

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of occupation-based practice and exercise training on upper extremity function of people with Multiple Sclerosis

Protocol summary

Study aim

Comparison of the effect of occupation-based intervention with exercise-based intervention on occupational performance, satisfaction of occupational performance, hand dexterity, muscle tone and fatigue of patients with multiple sclerosis

Design

Randomised control trial with control group, with a parallel group design, single blind, randomised controlled trial

Settings and conduct

In this randomized clinical trial, eligible patients will be recruited and randomly assigned to one of two groups. Intervention will take place in Isfahan Multiple sclerosis center. Control group will receive exercise based intervention. Intervention group will receive 12 sessions of occupation-based intervention. After the end of treatment sessions the pretest and post-test scores of the two groups will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having Multiple sclerosis according to neurologist diagnosis, age: 18-50, Expanded Disability Status Scale score between 3 and 5.5, hand performance difficulty Exclusion criteria: History of relapse during the last 6 months, Neurological, rheumatic, musculoskeletal or orthopedic disorders that interfere with treatment.

Intervention groups

Intervention group: Occupation-based intervention involves a type of client-centered therapy in which the client and therapist work together to select meaningful activities based on interests, needs, health and participation in the daily activities of the client then they plan the intervention. Occupation-based intervention will be in one-hour sessions, twice a week for six weeks. Control group: Exercise-based intervention physical activity that is usually performed regularly with the aim of promoting or maintaining physical or health fitness.

Treatment will be in one-hour sessions, twice a week for six weeks.

Main outcome variables

dexterity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190809044482N1**

Registration date: **2020-05-01, 1399/02/12**

Registration timing: **retrospective**

Last update: **2020-05-01, 1399/02/12**

Update count: **0**

Registration date

2020-05-01, 1399/02/12

Registrant information

Name

Sara Afshar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0036

Email address

afsharsara262@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of occupation-based practice and exercise training on upper extremity function of people with Multiple Sclerosis

Public title
Effect of occupation-based practice on upper extremity function of people with Multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients with Multiple Sclerosis diagnosed with neurologist Expanded Disability Status Scale score between 3-5.5 Montreal Cognitive Assessment score more than 24 at least one effected hand in Coin Rotation Task and 9 hole peg test age between 18-50
Exclusion criteria:
 relapse in the past 6 month patients with other neurologic disorders patients with rheumathologic disorders patients with orthopedic disorders patients with musculoskeletal disorders that have effect on hand mobility

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients in the study will be randomly assigned to the intervention or control group. Randomization using GraphPad software provides a string of random codes A (intervention group) and B (control group) completely randomly. This list is provided to the clinic secretary to enter patients into study groups based on their entry into the clinic. Allocation concealment will be performed by the secretary of the multiple sclerosis center.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients will be aware of the type of intervention, but the evaluator will be someone else who will not be aware of the type of intervention. Therefore, the study will be conducted as a single blind study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of University of Social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar alley, Daneshjoo bulvar, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2018-03-15, 1396/12/24

Ethics committee reference number

IR.USWR.REC.1396.319

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

dexterity

Timepoint

before the intervention and 7 weeks after intervention

Method of measurement

Nine Hole Peg Test

Secondary outcomes

1

Description

occupational performance

Timepoint

before intervention and 7 weeks after intervention

Method of measurement

Canadian occupational performance measure

Intervention groups

1

Description

Intervention group: Occupation-based intervention involves a type of client-centered therapy in which the client and therapist work together to select meaningful activities based on interests, needs, health and participation in the daily activities of the client then they plan the intervention. Occupation-based intervention will be in one-hour sessions, twice a week for six weeks.

Category

Rehabilitation

2

Description

Control group: exercise based intervention. Intervention will be performed in the form of predetermined exercises, with a specific intensity and schedule. Intervention will be 6 weeks, twice a week, 60 minutes per sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan MS center

Full name of responsible person

Fereshteh Ashtari

Street address

Isfahan MS center, Bahonar Ave., Hedayat Ave.

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Isfahan

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8158844799

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isfahan-society@yahoo.com

Web page address

<https://clinic24h.com/projects/%D9%85%DA%A9%D8%B2-ms-%D8%A7%D8%B5%D9%81%D9%87%D8%A7%D9%86/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr. Mohammadreza Khodaei Ardakani

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar alley, Daneshjoo Blv., Velenjak, Tehran

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Email

amozesh@uswr.ac.ir

Web page address

<http://www.uswr.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Sara Afshar

Position

PhD candidate Student

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

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Position

Phd condidate student

Latest degree

Master

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After the completion of this study, a manuscript regarding the documentation and the results of the study will be prepared and published. If more details are needed, individuals can send their request by email to the person responsible for scientific accountability.

When the data will become available and for how long

8 months after publishing the results

To whom data/document is available

Researchers who are working in academic and scientific institutions

Under which criteria data/document could be used

The use of documents is allowed with written permission.

From where data/document is obtainable

Sara Afshar, afsharsara262@gmail.com

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

Request by email

Comments