Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of using simultaneous or single anodal tDCS on the dorsolateral pre frontal cortex area(DLPFC) and cerebellum on neuromodulation, balance and gait in people with relapsing-remitting multiple sclerosis: a double-blind clinical study

Protocol summary

Study aim

Comparison of the effect of simultaneous direct current stimulation of the DLPFC and Cerebellum cortex, stimulation of the cerebellum and DLPFC alone on neuromodulatation , balance, walking, spasticity and fatigue of people with multiple sclerosis along with task-oriented exercises

Design

Randomized clinical trial without control group, with parallel groups, double-blind. For randomization, the block size of four will be used for randomization, and the sequences will be calculated by the random assignment software version 2.0.

Settings and conduct

The diagnosis will be made at the MS Research Center of Imam Khomeini Hospital and the treatment will be made at the Research Center of the Rehabilitation Faculty of Shahid Beheshti University of Medical Sciences. First, the course of the disease will be diagnosed by a neurologist. In this study, people with multiple sclerosis, the person evaluating the outcome and the person evaluating the results are blind to the treatment groups.tDCS in all three groups (first group of task-oriented training + a-tDCSCB/DLPFC) / second group (task-oriented training + a-tDCSCB) / third group (task-oriented training + a-tDCS DLPFC) in the amount of 2 mA and twenty minutes will be received.The exercises will be done for four weeks (3 times a week and a total of 12 sessions) along with tDCS.

Participants/Inclusion and exclusion criteria

1- Age between 55-20 years 2- Existence of relapsing-remitting MS 3- An attack caused by multiple sclerosis during the last month; Not being in the stable phase of MS 4- Not suffering from other neurological disorders 5- Inability to stand or walk with or without the use of an assistive device

Intervention groups

First group (task-oriented training + a-tDCS CB/DLPFC) / second group (task-oriented training + a-tDCSCB) / third group (task-oriented training + a-tDCS DLPFC)

Main outcome variables

Balance by TUG test

General information

Reason for update

Acronym

tDCS

IRCT registration information

IRCT registration number: **IRCT20200125046249N2**
Registration date: **2025-05-01, 1404/02/11**
Registration timing: **prospective**

Last update: **2025-05-01, 1404/02/11**
Update count: **0**

Registration date

2025-05-01, 1404/02/11

Registrant information

Name

Faezeh Abaschian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 7971

Email address

faezeh_abaschian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of using simultaneous or single anodal tDCS on the dorsolateral pre frontal cortex area(DLPFC) and cerebellum on neuromodulation, balance and gait in people with relapsing-remitting multiple sclerosis: a double-blind clinical study

Public title

Comparison of the effect of using simultaneous or single anodal tDCS on the dorsolateral pre frontal cortex area(DLPFC) and cerebellum on brain neuromodulatation, balance and gait in people with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20-55 years old Presence of relapsing-remitting MS The average level of disability is between 2 and 5 in EDSS Having at least third middle school education in order to fill out the questionnaires Receiving stable drug treatments in the last 6 months Having a balance disorder based on the timed up and go test Absence of fixed contract not suffering from other neurological disorders Absence of obvious postural disorders in the spine No history of lower limb surgery Absence of cardiovascular diseases and diabetes Absence of any intracranial metal implants or other implanted devices such as pacemakers, cochlear implants Inability to stand or walk with or without the use of an assistive device

Exclusion criteria:

Multiple sclerosis attack within the last month Not being in the stable phase of MS pregnancy Dissatisfaction with treatment Inability to stand or walk with or without the use of an assistive device

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible cases will be randomly assigned to three tDCS groups of cerebellum and dorsolateral prefrontal cortex or cerebellum and dorsolateral prefrontal cortex, each one alone with block randomization. A block size of four will be used for randomization, and sequences will be calculated by random assignment software version 2.0. Coordinators will have exclusive access to the numbered and sealed envelopes that will indicate each patient's treatment assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients do not know which group they are in and what intervention they are receiving. Also, the outcome assessor and data analyst do not know about the allocation of groups.

Placebo

Not 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

Damavand street, across from Buali hospital, Tehran, Iran. SBMU School of Rehabilitation Sciences

City

Tehran

Province

Tehran

Postal code

1616913111

Approval date

2024-12-14, 1403/09/24

Ethics committee reference number

IR.SBMU.RETECH.REC.1403.511

Health conditions studied

1

Description of health condition studied

Multiple sclerosis(MS)

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description
Balance score in Timed up and go test
Timepoint
Balance measurement at the beginning of the study (before the start of the intervention) and after 4 weeks and one month after the last treatment session
Method of measurement
Timed up and go test (TUG)

Secondary outcomes

1

Description
Investigating static balance along with cognitive work through pressure point fluctuations on the force plate
Timepoint
Measuring static balance along with cognitive work at the beginning of the study (before the start of the intervention) and 4 weeks after the treatment and one month after the last treatment session.
Method of measurement
Force plate

2

Description
Investigating spasticity by modified Ashworth questionnaire
Timepoint
Assessment of spasticity at the beginning of the study (before the start of the intervention), 4 weeks after the treatment and one month after the last treatment session.
Method of measurement
Modified Ashworth scale

3

Description
Assessment of gait by 12-item gait scale in multiple sclerosis (12-MSWS)
Timepoint
Assessment of walking at the beginning of the study (before the start of the intervention), 4 weeks after the treatment and one month after the last treatment session
Method of measurement
12-item walking scale in people with multiple sclerosis(12-MSWS)

4

Description
Assessment of neuromodulation by somatosensory evoked potentials
Timepoint
Evaluation of neuromodulation at the beginning of the study (before the start of the intervention), 4 weeks after the treatment and one month after the last treatment session.
Method of measurement
Somatosensory evoked potential apparatus

5

Description
Examining the level of fatigue using the modified MS fatigue questionnaire(MFIS)
Timepoint
Evaluation of fatigue at the beginning of the study (before the intervention), 4 weeks after the treatment and one month after the last treatment session
Method of measurement
Modified fatigue impact scale(MFIS)

Intervention groups

1

Description
Intervention group: Task-oriented training + anodal tDCS cerebellum and DLPFC
Category
Rehabilitation

2

Description
Intervention group: Task-oriented training + anodal tDCS cerebellum
Category
Rehabilitation

3

Description
Intervention group: DLPFC anodal tDCS
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Faezeh Abbaschian
Street address
No. 18, Azadeghan dead end, Ahmadian Ave, Torkamanestan St, Motahari St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
No.18, Azadeghan deadend, Shahid Ahmadian Ave, Torkamanestan St, Motahari St
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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
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
Minoo khalkhali Zavieh
Position
Associate professor
Latest degree
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Other areas of specialty/work
Physiotherapy
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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