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
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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
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9138813944
Phone
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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
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Position
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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