Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing effects of Cognitive Orientation to daily Occupational Performance (CO-OP) approach and exercise training on participation, and fatigue in people with Multiple Sclerosis

Protocol summary

Study aim

The aim of this study was to compare the effect of Cognitive Orientation to daily Occupational performance (CO-OP) approach on the participation of people with multiple sclerosis in daily life activities (their performance and satisfaction), participation in social activities and their degree and severity of fatigue with exercise-based therapies.

Design

The present study is a parallel single-blind randomized clinical trial designed as a pretest-posttest. The predicted sample size is 30 people (15 people in each group). A random sequence created by randomization.com will be used for randomization.

Settings and conduct

Participants in the treatment group receive a CO-OP approach. One-hour individual sessions will be held twice a week for 5 weeks at home. Participants in the control group will receive stretching exercises, strengthening exercises and balance exercises for 5 weeks, 3 sessions per week and a total of 15 sessions of 45 minutes. These exercises will be performed in the clinic. Because the participants are not related to each other, they are blinded.

Participants/Inclusion and exclusion criteria

Participants are people with multiple sclerosis diagnosed by a neurologist, aged 18-50, with an EDSS score between 3-5.5, and score ,ore than 26 in MoCA . People who have a history of CO-OP treatment or similar treatments or who have neurological, rheumatic, or orthopedic disorders that interfere with treatment will not be included in the study.

Intervention groups

The intervention group includes people with multiple sclerosis with an EDSS score of 3 to 5.5 who receive a Cognitive Orientation to daily Occupational performance (CO-OP) approach. The control group includes people with multiple sclerosis with an EDSS score of 3 to 5.5 who receive exercise therapy intervention.

Main outcome variables

Participation in activity of daily living and social. fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210621051643N1**
Registration date: **2021-06-22, 1400/04/01**
Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**
Update count: **0**

Registration date

2021-06-22, 1400/04/01

Registrant information

Name

Mehrdad Saeidi Borujeni

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effects of Cognitive Orientation to daily Occupational Performance (CO-OP) approach and exercise training on participation, and fatigue in people with Multiple Sclerosis

Public title

Investigating effects of CO-OP approach on people with Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of multiple sclerosis by a neurologist Age between 18-50 years EDSS score between 3 and 5.5 Score more than 26 in the MoCA assessment

Exclusion criteria:

Recurrence of symptoms or the onset of a new attack during the intervention period History of receiving CO-OP treatment or similar treatments Existence of neurological, rheumatic or orthopedic disorders that interfere with treatment

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

we use simple sampling method and simple randomization for allocation of samples into the two group in the present study. For this purpose, before starting the study, a sequence of letters a and b (so that both are equal) is created through randomization.com, according to the sample size. After the start of the study, each participant who met the entry requirements will receive a number based on the time of entry into the study and will receive intervention a or b from a pre-prepared sequence list.

Blinding (investigator's opinion)

Single blinded

Blinding description

The people in charge of the initial and final evaluations as well as the people in charge of data analysis are not aware of the category of participants. Depending on the nature of the study, researchers and participants will be aware of the type of categorization.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University Social welfare and Rehabilitation Sciences

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Kodakyar Ave., Daneshjo Blvd.,Evin

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Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.USWR.REC.1399.087

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

Participation and Satisfaction in Activity of Daily Living (ADL)

Timepoint

Before the intervention ,After the intervention, follow-up period of 3 months

Method of measurement

Canadian Occupational Performance Measure (COPM)

Secondary outcomes

1

Description

Depression score

Timepoint

Before intervention, after intervention, 3-month follow-up

period

Method of measurement

Beck Depression Inventory II (BDI-II)

2

Description

Quality of life score

Timepoint

Before intervention, after intervention, 3-month follow-up period

Method of measurement

Multiple Sclerosis Impact Scale (MSIS-29)

3

Description

Social participation

Timepoint

Before intervention, after intervention, 3-month follow-up period

Method of measurement

Community Integration Questionnaire (CIQ)

4

Description

Intensity and effect of fatigue

Timepoint

Before intervention, after intervention, 3-month follow-up period

Method of measurement

Fatigue Impact Scale (FIS) & Fatigue Severity Scale (FSS)

Intervention groups

1

Description

Intervention group: The CO-OP approach is implemented in 10 sessions. In the first session, performance goals are determined by the authorities using the COPM questionnaire. The therapist then teaches the general problem-solving strategies (goal, plan, execution, check) and how to use field-specific strategies to design and execute the plan and achieve the intended goal. Then, for example, an experimental goal is selected and the general and specific strategies of the field for that goal are practiced with the authorities. From the third session onwards, work on the selected goals of the clients begins. The client plans for its own purposes. The therapist, as an active observer, guides the client through guided discovery, if, given his or her expertise, the program is likely to pose a risk to the client or contain items that make it impossible to reach the target. Guides. Upon entering the program implementation section, dynamic activity analysis is performed by the therapist to identify the needs and obstacles of program implementation at each stage and eliminate them using field-specific cognitive strategies.

Category

Rehabilitation

2

Description

Control group: Participants in the control group will receive stretching exercises, strengthening exercises and balance exercises for 6 weeks, 3 sessions per week and a total of 18 sessions of 45 minutes. These exercises will be performed in the clinic. At the discretion of experts, the type of exercise and the duration and intensity of each exercise may vary according to the circumstances of each client.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran MS Society, Sina hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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https://researchdeputy-en.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
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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
Since the all rights of this study are at the disposal of the University of Social Welfare and Rehabilitation Sciences, any decision regarding the publication of data is at the disposal of this university.
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
Not applicable
Data Dictionary
Not applicable