

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effectiveness of HABIT-ILE Training on Participation in Activities of Daily Living and Occupational Performance in Patients with Multiple Sclerosis

#### Protocol summary

##### Study aim

The Effectiveness of HABIT-ILE Training on Participation in Activities of Daily Living and Occupational Performance in Patients with Multiple Sclerosis

##### Design

A randomized, single-blind, parallel-group, controlled clinical trial will be conducted on 48 patients who will be classified into two groups: control and intervention. Random Allocation Software (RAS) will be used for randomization.

##### Settings and conduct

The necessary therapeutic facilities and equipment, such as occupational therapy clinics, functional and balance tools, and appropriate space for targeted exercises, are available at Ghaem Hospital in Mashhad.

##### Participants/Inclusion and exclusion criteria

Patients who received a diagnosis of multiple sclerosis (MS) by a physician or based on McDonald criteria; had the ability to perform active movements against gravity in the joints of the upper and lower limbs; had at least 20 degrees of extension in the wrist joint and 10 degrees of extension in the MP and IP joints; patients aged 20 years and older; consented to enter the study; and patients who were able to participate in two-handed exercises and were able to follow the training courses.

##### Intervention groups

The intervention group will receive HABIT-ILE exercises for 4 weeks, 3 one-hour sessions per week, in addition to regular occupational therapy services. HABIT-ILE exercises consist of structured bimanual activities involving the trunk and lower extremities, designed based on the HABIT exercise methodology.

##### Main outcome variables

The main outcomes include the assessment of the individual's ability to participate in activities of daily living and occupational function, which will be measured by the Barthel index, FIM, and COPM in two stages before

and after the end of the four weeks of intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250826067002N1**

Registration date: **2025-09-05, 1404/06/14**

Registration timing: **prospective**

Last update: **2025-09-05, 1404/06/14**

Update count: **0**

##### Registration date

2025-09-05, 1404/06/14

##### Registrant information

##### Name

Alireza Amiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3884 6711

##### Email address

alireza.amiri.ot@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-09-23, 1404/07/01

##### Expected recruitment end date

2025-12-22, 1404/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The Effectiveness of HABIT-ILE Training on Participation in Activities of Daily Living and Occupational Performance in Patients with Multiple Sclerosis

**Public title**

The Effectiveness of HABIT\_ILE on Activities of Daily Living

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of multiple sclerosis Ability to active anti-gravity movements in upper and lower extremities At least 20 degrees of extension in wrist At least 10 degrees of extension in IP and MP joints At least 20 years of age Informed consent to participate in the study Participation in two-handed exercises and the ability to follow training sessions

**Exclusion criteria:**

Complete paralysis in any of the upper limbs Presence of severe cognitive impairments affecting exercise

**Age**

From **20 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the block randomization method is used to generate the random allocation sequence. The allocation sequence will be generated using Random Allocation Software (RAS). RAS is a simple and practical tool for generating random allocation sequences in randomized clinical trials (RCTs). This software is freely available to researchers. RAS allows for the creation of a variety of randomization methods, such as simple randomization, block randomization, and randomization with unequal allocation. These features make RAS a suitable tool for designing interventional studies. In the block randomization method, RAS allows the size of the blocks (e.g., 4, 6, or 8) to be specified and the sequence of allocation to different groups (e.g., intervention and control) to be randomly determined within each block. The order of groups within blocks can also be set to be fixed or random, which helps to increase the accuracy of the allocation concealment method.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

To conceal allocation, opaque, randomly numbered envelopes will be used. The order of the envelopes will

be in accordance with the sequence generated by the RAS software, and each envelope will contain the corresponding group assignment. The envelopes will be prepared by an individual independent of the research team and will only be opened when the participant enters the study.

**Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Azadi sq. Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Approval date**

2025-08-16, 1404/05/25

**Ethics committee reference number**

IR.MUMS.FHMPM.REC.1404.144

**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**

The main outcomes include the assessment of the individual's ability to participate in activities of daily living and occupational functioning.

**Timepoint**

In two stages, before the intervention and after the end of the four weeks of intervention

**Method of measurement**

by the Barthel index, FIM, and COPM tools

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: HABIT-ILE exercises will be given for 4 weeks, 3 one-hour sessions per week, in addition to regular occupational therapy services. HABIT-ILE exercises consist of structured bimanual activities involving the trunk and lower extremities, designed based on the HABIT exercise methodology.

#### Category

Rehabilitation

### 2

#### Description

Control group: The control group will only continue the standard occupational therapy interventions they received before the study began.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital

##### Full name of responsible person

Hosein Mohsenzadeh

##### Street address

Qaem Hospital, Dr. Shariati Square, beginning of Ahmadabad Avenue, Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9919991766

##### Phone

+98 51 3840 0001

##### Email

ghaem-dabir@mums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

University Street, Next to Hoveyzeh Cinema, Qorashi

Building

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

vcresearch@mums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Alireza Amiri

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Occupational Therapy

##### Street address

Occupational Therapy Department, School of Paramedical and Rehabilitation Sciences, Mashhad University of Medical Sciences, Azadi sq., Mashhad, Iran

##### City

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9177948964

##### Phone

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##### Email

Alireza.Amiri.ot@gmail.com

## Person responsible for scientific

## inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Amiri

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Assistant professor

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Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

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Alireza Amiri

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Assistant professor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

If necessary, de-identified data will be published.

**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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is 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**

De-identified data that led to the study results.

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

After the study is completed

**To whom data/document is available**

Researchers

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

Through correspondence with the corresponding author

**From where data/document is obtainable**

correspondence with the corresponding author

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

The documents will be reviewed first and provided if approved.

**Comments**