

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 2026

### Evaluation and comparison of gait pattern of patients with multiple sclerosis before and after an aerobic exercise course by fixed bicycle plus direct brain stimulation (tDCS)

#### Protocol summary

##### Study aim

Evaluation and comparison of gait pattern of patients with multiple sclerosis before and after an aerobic exercise course by fixed bicycle plus direct brain stimulation (tDCS)

##### Design

Ten patients with multiple sclerosis with Expanded Disability Status Scale (EDSS) score of less than 6 were included in the study. Initially demographic information and quality of life questionnaire will be filled for them. Gait analysis is then performed for them, after that the patient undergoes 12 sessions of fixed-bike exercise and brain stimulation, and again the questionnaires are filled and re-analyzed.

##### Settings and conduct

Imam khomeini hospital, Tehran university of medical science.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: the patients with multiple sclerosis; with mild to moderate involvement; with Expanded Disability Status Scale (EDSS) < 6, Exclusion criteria: history of convulsion and major disease; History of other major disease; history of head trauma

##### Intervention groups

12 session exercise with fixed bicycle with brain stimulation (TDCS), 2 times in week, 6 week

##### Main outcome variables

gait analysis variables include: walking velocity; cadence number, step number, cadence length, cadence angels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180703040321N2**

Registration date: **2020-02-29, 1398/12/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-29, 1398/12/10**

Update count: **0**

##### Registration date

2020-02-29, 1398/12/10

##### Registrant information

###### Name

mohaddeseh Azadvari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2291

###### Email address

m-azadvari@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-05, 1398/10/15

##### Expected recruitment end date

2020-03-18, 1398/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation and comparison of gait pattern of patients with multiple sclerosis before and after an aerobic exercise course by fixed bicycle plus direct brain stimulation (tDCS)

##### Public title

Evaluation of exercise plus brain stimulation on gait of patients with multiple sclerosis

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

multiple sclerosis patient mild to moderate involvement, EDSS < 6

**Exclusion criteria:**

history of convulsion history of other major disease such as stroke and ...

**Age**

From **18 years** old to **65 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **10**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

**Street address**

Imam Khomeini hospital, at the end of Keshavarz Blvd, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Approval date**

2020-01-04, 1398/10/14

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1398.241

**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**

gait velocity

**Timepoint**

Before and after intervention

**Method of measurement**

according gait analysis results

**2**

**Description**

steps number

**Timepoint**

Before and after intervention

**Method of measurement**

According gait analysis results

**3**

**Description**

Cadance number

**Timepoint**

Before and after intervention

**Method of measurement**

According gait analysis results

**4**

**Description**

Step length

**Timepoint**

Before and after intervention

**Method of measurement**

According gait analysis results

**5**

**Description**

cadance Length

**Timepoint**

Before and after intervention

**Method of measurement**

According gait analysis results

**6**

**Description**

gait angels

**Timepoint**

Before and after intervention

**Method of measurement**

According gait analysis results

## Secondary outcomes

1

### Description

evaluation of quality of life

### Timepoint

befor and after intervention

### Method of measurement

MSQL-54 questionnaire

## Intervention groups

1

### Description

Intervention group: multiple sclerosis patients, at first we analysis gait of the patients, after that the patients will doing exercsie with TDCS for 12 session, after that we will analysis the patients gait again and will compare before and after gait analysis results.

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam khomeini hospital

#### Full name of responsible person

Mohaddeseh Azadvari

#### Street address

Imam Khomeini Hospital Complex, Tohid Squire,  
Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۱۹۷۳۳۱۴۱

#### Phone

+98 21 6119 2291

#### Email

drazadvari@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohammad Ali Sahraian

#### Street address

Central Building of Tehran University of Medical  
Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran,

Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1416753955

#### Phone

+98 21 8889 6694

#### Email

sahraian1350@yahoo.com

#### 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

Mohaddeseh Azadvari

#### Position

1. Assistant professor of physical medicine and  
rehabilitation

#### Latest degree

Specialist

#### Other areas of specialty/work

Physical Medicine

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Imam Khomeini Hospital Complex, Tohid Squire,  
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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 of physical medicine and rehabilitation

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Specialist

**Other areas of specialty/work**

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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**

after finishing study, without name

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

six months after publishing results

**To whom data/document is available**

all researchers

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

for study

**From where data/document is obtainable**

send email for Dr Azadvari

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

request by email

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohaddeseh Azadvari

**Position**

1. Assistant professor of physical medicine and rehabilitation

**Latest degree**

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**Other areas of specialty/work**

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