

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 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 lifestyle; (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

Name

Fatemeh Pakrad

Name of organization / entity

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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

Hamadan, 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/د/پ

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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Full name of responsible person

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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,

City

Hamadan

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**Contact****Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

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Web page address**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