Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Samaneh Farnia

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 currency 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 inervention
Method of measurement
HADS questionnaire

2

Description
Sleep quality
Timepoint
Before intervention, after 15 sessions of intervention and 10 days after the end of inervention
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

Samaneh Farnia

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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MD

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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