Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Isfehan MS center, Bahonar Ave., Hedayat Ave.

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isfahan-socity@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 Khodaee 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

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Full name of responsible person
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Position
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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
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