Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Transcranial Direct Current Stimulation on Balance in People with Parkinson’s Disease

Protocol summary

Study aim
comparision the effect of several target of transcranial direct current stimulation (tDCS) including M1, DLPFC and M1-DLPFC on balance in people with Parkinson's disease (PD)

Design
Double blind Cross-over trial. block randomization

Settings and conduct
This study will be conducted in Parkinson's disease association in Isfahan. 25 patients with PD will recieve four conditions include M1, DLPFC, M1-DLPFC, and sham in a counterbalance random order

Participants/Inclusion and exclusion criteria
Inclusion criteria: (1) Patients with Parkinson's Disease (2) Age 40 or older (3) Stages 2,3 on the Hoehn and Yahr scale (4) Ability to walk independently for at least 10 m (5) Montreal Cognitive Assessment score ≥ 24 (6) No change in medication prescription during and since 3 weeks before the study Exclusion criteria: (1) Any deformity of the lower limbs (2) using central nervous system medications other than for PD, e.g., antiepileptic or antidepressant drugs (3) Contraindications of using tDCS, such as having metal implants in the head, pacemaker, pregnancy, history of brain damage, history of epilepsy and seizures, and intermittent headaches (4) patients with neurological diseases other than PD, psychiatric diseases, or patients with drug or alcohol abuse.

Intervention groups
the active set-up, the tDCS device will apply a constant current of for 20 minutes. the intensity of tDCS will be 3 mA. For M1 stimulation, The anode will be place over Cz and the cathode will be applied over the left shoulder. For DLPFC stimulation, anode and cathode electrodes will be placed over F3 and right shoulder respectively. The sham tDCS set-up will receive the same electrode placement and duration of stimulation, but the device will be turned off after 30 seconds.

Main outcome variables
Before/after Berg balance scale; Mini-BESTest; Timed Up and Go(single/dual task)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240902062940N1**
Registration date: **2024-12-08, 1403/09/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-08, 1403/09/18**
Update count: **0**

Registration date
2024-12-08, 1403/09/18

Registrant information

Name
Negar Zare

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3792 5000

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negar.zare.789@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-30, 1403/07/09

Expected recruitment end date
2025-02-27, 1403/12/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Transcranial Direct Current Stimulation on Balance in People with Parkinson’s Disease

Public title
The Effect of Transcranial Direct Current Stimulation on Balance in People with Parkinson’s Disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosed with PD by a neurologist Age 40 or older Stages 1–3 on the Hoehn and Yahr scale Ability to walk independently for at least 10 m without using walking aids A score of ≥ 24 on Montreal Cognitive Assessment (MoCA-P) No change in medication prescription 3 weeks prior to study and during the study

Exclusion criteria:
ny deformity of the lower limbs(2) using central nervous system medications other than for PD, e.g., antiepileptic or antidepressant drugs (3) Contraindications of using tDCS, such as having metal implants in the head, pacemaker, pregnancy, history of brain damage, history of epilepsy and seizures, and intermittent headaches (4) patients with neurological diseases other than PD, psychiatric diseases, or patients with drug or alcohol abuse.

Age
From **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
All participants will be randomly assigned to a 4*25 block randomization, using a web-based randomization system (http://www.randomization.com) and will recieve all four stimulation conditions, including real M1+DLPFC tDCS, real M1 tDCS, real DLPFC tDCS and sham tDCS.

Blinding (investigator's opinion)
Double blinded

Blinding description
To ensure blinding of participants, the stimulating apparatus will be positioned out of sight and as for investigator blinding, the stimulation or sham protocol will be applied by another expert.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Rehabilitation faculty Isfahan university of medical science, Hezar jarib street

City
Isfehan

Province
Isfehan

Postal code
8174673461

Approval date
2024-08-20, 1403/05/30

Ethics committee reference number
IR.MUI.REC.1403.015

Health conditions studied

1

Description of health condition studied
People with Parkinson's Disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Berg balance scale score

Timepoint
before/after intervention

Method of measurement
Berg Balance Scale

2

Description
the score of Mini-BESTest (Balance Evaluation Systems Test)

Timepoint
before/after intervention

Method of measurement
Mini-Balance Evaluation Systems Test

3

Description
Timed Up and Go Test

Timepoint
before/after intervention

Method of measurement
Timed Up and Go Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: each participant receives four sessions ofactive set-up, the tDCS device will apply a constant current of for 20 minutes with the ramp up-ramp down duration of 30 sec. the intensity of tDCS will be 3 mA The current will be delivered through four saline-soaked surface electrodes measuring 5x7 cm, connected to a direct current stimulator. Channel A of the device will be used for M1 stimulation. The anode will be place over Cz and the cathode will be applied over the left shoulder. For DLPFC stimulation, anode and cathode electrodes of channel B will be placed over F3 and right shoulder respectively.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation faculty
Full name of responsible person
Dr. Javid Mostamand
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Rehabilitation faculty, Isfahan University of medical science, Hezar jarib stree
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
DR. Javid Mostamand
Position
professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
some data will be published

When the data will become available and for how long
6 month after publishing the articles

To whom data/document is available
academic staff

Under which criteria data/document could be used
for research

From where data/document is obtainable
negar.zare.789@gmail.com

What processes are involved for a request to access data/document
sending an email to corresponding person

Comments