system, the anodal electrode will place in the F3 region of the left hemisphere, and the cathodal electrode will place in the F4 region of the right hemisphere. After 5 daily sessions, it is better to have the next 5 sessions every other day.

Category

Rehabilitation

2

Description

Second intervention group: In the second intervention group, Mindfulness-Based Cognitive Therapy (MBCT) is administered as an 8-week program. The class time include 2-2.5 h weekly. Participants encourage to complete daily home practice for 6 days per week. The duration of home sessions are about 45 min.

Category

Rehabilitation

3

Description

Control group: The sham group will receive no stimulation despite the electrodes being placed in and will not participate in the MBCT classes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

Dr. Somayeh Hasani Kia

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5th floor, Hashemi Medical Complex, Hassani Street, Urmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Urmia

Full name of responsible person

Esmaeil Soleimani

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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
The University of Urmia
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

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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