Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effectiveness of Comorbid Transcranial Direct Current Stimulation and Upper Limb Occupational Therapy on Occupational Performance and Fine Motor Movement in People with Multiple Sclerosis: A Randomized Controlled Trial

Protocol summary

Study aim
Determining the combined effectiveness of transcranial direct current stimulation (tDCS) and limb occupational therapy exercises on work performance and fine hand movements in people with multiple sclerosis

Design
A Double-blind randomized controlled clinical trial study

Settings and conduct
Individuals with MS who meet the inclusion criteria will be identified through information registered in MS associations and the objectives and methods of the study will be fully explained to them. After obtaining consent, participants will be randomly assigned to two intervention and control groups using a block randomization method (using software). The outcome assessor and participants are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: definite diagnosis of multiple sclerosis according to McDonald criteria; age between 18 and 65 years old; right-handedness; score between 2 and 5 on the Extended Disability Status Scale (EDSS); no similar treatments in the past three months; existence of impairment in fine hand movements; score higher than 22 on the Mini-Mental State Examination (MMSE). Exclusion criteria: presence of other neurological diseases or severe cognitive disorders; Pregnancy; having metal devices such as (pacemakers) that interfere with TDCS.

Intervention groups
tDCS (2mA, 20 min) will be applied using a validated device. The anodal electrode will be placed over the left primary motor cortex (C3), and the cathodal electrode over the right frontopolar region (Fp2), with ramp-up/down. The control group will receive sham stimulation (30 s) in a double-blind manner. Concurrently, participants will undergo 30 minutes of occupational therapy, including fundamental motor (e.g., finger exercises), fine motor, and functional exercises.

Main outcome variables
Canadian Occupational Performance Measurement; Jebsen Taylor Hand Function Test; Nine-hole peg test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211220053459N3**
Registration date: **2025-09-26, 1404/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-26, 1404/07/04**
Update count: **0**

Registration date
2025-09-26, 1404/07/04

Registrant information

Name
Fatemeh Motaharinezhad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2026-04-20, 1405/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Comorbid Transcranial Direct Current Stimulation and Upper Limb Occupational Therapy on Occupational Performance and Fine Motor Movement in People with Multiple Sclerosis: A Randomized Controlled Trial

Public title
The Effectiveness of Comorbid Transcranial Direct Current Stimulation and Upper Limb Occupational Therapy in People with Multiple Sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of multiple sclerosis according to the McDonald criteria Age between 18 and 65 years Right-handedness Score between 2 and 5 on the Expanded Disability Status Scale (EDSS) No similar treatments in the past three months Presence of impairment in fine hand movements Score higher than 22 on the Mini-Memory Cognitive Assessment (MMSE)
Exclusion criteria:
Presence of other neurological diseases or severe cognitive impairment Pregnancy Having metal devices (such as pacemakers) that interfere with TDCS Uncooperative in performing exercises
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into two groups of intervention and control by Stratified Balanced Block Randomization with an equal block method. Out of a maximum of 20 modes for the six blocks, three will be in the intervention group or A, and three in the control group will be created using the RANDBETWEEN (1,20) command in Excel software. Participants will be divided equally into two groups according to the random sequence created.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, blinding will be implemented as follows: Participants: Individuals enrolled in the study will remain unaware of their assignment to either the intervention or control group. It should be noted that prior to enrollment, all participants will receive the necessary information within the framework of informed consent; however, the specific details of the intervention they will receive will not be disclosed. Outcome assessors: Those responsible for data collection and evaluation of the primary outcomes will be blinded to group allocation in order to minimize the risk of bias in recording and analyzing data. Other members of the research team (including the principal investigator and study staff) will be aware of group allocation due to the nature of the intervention; however, every effort will be made to ensure that this knowledge does not influence the conduct of the study or the interpretation of its results.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Semnan University of Medical Sciences
Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran.
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2025-07-21, 1404/04/30
Ethics committee reference number
IR.SEMUMS.REC.1404.122

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Occupational performance
Timepoint
Before, after and one month after the intervention
Method of measurement
Canadian Occupational Performance Measurement

2

Description
Hand Function
Timepoint
Before, after and one month after the intervention
Method of measurement
The Jebsen-Taylor Manual Function Test

3

Description
Hand skill
Timepoint
Before, after and one month after the intervention
Method of measurement
Nine-hole peg test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, the therapeutic intervention will consist of anodal transcranial direct current stimulation (tDCS) combined with specialized upper limb occupational therapy exercises. The aim of this combined intervention is to improve work performance and fine motor skills in patients with multiple sclerosis.Transcranial direct current stimulation (tDCS) (25)During each session, transcranial direct current stimulation will be performed using a validated tDCS device. The current intensity in this intervention will be 2 mA and the duration will be 20 min. The anodal electrode will be placed over the left primary motor cortex (area C3 in the international 10–20 EEG system) and the cathodal electrode over the right frontopolar region (area Fp2). Stimulation will be delivered with gradual ramp-up and ramp-down to minimize burning sensation. Upper limb occupational therapy exercises (27). Concurrently, participants undergo 30 minutes of specialized occupational therapy. These exercises consist of three categories of activities: Fundamental motor exercises (e.g., finger opening and closing, wrist and finger flexion/extension, forearm rotation)Fine motor exercises (e.g., bead picking, play dough, coin picking, buttoning and unbuttoning)Functional exercises related to daily living (e.g., folding a towel, picking up a glass, writing, tapping with a finger, drawing a circle)The exercises are based on the principles of Activity-Based Rehabilitation and are selected as meaningful exercises to help promote the individual's participation in daily life (28). The intensity and level of the exercises are adjusted and modified by a trained occupational therapist according to the participant's ability level. Intervention The above interventions are delivered in the form of 10 in-person therapy sessions over 2 weeks (5 sessions per week). Each session consists of 20 minutes of tDCS and 30 minutes of occupational therapy exercises.
Category
Rehabilitation

2

Description
Control group: In the control group, the device is turned on for only a short time (30 seconds) and then turned off, without the participant or the assessor being aware of the type of stimulation (double-blind).Upper limb occupational therapy exercises (27)Concurrently, participants undergo 30 minutes of specialized occupational therapy exercises. These exercises consist of three categories of activities:Fundamental motor exercises (e.g., finger opening and closing, wrist and finger flexion/extension, forearm rotation)Targeted fine motor exercises (e.g., bead picking, play with play dough, coin grasping and moving, buttoning and unbuttoning)Functional exercises related to daily living (e.g., folding a towel, picking up a glass, writing, tapping with a finger, drawing a circle)The exercises are based on the principles of Activity-Based Rehabilitation and are selected as meaningful exercises to help promote the individual's participation in daily life (28). The intensity and level of exercises are adjusted and modified by a trained occupational therapist according to the participant's ability level.Intervention ScheduleThe above interventions are delivered in the form of 10 in-person therapy sessions over 2 weeks (5 sessions per week). Each session consists of 20 minutes of tDCS and 30 minutes of occupational therapy exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuromuscular Rehabilitation Research Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Semnan 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
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Fatemeh Motaharinezhad
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

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When the data will become available and for how long

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To whom data/document is available

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Under which criteria data/document could be used

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From where data/document is obtainable

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What processes are involved for a request to access data/document

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Comments