Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The Effect of Occupation-Based Interventions on Adaptive Response in Caregivers of People with Multiple Sclerosis Based on the Model of Occupational Adaptation

Protocol summary

Study aim

Investigating Impact of Occupation-based Interventions on the Adaptive Response in Caregivers of people with MS Based on the Model of Occupational Adaptation

Design

In a single blind randomized controlled clinical trial, 24 caregivers of MS patients will be randomly allocated into intervention (12 caregivers) and control (12 caregivers) groups.

Settings and conduct

The location of the evaluations and interventions is Shafa Yahyayan Hospital and assessor has been blinded before and after the interventions in two groups.

Participants/Inclusion and exclusion criteria

Caregivers: A caregiver can be one of family members of the patient that does not receive wages for caring. The ability to speak in Persian and reading and writing, should be between the ages of 18-60, engaging in caring for at least 6 months and 4 hours every day. Have the enough ability and time to participate in an intervention program independently. No serious psychological disturbances. People with MS: According to McDonald's diagnostic criteria, the patient has a definitive MS diagnosis. The MMSE cognitive test be higher than 22 . Have an EDSS score of 5-8 and finally ages of 18-60.

Intervention groups

Intervention will be conducted by a trained occupational therapist in 6 sessions of two hours over a period of 6 weeks. The intervention group will receive a treatment based of occupational adaptation model, and the control group will receive routine occupational therapy treatments in a format of pamphlet or a booklet

Main outcome variables

1- Level of occupational performance 2- Satisfaction of occupational performance 3- Occupational adaptation 4- Adaptive response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029260N3**
Registration date: **2019-04-02, 1398/01/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-02, 1398/01/13**
Update count: **0**

Registration date

2019-04-02, 1398/01/13

Registrant information

Name

Afsson Hassani Mehraban

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 22227124

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mehraban.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-16, 1397/12/25

Expected recruitment end date

2019-09-16, 1398/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Occupation-Based Interventions on Adaptive Response in Caregivers of People with Multiple Sclerosis Based on the Model of Occupational Adaptation

Public title
The Effect of Occupation-Based Interventions in Caregivers of People with Multiple Sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
caregivers: Caregivers: A caregiver can be one of family members of the patient, including the spouse, father, mother and children that does not receive wages for caring. If the patient has more than a caregiver, depending on the amount of hours of patient caring, the main caregiver is selected. The ability to speak in Persian and reading and writing, should be between the ages of 18-60, engaging in caring for at least 6 months and 4 hours every day. Have the enough ability and time to participate in an intervention program independently. People with MS: According to McDonald's diagnostic criteria, the patient has a definitive MS diagnosis. People with MS: The MMSE cognitive test be higher than 22 . People with MS:Have an EDSS score of 5-8 People with MS: Ages of 18-60.

Exclusion criteria:
Having serious psychological disturbances

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Block: In this method, the number of participants are assigned to each group are the same and the size of all blocks is equal (for example, in a double-blind trial, 8 blocks are containing 4 participants in the intervention group and 4 participants in the control group)

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome evaluator: The person or people who evaluate the outcome or non-outcome of the outcome in the participants or collect data on the outcome variables.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of Iran University of Medical Sciences

Street address
Hemmat highway

City
Tehran

Province
Tehran

Postal code
-

Approval date
2018-12-26, 1397/10/05

Ethics committee reference number
IR.IUMS.REC.1397.742

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
level of occupational performance

Timepoint
first, final, one month and three month after intervention

Method of measurement
Canadian Occupational Performance Measure(COPM)

2

Description
satisfaction of occupational performance

Timepoint
first, final, one month and three month after intervention

Method of measurement
Canadian Occupational Performance Measure(COPM)

3

Description
occupational adaptation

Timepoint
first, final, one month and three month after intervention

Method of measurement
Relative Mastery Measurement Scale(RMMS)

4

Description
adaptive response
Timepoint
first, final, one month and three month after intervention
Method of measurement
The coping with multiple sclerosis caregiving inventory(CMSCI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention will be conducted by a trained occupational therapist in 6 sessions of two hours over a period of 6 weeks. The intervention group will receive a treatment based of occupational adaptation model. This intervention program is based on two phase studies, a detailed review of resources and a qualitative phase of content analysis. In this intervention program, caregivers' occupational problems are treated.
Category
Rehabilitation

2

Description
Control group: the control group will receive routine occupational therapy treatments, Includes training and essential counseling, in a format of pamphlet or a booklet
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Yahyayean Hospital
Full name of responsible person
Fatemeh Motaharinezhad
Street address
Mojahedin Eslam Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Seyed Kazem Malakoti
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Hemmat highway
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
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Fatemeh Motaharinezhad
Position
phD candidate
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
-
When the data will become available and for how long
-
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments