Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of cerebellum tDCS and prefrontal on gait parameters, balance and fatigue in patients with multiple sclerosis

Protocol summary

Study aim
Comparison of the effect of Cerebellum tDCS and Prefrontal tDCS on gait parameters, balance and fatigue in patients with Multiple Sclerosis

Design
Clinical trial with a control group, parallel groups, double-blind, randomization with a simple pseudo-randomization method will be on 51 patients. Treatment will be 20 min of stimulation, 1.5 mA and balance exercises.

Settings and conduct
Men and women with MS living in Tehran who voluntarily want to participate in this study and meet the inclusion criteria, constitute the statistical population. This double-blind randomized clinical trial will be performed at Shahid Beheshti School of Rehabilitation of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of MS by a neurologist; MS type relapsing remitting and secondary progressive type; the EDSS score should be between 3.5 and 6.5; age range between 18 to 50 years. Exclusion criteria: severe mental and cardiac patients; cognitive impairment and severe depression; orthopedic disorders.

Intervention groups
DLPFC tDCS group: The tDCS anodal will placed to stimulate the left dorsolateral prefrontal cortex (left DLPFC) across the F3 region and the reference electrode across the right supraorbital region. cerebellum tDCS group: The tDCS anodal will placed 1-2 cm below and 3-4 cm laterally inion (right) to stimulate the right cerebellum and the reference electrode across buccinator muscle of the same side. In control group: The “Fade-in Short stimulation Fade-out (FiSsFo) approach” will be used to maintain the blinding integrity and thus will created the assumed initial cutaneous sensations. The electrodes will be randomly placed in the same positions for cerebellum or DLPFC stimulation. The stimulator will be turned off after 30seconds of stimulation without the participant’s knowledge.

Main outcome variables
Balance; gait parameters; fatigue

General information

Reason for update
Hello, In the design of the study, 10 minutes for balance exercises was a typing mistake and it was 20 minutes of tDCS and balance exercises, and please correct it. Thanks.

Acronym

IRCT registration information
IRCT registration number: **IRCT20220111053689N1**
Registration date: **2022-03-03, 1400/12/12**
Registration timing: **prospective**

Last update: **2023-09-26, 1402/07/04**
Update count: **3**

Registration date
2022-03-03, 1400/12/12

Registrant information

Name
narges jahantigh akbari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7754 8496

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-09, 1400/11/20

Expected recruitment end date
2022-06-20, 1401/03/30

Actual recruitment start date

2022-03-11, 1400/12/20

Actual recruitment end date

2023-01-20, 1401/10/30

Trial completion date

empty

Scientific title

Comparison of the effect of cerebellum tDCS and prefrontal on gait parameters, balance and fatigue in patients with multiple sclerosis

Public title

Comparison of the effect of cerebellum tDCS and prefrontal 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 The EDSS score should be between 3.5 to 5

Exclusion criteria:

Severe mental and cardiac patients Patients who experience severe cognitive impairment and depression Orthopedic disorders that can negatively affect balance

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **51**

Actual sample size reached: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomly will be assigned through simple pseudo-randomization procedures using computer-generated list of random numbers to one of the three groups: (1) the group will received a-tDCS over dorsolateral prefrontal cortex and balance training, (2) the group will received a-tDCS over cerebellum and balance training and (3) the control group will received sham a-tDCS and balance training. The pseudo-randomized numbers of 1, 2 and 3 will be applied by one of the researchers to assign individuals to these groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The data analyzer will be blinded to the allocation of patients to the two groups of intervention and control, and data collection will be done in a separate room to the treatment department also, patients will be blinded depending on the treatment they receive and each of them will be treated in a separate room.

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

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

2021-11-07, 1400/08/16

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.499

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

8A40

ICD-10 code description

Multiple sclerosis or other white matter disorders

Primary outcomes

1

Description

Balance

Timepoint

Before intervention-After intervention

Method of measurement

Force plate

2

Description

Gait parameters

Timepoint

Before intervention-After intervention

Method of measurement

Motion analyze

3

Description
Balance
Timepoint
Before intervention-After intervention
Method of measurement
berg balance scale

4

Description
balance
Timepoint
Before intervention-After intervention
Method of measurement
Timed Up و Go test

5

Description
fatigue
Timepoint
Before intervention-After intervention
Method of measurement
Fatigue Severity Scale (FSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: in this group, the anodal tDCS is placed to stimulate the left dorsolateral prefrontal cortex (left DLPFC) across the F3 region and the reference electrode across the right supraorbital region.
Category
Rehabilitation

2

Description
Intervention group 2: 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 the ipsilateral muscle of the ipsilateral or supraorbital or forehead area.
Category
Rehabilitation

3

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
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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Email
zarghi@sbmu.ac.ir
Grant name
Shahid Beheshti University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Dr. Afshin Zarghi
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

Street address

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

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Email

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Person responsible for scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

researcher

Latest degree

Ph.D.

Other areas of specialty/work

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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