

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Sep 2026

### Effect of dual task training on somatosensory, balance, activity of daily living and Community participation in patient with relapsing-remitting Multiple sclerosis: Double Blind Clinical Trial

#### Protocol summary

##### Study aim

Effect of cognitive-motor dual task training on somatosensory, balance, activity of daily living and community integration in patient with relapsing-remitting Multiple sclerosis

##### Design

A prospective study of a blind clinical trial with two parallel, randomized groups

##### Settings and conduct

The samples are selected from the clients of the Multiple Sclerosis Society of Isfahan and randomly divided into two groups. Before the randomization, patients are described, which will be divided into two groups with two different programs. After obtaining patient consent and collecting demographic data, EDSS will be used to diagnose patients' incapacity. Clients, the person who evaluates, and the person who performs the rehab program do not know the type of group (intervention, control).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of multiple sclerosis, EDSS 2-5/5, Ability to stand without any support, Having a sensory problem on the soles of the foot, Remitting during the last 30 days, Having the ability to read and write, The doctor confirmed to participate in research  
Exclusion criteria: People with diseases such as diabetes, epilepsy and with any problem in the musculo-skeletal system: History of surgery, History of fractures, and ... that disturbs the balance, Receive corticosteroid treatment one month before the study, MMSE-less than 24, Uncorrected visual disorders, Relapsing, Inability to walk a distance of 25 feet with or without assistive device

##### Intervention groups

Intervention group: cognitive-motor dual task training  
control group: balance training

##### Main outcome variables

Intervention(cognitive-motor dual task training):  
independent variable Somatosensory: dependent  
variable Balance: dependent Community integration:  
dependent Instrumental activity of daily living:  
dependent Activity of daily living: dependent

#### General information

##### Reason for update

##### Acronym

Dual Task Training DTT

##### IRCT registration information

IRCT registration number: **IRCT20180523039792N1**

Registration date: **2019-06-13, 1398/03/23**

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

Last update: **2019-06-13, 1398/03/23**

Update count: **0**

##### Registration date

2019-06-13, 1398/03/23

##### Registrant information

##### Name

Shirin Saberimobarake

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 5229

##### Email address

shirin.saberi69@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Effect of dual task training on somatosensory, balance, activity of daily living and Community participation in patient with relapsing-remitting Multiple sclerosis: Double Blind Clinical Trial

**Public title**  
Effect of dual task training on somatosensory, balance, Community participation and activity of daily living in Multiple sclerosis

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Diagnosis of Neurologist EDSS Score 2-5/5 (To be able to complete walking tests) Ability to stand without any support Having a sensory problem on the soles of the foot relapsing During the last 30 days Having the ability to read and write The doctor confirmed to participate in research  
**Exclusion criteria:**  
 Diseases such as diabetes, epilepsy and ... Any problem in the musculoskeletal system: history of surgery, history of fractures, etc., which disturbs the balance. Corticosteroid treatment one month before the study MMSE less than 24 Uncorrected visual disorders Exacerbation of symptoms Inability to walk 25 ft with or without assistive device Major depression

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Method: Restricted Randomization by random allocation rule method: first, a sample size determine and then randomly assign a set of them to Group A and assign the remainder to Group B. Random unit: Individual Non-transparent envelopes are used to hide random assignments In this method, first, a random sequence is created using the above method. Then, based on the sample size of the research, a number of envelopes with an aluminum wrapper (in order to avoid the clarity of the contents of the envelopes) are prepared and each

random sequence created on a card is recorded and the cards is placed inside the envelopes. At the time of the start of the registration of the participants, one of the envelopes shall be opened in accordance with the order of entry of the eligible participants, and the group allocated to that participant shall be revealed. Process execution: One person will create a random sequence, the other will examine the participants in terms of inclusion and exclusion criteria and enroll them in the study, and the third person will assign the participants to the groups.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

The participant will be notified in two groups whose programs are different. Practitioners who train the intervention program do not know about the intervention and control group program.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Isfahan university of medical sciences

##### **Street address**

Isfahan university of medical sciences, Hezarjrib Ave.

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

81745-164

#### **Approval date**

2018-11-14, 1397/08/23

#### **Ethics committee reference number**

IR.MUI.RESEARCH.REC.1397.314

### **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**

Somatosensory

#### **Timepoint**

Before the intervention, immediately after the intervention, one week after the end of the intervention

#### **Method of measurement**

monofilament

### 2

#### **Description**

Balance

#### **Timepoint**

Before the intervention, immediately after the intervention, one week after the end of the intervention

#### **Method of measurement**

Berg balance scale

### 3

#### **Description**

Balance

#### **Timepoint**

Before the intervention, immediately after the intervention, one week after the end of the intervention

#### **Method of measurement**

Force plate

## Secondary outcomes

### 1

#### **Description**

Activities of daily living (basic, instrumental)

#### **Timepoint**

Before the intervention, immediately after the intervention, one month after the end of the intervention

#### **Method of measurement**

Barthel index score Lawton instrumental activity of daily living

### 2

#### **Description**

Community integration

#### **Timepoint**

Before the intervention, immediately after the intervention, one month after the intervention

#### **Method of measurement**

Community integration Questionnaire

## Intervention groups

### 1

#### **Description**

Intervention group: Dual cognitive-motor exercises. At the beginning of the session, warm-up exercises are

performed for 10 minutes, then balanced exercises begin. Each exercise consists of 2 courses, depending on the person's level of ability, each course performed one to two minutes and for repetitive exercises 10 to 15 repetitions. The rest time between each period is also 1 to 2 minutes. The intervention group performs the second cycle exercises with cognitive activity. At the end, the cooling exercises will take about 10 minutes.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: Dual cognitive-motor exercises. At the beginning of the session, warm-up exercises are performed for 10 minutes, then balanced exercises begin. Each exercise consists of 2 courses, depending on the person's level of ability, each course performed one to two minutes and for repetitive exercises 10 to 15 repetitions. The rest time between each period is also 1 to 2 minutes. At the end, the cooling exercises will take about 10 minutes.

#### **Category**

Rehabilitation

## Recruitment centers

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Isfahan MS Society

##### **Full name of responsible person**

Shirin Saberimobarake

##### **Street address**

No. 2, Behesht Building (Ground Floor)., Opposite the Al-Kareem Mosque., Bozorgmehr Street

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shirin.saberi69@gmail.com

## Sponsors / Funding sources

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Dr Yousef Gheysari

##### **Street address**

Faculty of Rehabilitation Sciences., Isfahan University of Medical Sciences., Hezarjrib Street

##### **City**

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 shirin.saberi69@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
 Yes  
**Title of funding source**  
 Esfahan 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**  
 Esfahan University of Medical Sciences  
**Full name of responsible person**  
 Shirin Saberimobarake  
**Position**  
 Researcher  
**Latest degree**  
 Master  
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 Occupational Therapy  
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 Musculoskeletal research center, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences, Hezar Jrib Ave.  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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