

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 neuromodulation , 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

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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 neuromodulation, 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

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No.18, Azadeghan deadend, Shahid Ahmadian Ave,
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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

Ph.D.

Other areas of specialty/work

Physiotherapy

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Imam Hossein (AS) Square, Damavand Street (New
Tehran), in front of Bo Ali Hospital, Faculty of
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Position

Associate professor

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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