

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

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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 nodes 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

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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 Schedule 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fatemeh Motaharinezhad

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Famili Rehabilitation Clinic, Ayatollah Madani Blvd,
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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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Full name of responsible person
Fateme Motaharinezhad
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Latest degree
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Other areas of specialty/work

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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)

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

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

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

Comments