Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of applying continuous care model versus no intervention on lifestyle and quality of life in multiple sclerosis patients

Protocol summary

Summary

Objective: Investigating the effect of applying continuous care model on lifestyle and quality of life in multiple sclerosis patients. Design: Randomized semi-experimental study with intervention and control groups. Sample size: 70 patients divided into two groups of intervention and control. Methods: multiple sclerosis patients who will visit Hamadan MS Association in 1392. Inclusion criteria: (a) patients without history of coronary and pulmonary diseases, psychiatric disorders or any other acute diseases with neurologist diagnosis; (b) Ages between 20 to 45 years; (c) Definite diagnosis of multiple sclerosis by a neurologist; (d) Settling in Hamadan for participating in educational sessions; (e) No visual and auditory defects with a specialist diagnosis; (f) At least six months history of disease. Exclusion criteria: (a) multiple sclerosis exacerbation or contracting another illness during the study; (b) Simultaneously contributing in other self-care programs which are affecting the life-style; (c) Patients with progressive-relapsing multiple sclerosis. Interventions: Patients in the intervention group will be educated according to continuous care model, in 8, one hour sessions, for 1 month and they will be followed for 2 months and the control group will receive routine care. Primary outcome: life's quality will be evaluated in accordance with 54 items questionnaire of life's quality of multiple sclerosis patients before, 1 month and 2 months after education. Secondary outcome: Lifestyle will be evaluated in accordance with questionnaire of lifestyle of multiple sclerosis patients, before, 1 month and 2 months after education.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021112439N1**
Registration date: **2013-06-25, 1392/04/04**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2013-06-25, 1392/04/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice_chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2013-10-07, 1392/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of applying continuous care model versus no intervention on lifestyle and quality of life in multiple sclerosis patients

Public title

The effect of continuous care on lifestyle and quality of life in multiple sclerosis patients

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: (a) patients without history of coronary and pulmonary diseases, psychiatric disorders or any other acute diseases with neurologist diagnosis; (b) Ages between 20 to 45 years; (c) Definite diagnosis of multiple sclerosis by a neurologist; (d) Settling in Hamadan for participating in educational sessions; (e) No visual and auditory defects with a specialist diagnosis; (f) At least six months history of disease. Exclusion criteria: (a) MS exacerbation or contracting another illness during the study; (b) Simultaneously contributing in other self-care programs which are affecting the life-style; (c) Patients with progressive-relapsing multiple sclerosis.
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Human Subject Review Board of Hamadan University of Medical Sciences
Street address
Hanmadan, Hamadan University of Medical Sciences
City
Hamadan
Postal code
Approval date
2013-04-10, 1392/01/21
Ethics committee reference number
16/35/9/49/پ/د

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
Quality of life in multiple sclerosis patients
Timepoint
Before intervention, one month and two months after intervention
Method of measurement
MSQoL-54 questionnaire

Secondary outcomes

1

Description
Lifestyle in multiple sclerosis patients
Timepoint
Before intervention, one month and two months after intervention
Method of measurement
Questionnaire of lifestyle of multiple sclerosis patients

Intervention groups

1

Description
Intervention group: in intervention group, patients will be divided into 3 groups based on their score of Expanded Disability Status Scale (EDSS). These 3 groups will be equalized based on type of MS, education, occupation, sex and age distribution and will be educated in accordance with continuous care model.
Category
Other

2

Description
Control group: in the control group the patients will be received only routine cares
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian hospital

Full name of responsible person
Fatemeh Ashtarani
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Shahid Fahmideh Ave, Hamadan University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor of Research and Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr. Heidar Tavilani
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Shaheed Fahmideh Ave, Hamadan University of Medical Sciences,
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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
Vice-chancellor of Research and Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty