

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effects of Transcranial direct-current stimulation (tDCS) on the treatment of depressive and anxiety symptoms and improve quality of sleep in patients with chronic renal diseases on dialysis- a randomized double-blind placebo controlled trial

Protocol summary

Summary

Comorbidity of psychiatric disorders and end stage renal diseases (ESRD) which need special medication regimen, is a major challenge in front of nephrologists and psychiatrists. The main question of this study is whether the use of tDCS intervention - as a non-pharmacological treatment of mental disorders - can be effective on anxiety disorders, depression and sleep problems in chronic renal patients on dialysis. Subjects of two "anxiety-depression" and "sleep disorders" groups were selected from undergone hemodialysis patients with ESRD who referred to Fatemeh Zahra and Imam Khomeini hospitals of Sari, Mazandaran, Iran. Hospital Anxiety and Depression Scale (HADS) and Pittsburgh Sleep Quality Index (PSQI) questionnaire were used for each patient. tDCS intervention was performed according to protocol for 15 sessions. In addition to the pre-test, post-test at the end of 15 sessions, another test was also carried out after 10 days to follow-up the intervention effects. Results shows that even there has been a little reduction in scores of patients with symptoms of depression and anxiety after tDCS in compare to before that, but this reduction wasn't significant, so tDCS had no significant effect on improving symptoms of depression and anxiety. But the results of sleep disorder group, shows that there is a significant difference between the average scores of experimental group in three periods (before, after 15 sessions and 10 days after the end of intervention). Thus, it can be said that tDCS intervention has had positive effects on improving sleep quality

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020311885N8**

Registration date: **2017-04-01, 1396/01/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-01, 1396/01/12

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran Research Center of Psychiatry and Behavioral Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Transcranial direct-current stimulation (tDCS) on the treatment of depressive and anxiety symptoms and improve quality of sleep in patients with chronic renal diseases on dialysis- a randomized double-blind placebo controlled trial

Public title

Effects of Transcranial direct current stimulation (tDCS) on the treatment of depressive and anxiety symptoms and improve quality of sleep in patients with chronic renal diseases on dialysis

Purpose

Treatment

Inclusion/Exclusion criteria

History of head trauma in patient; history of epilepsy in patients or their families; past history of bipolar dx. or psychotic dx.; acute suicidal ideas; consumption of neuroleptics during the study; addiction to drugs or alcohol; pregnancy; having metal prosthesis or implant; severe anorexia; past history of neurologic dx. , serious medical illness.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **85**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences Ethics Committee

Street address

Mazandaran University of Medical Sciences, Moallem square

City

Sari

Postal code

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MAZUMS.REC.95.1819

Health conditions studied

1

Description of health condition studied

Chronic renal diseases

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

Primary outcomes

1

Description

Anxiety, depression

Timepoint

Before intervention, after 15 sessions of intervention and 10 days after the end of intervention

Method of measurement

HADS questionnaire

2

Description

Sleep quality

Timepoint

Before intervention, after 15 sessions of intervention and 10 days after the end of intervention

Method of measurement

PSQI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In main intervention, Subject of two "anxiety and depression" and "sleep disorders" groups were under tDCS.F3-Fp2 protocol was used in main intervention group according to 10-20 system of regions of the brain, the area (F3) Dorsolateral Prefrontal Cortex (DLPFC) was stimulated with anode and contralateral supraorbital (Fp2) under cathodic inhibition. The stimulation started in ascending mode up to 2 mA, and with the enhanced of 2 mA continues for 20 minutes and then, the device automatically shuts down.

Category

Treatment - Devices

2

Description

in placebo group, Subject of two "anxiety and depression" and "sleep disorders" groups were under tDCS.F3-Fp2 protocol was used in main intervention group according to 10-20 system of regions of the brain, the area (F3) Dorsolateral Prefrontal Cortex (DLPFC) was stimulated with anode and contralateral supraorbital (Fp2) under cathodic inhibition. The stimulation started in ascending mode up to 2 mA, and with the enhanced of 2 mA continues for 30 seconds and then, the device automatically shuts down

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam khomini hospital

Full name of responsible person**Street address****City**

sari

2**Recruitment center****Name of recruitment center**

Fatemeh zahra hospital

Full name of responsible person**Street address****City**

sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of research and technology, Mazandaran university of medical sciences

Full name of responsible person

Maryam Javadian

Street address

Imam Squar, serah-e- jooybar, Valiasr Highway

City

Sari

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of research and technology, Mazandaran university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty