

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effects of rTMS and tDCS combined with postural exercises on balance, postural stability and level of fear of falling in patients with Multiple sclerosis: a double-blind randomized controlled trial

#### Protocol summary

##### Study aim

Comparison of the effects of rTMS and tDCS combined with postural exercises on balance, postural stability, and level of fear of falling in patients with Multiple sclerosis

##### Design

A randomized, double-blinded, sham-controlled clinical trial with a parallel-group design of 60 patients. Block randomization using Random allocation software is performed with Sealed envelopes.

##### Settings and conduct

The study is conducted in the Research Centre of Neuromuscular Rehabilitation of Semnan University of Medical Sciences (Iran). All participants are blind to the sham and active applications of the rTMS and tDCS. All outcome measures are taken before and after the intervention by a blinded physiotherapist.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age > 20 and <65 years; disability between 4.5 and 6.5 on the Expanded Disability Status Scale (EDSS); walking ability according to the EDSS score; a minimal leg spasticity score  $\leq 1$  on the Modified Ashworth spasticity scale; exclusion criteria: Pregnant women; neurological, orthopedic, and severe cardiac comorbidities; peripheral vestibular disorders (i.e., positional paroxysmal vertigo, Meniere's disease, and acoustic neuroma); blindness in one or both eyes; exacerbation in the past 2 months or during the study.

##### Intervention groups

Three groups: cerebellar rTMS with postural training, cerebellar tDCS with postural training, sham rTMS, and tDCS with postural training.

##### Main outcome variables

The Berg Balance Score (BBS) and the stability indices at both static and dynamic levels of the Biodex Balance System are evaluated before and after the intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210905052374N1**

Registration date: **2021-11-14, 1400/08/23**

Registration timing: **prospective**

Last update: **2021-11-14, 1400/08/23**

Update count: **0**

##### Registration date

2021-11-14, 1400/08/23

##### Registrant information

##### Name

Mostafa Rahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7753 3939

##### Email address

rahimim@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-09-22, 1401/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effects of rTMS and tDCS combined with postural exercises on balance, postural stability and level of fear of falling in patients with Multiple sclerosis: a double-blind randomized controlled trial

### Public title

Effects of rTMS and tDCS in balance of MS patients

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Clinically definite MS Age > 20 and <65 years Disability between 4.5 and 6.5 on the Expanded Disability Status Scale (EDSS) Walking ability according to the EDSS score A minimal leg spasticity score ≤ 1 on the Modified Ashworth spasticity scale

#### Exclusion criteria:

Pregnant women Neurological, orthopedic and severe cardiac comorbidities Peripheral vestibular disorders (i.e., positional paroxysmal vertigo, Meniere's disease, and acoustic neuroma) Blindness in one or both eyes Exacerbation in the past 2 months Exacerbation during the study

### Age

From **20 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

We will use the Block randomization method of the Restricted randomization method. Block randomization will be done by using Random allocation software and sealed envelopes.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

All participants are blind to the sham and active applications of the rTMS and tDCS. All outcome measures are taken before and after the intervention by a blinded physiotherapist.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

District 12, Enghelab St, Pich-e-Shemiran. Tehran University of Medical Sciences - School of Rehabilitation

##### City

Tehran

##### Province

Tehran

##### Postal code

11489-65111

##### Approval date

2021-06-30, 1400/04/09

##### Ethics committee reference number

IR.TUMS.FNM.REC.1400.107

## Health conditions studied

### 1

#### Description of health condition studied

Multiple Sclerosis (MS)

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The stability indices at both static and dynamic levels of the Biodex Balance System

#### Timepoint

Before and after the intervention

#### Method of measurement

The Biodex Balance System (302-950 model, Biodex Medical Systems, Inc., New York, USA)

## Secondary outcomes

### 1

#### Description

The Berg Balance Scale Score

#### Timepoint

Before and after the intervention

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Participants in intervention group 1(cerebellar rTMS with postural training) receive 20 min of rTMS on their cerebellum during progressive postural training on the Biodex Balance System. Participants in intervention group 2 (cerebellar tDCS with postural training) receive 20 min of rTMS on their cerebellum during progressive postural training on the Biodex Balance System. In the sham rTMS and tDCS group (sham rTMS, and tDCS with postural training), participants receive only 30 s of stimulation at the beginning of a postural training session.

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Neuromuscular Rehabilitation Research Centre of Semnan University of Medical Sciences

**Full name of responsible person**

Mostafa Rahimi

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District 12, Enghelab St, Pich-e-Shemiran. Tehran University of Medical Sciences - School of Rehabilitation

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rahimim@sina.tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotoohi

**Street address**

Quds Street, Keshavarz Blvd, Central University Organization, sixth floor

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vcr@tums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mostafa Rahimi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mostafa Rahimi  
**Position**  
Assistant professor  
**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

### When the data will become available and for how long

Starting 6 months after publication.

### To whom data/document is available

Anyone interested can access the data.

### Under which criteria data/document could be used

Any kind of analysis is allowed, provided that if the information is used somewhere, the source will be mentioned.

### From where data/document is obtainable

Mostafa Rahimi rahimim@sina.tums.ac.ir 0098 912 2070616

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

All he/she has to do is send an email and he/she will receive the information within a month.

### Comments