Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Action Observation Training on hand function, strength and fatigue in individuals with Multiple Sclerosis

Protocol summary

Study aim

* Determining and comparing hand function in multiple sclerosis patients before and after intervention in two intervention and control groups * Determining and comparing hand strength (grip strength) in multiple sclerosis patients before and after the intervention in two groups. * Determining and comparing hand strength (pinch between thumb and index finger pad) in multiple sclerosis patients before and after intervention in two groups. * Determination and comparison of fatigue in multiple sclerosis patients before and after the intervention in two intervention and control groups

Design

A clinical trial with a control group, with parallel groups, a blind strain, non-randomized, phase 3 on 30 patients.

Settings and conduct

The sessions will be individual. the patient carefully watches the videos including the tasks and activities performed with the upper limbs and hands, the written instructions, and the number of repetitions. After watching the movie, he imitates and executes the tasks and activities he has seen. The place of conducting is the occupational therapy clinic of Ahvaz Rehabilitation Faculty. The outcome assessor and the data analyst do not know whether the assessed person is in the control group or in the intervention group

Participants/Inclusion and exclusion criteria

People with MS who have more affected on one side of their upper limb and less than 10 years have passed since they got the disease. People who do not want to participate in the intervention or fill in the information incompletely will be excluded from the intervention.

Intervention groups

The control group received the usual physiotherapy interventions, and the intervention group received 12 sessions of occupation-based AO interventions in addition to physical therapy. The interventions are 3 sessions per week for 45-60 minutes.

Main outcome variables

hand function, strength, and fatigue in individuals with MS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240302061148N1**
Registration date: **2024-06-04, 1403/03/15**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-04, 1403/03/15**
Update count: **0**

Registration date

2024-06-04, 1403/03/15

Registrant information

Name

Fatemeh Savaedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4822 6676

Email address

f-savaedi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-25, 1403/03/05

Expected recruitment end date

2024-07-26, 1403/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Action Observation Training on hand function, strength and fatigue in individuals with Multiple Sclerosis

Public title
Effect of Action Observation Training on hand function, strength and fatigue in individuals with Multiple Sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients diagnosed with MS between the ages of 18 and 63 have problems with hand function and performing daily activities. According to the EDSS scale, they receive a score of 6. Patients who have more weakness on one side of their body feel weaker and are unable to do things with that hand The duration of the disease is less than 10 years. Do not have neurological problems, other related diseases, or issues with sensation, comprehension (apraxia), vision, or hearing. The patient can participate in the study if their vision is corrected with glasses and their hearing is corrected with hearing aids. Obtaining a score of at least 23 on the MMSE test

Exclusion criteria:
Incomplete information in demographic information forms or evaluation questionnaires Non-referral and lack of cooperation from the patient throughout the treatment Absence from more than three treatment sessions Experiencing MS attacks during treatment

Age
From **18 years** old to **63 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the outcome evaluator is blinded to whether the individual is in the intervention group or the control group. The data analyst is also blinded to whether the information is related to the control group or the intervention group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz JondiShapour University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences Campus, Faculty of Rehabilitation

City
Ahvaz

Province
Khouzestan

Postal code
6471764544

Approval date
2024-04-24, 1403/02/05

Ethics committee reference number
IR.AJUMS.REC.1403.020

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G37.3

ICD-10 code description
Acute transverse myelitis in demyelinating disease of central nervous system

Primary outcomes

1

Description
The hand function score; a higher score on this questionnaire indicates greater impairment in hand function

Timepoint
At the beginning of the study and after 12 intervention sessions

Method of measurement
Arm Function in Multiple Sclerosis Questionnaire (AMSQ): This questionnaire contains 31 items assessing hand and upper limb function, utilizing a 6-point scale from 1 (no limitation in activity at all) to 6 (not able to perform the activity). A higher score on this questionnaire indicates greater impairment in hand function.

2

Description
Fatigue Severity Scale - The Fatigue Severity Scale (FSS) is a 9-item scale that measures the severity of fatigue

and its effect on a person's activities and lifestyle in patients with a variety of disorders.

Timepoint

At the beginning of the study and after 12 intervention sessions

Method of measurement

FSS: This scale evaluates the intensity of fatigue in people with MS on a 7-point scale from 1 (completely disagree) to 7 (completely agree). According to the scoring system outlined in this questionnaire, a score below 36 indicates no fatigue, while a score of 36 and above requires evaluation by a doctor.

3

Description

grip power

Timepoint

At the beginning of the study and after 12 intervention sessions

Method of measurement

Dynamometer

4

Description

Pinch strength (strength between thumb and forefinger)

Timepoint

At the beginning of the study and after 12 intervention sessions

Method of measurement

Pinch gauge

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine physiotherapy interventions, patients in the intervention group receive Action Observation treatment for 12 sessions, with each session lasting 1 hour.

Category

Rehabilitation

2

Description

Control group: Patients in the control group only received routine physiotherapy interventions for 12 sessions, with each session lasting 1 hour.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Khuzestan MS Association

Full name of responsible person

DR. Nastaran Majdinasab

Street address

Ahvaz Jundishapur University of Medical Sciences Campus, Faculty of Rehabilitation

City

Ahvaz

Province

Khouzestan

Postal code

6135733133

Phone

+98 61 3374 3660

Email

ahvaz-rehab@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoush Zakerkish

Street address

Golestan Blvd., University City, Jundishapur University of Medical Sciences, Ahvaz Research and Technology Development Vice

City

Ahvaz

Province

Khouzestan

Postal code

6135715756

Phone

+98 61 3373 8383

Email

itc@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Mahsa Fadavi-Ghaffari

Position
Faculty member of Ahuz University of Medical Sciences (Lecturer))

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

Street address
Ahvaz Jundishapur University of Medical Sciences Campus, Faculty of Rehabilitation

City
Ahvaz

Province
Khouzestan

Postal code
6136843847

Phone
+98 61 3374 3101

Email
mahsafadavimsc93@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mahsa Fadavi-Ghaffari

Position
Member of the academic faculty of Jundishapur Ahvaz University of Medical Sciences (lecturer))

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

Street address
Ahvaz Jundishapur University of Medical Sciences Campus, Faculty of Rehabilitation

City
Ahvaz

Province
Khouzestan

Postal code
6136843847

Phone
+98 61 3374 3101

Email
mahsafadavimsc93@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Savaedi

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

Street address
Ahvaz Jundishapur University of Medical Sciences Campus, Faculty of Rehabilitation

City
Ahvaz

Province
Khouzestan

Postal code
6471764544

Phone
+98 61 3374 3101

Email
fatemeh.savaedi2000@gmail.com

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