Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of multi-session anodal trans-cranial direct current stimulation of cerebellum and dorsolateral prefrontal cortices on balance and gait spatial-temporal parameters in patients with multiple sclerosis

Protocol summary

Study aim
Comparing the effects of multi-session anodal trans-cranial direct current stimulation (tDCS) of cerebellum and dorsolateral prefrontal cortices (DLPFC) on balance and gait spatial-temporal parameters in patients with multiple sclerosis (MS)

Design
Subjects will be randomly divided into three groups, DLPFC, Cerebellum tDCS and control group. The treatment plan will be included 20 minutes of brain stimulation with 1.5 mA tDCS and balance training.

Settings and conduct
Multiple sclerosis (MS) patients in Tehran will participate. This double-blind randomized controlled trial (RCT) will be conducted in Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of MS by a neurologist; MS type relapsing remitting and secondary progressive type; age range between 18 to 60 years. Exclusion criteria: patients who experience cognitive impairment and severe depression; orthopedic disorders that can negatively affect balance.

Intervention groups
DLPFC tDCS group: electrode is placed to stimulate the DLPFC and the reference electrode across the right supraorbital region. Cerebellum tDCS group: electrode is placed 1-2 cm below and 3-4 cm laterally inion (right) to stimulate the right cerebellum and the reference electrode across supraorbital. In the sham or control tDCS group: the “Fade-in Short stimulation Fade-out (FiSsFo) approach” was used to maintain the blinding integrity and thus create the assumed initial cutaneous sensations. In the sham a-tDCS group, while the electrodes were randomly placed in the same positions for cerebellum or DLPFC stimulation, the stimulator was turned off after 30seconds of stimulation without the participant’s knowledge.

Main outcome variables
balance parameters Gait spatial-temporal parameters

General information

Reason for update
10 minutes for balance exercises was a typing and writing mistake and it was corrected to 20 minutes of tDCS and balance exercises.

Acronym

IRCT registration information
IRCT registration number: **IRCT20220111053689N2**
Registration date: **2023-09-19, 1402/06/28**
Registration timing: **prospective**

Last update: **2024-03-14, 1402/12/24**
Update count: **1**

Registration date
2023-09-19, 1402/06/28

Registrant information

Name
narges jahantigh akbari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7754 8496

Email address
n.jahantigh.akbari@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-21, 1402/06/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effects of multi-session anodal trans-cranial direct current stimulation of cerebellum and dorsolateral prefrontal cortices on balance and gait spatial-temporal parameters in patients with multiple sclerosis

Public title
Comparing the effects of trans-cranial direct current stimulation in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of MS by a neurologist Relapsing Remitting MS and secondary progressive MS EDSS score should be between 3.5 to 5 Ability to stand for 30 seconds and walk 10 meters with or without an aid

Exclusion criteria:
Patients with mental disorders Patients with orthopedic problems cardiovascular patients

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the permuted block randomization technique with a block size of 3 will be used in such a way that patients are first divided into homogeneous groups according to important background factors, and in each class, 3 samples per block will be included. A total of 16 blocks of 3 will be randomly assigned to each of the groups

Blinding (investigator's opinion)
Double blinded

Blinding description
The data analyst will be blinded to the allocation of patients to three groups. Data collection will be done in a separate environment from the treatment environment. Also, the patients will be blinded in three intervention and control groups, and each of them will be treated in separate rooms.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Imam Hossein Square, Damavand St. (New Tehran), in front of Bouali Hospital, Faculty of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1616913111

Approval date
2023-06-11, 1402/03/21

Ethics committee reference number
IR.SBMU.RETECH.REC.1402.161

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
F06.8

ICD-10 code description
Other specified mental disorders due to brain damage and dysfunction and to physical disease

Primary outcomes

1

Description
Gait spatial-temporal parameters

Timepoint
Before intervention-After intervention

Method of measurement
Motion analyze

2

Description
Balance parameters

Timepoint

Before intervention-After intervention

Method of measurement

Force plate

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: DLPFC tDCS group: In this group, the tDCS anodal will place to stimulate the left dorsolateral prefrontal cortex (left DLPFC), using the international system of 10-20 electroencephalography throughout the F3 area and the reference electrode across the right supraorbital region. The anode electrode in the size of 5 x 5 cm and the reference electrode in the size of 5 x 5 cm will be immersed in the isotonic sodium chloride solution and will be placed in the desired areas using the international 10-20 electroencephalography system.

Category

Rehabilitation

2

Description

Intervention group: cerebellum tDCS group: In this group, the tDCS anodal is placed 1-2 cm below and 3-4 cm laterally inion (right) to stimulate the right cerebellum and the reference electrode across supraorbital area. Anode electrode in size 5 x 5 cm and reference electrode in size 5 x 7 cm are immersed in isotonic sodium chloride solution and will be placed in the desired areas using the international 10-20 electroencephalography system.

Category

Rehabilitation

3

Description

Control group: In the sham or control tDCS group: the “Fade-in Short stimulation Fade-out (FiSsFo) approach” was used to maintain the blinding integrity and thus create the assumed initial cutaneous sensations. In the sham a-tDCS group, while the electrodes were randomly placed in the same positions for cerebellum or DLPFC stimulation, the stimulator was turned off after 30seconds of stimulation without the participant’s knowledge.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of rehabilitation of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Narges Jahantigh Akbari

Street address

Imam Hossein Hospital, at the beginning of Shahid Madani Street, Imam Hossein Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Narges Jahantigh Akbari

Position
researcher

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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