Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of collaborative care model on happiness of multiple sclerosis (M.S) patients and their caregivers

Protocol summary

Summary

(1) Objectives: The present study investigates the effect of collaborative care model on happiness of multiple sclerosis patients and their caregivers. (2) Design: The present study design base on collaborative care model (3) Setting and conduct: 80 caregivers and 80 patients were selected according to inclusion criteria then caregivers and patients randomly will be divided into case and control groups. Baseline happiness questionnaire completed before the intervention and then steps of collaborative care model will be engaged in case groups for 3 months. Happiness scores 1 month after the intervention will be compared with pre-intervention data in case and control groups. (4) Participants including major eligibility criteria: Patient and caregivers member of Ahvaz Multiple Sclerosis Society that have inclusion criteria. Inclusion criteria including: Age between 20 and 55 years, confirmed multiple sclerosis disease by a neurologist and Expanded Disability Status Score between 2 to 3. Exclusion criteria including: Pregnancy and increase in Expanded Disability Status Score at least 1 point with relapse or progression of the disease. (5) Intervention: Steps of collaborative care model including: motivation, preparation, involvement and evaluation will be engaged in case groups. (6) Main outcome measures (variables): Happiness

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051121474N3**
Registration date: **2015-06-07, 1394/03/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-07, 1394/03/17

Registrant information

Name
Somaye Ganjalivand
Name of organization / entity
Shiraz University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of collaborative care model on happiness of multiple sclerosis (M.S) patients and their caregivers

Public title

The effect of collaborative care model on happiness of multiple sclerosis (M.S) patients and their caregivers

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Multiple sclerosis disease confirm by a

neurologist; Expanded disability status scale between 2 to 3. Exclusion criteria: Pregnancy; Increase in Expanded Disability Status Score at least 1 point with relapse or progression of the disease.

Age
From **74 years** old to **39 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee, Shiraz University of Medical Science

Street address
Ethics committee of Shiraz University of Medical Science, Shiraz University of Medical Science, Zand Street, Shiraz, Fars, Iran.

City
Shiraz

Postal code
1978-71345

Approval date
2015-03-02, 1393/12/11

Ethics committee reference number
CT_9379_7399

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
Happiness

Timepoint
Before intervention and 1 month after intervention

Method of measurement
Oxford Happiness Scale

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention groups, education based on steps of collaborative care model including: Motivation, Readying, Involvement and Evaluation will be used for 3 month.

Category
N/A

2

Description
Control groups receive no intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Khuzestan MS Society

Full name of responsible person
Dr. Nastaran Majdinasab

Street address
Khuzestan MS Society, Faculty of Rehabilitation, Jondishapour University of Medical Science, Golestan Road, Ahvaz, Khuzestan, Iran.

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Science

Full name of responsible person
Dr.Seyyed Basir Hashemi

Street address
Vice chancellor for research, Shiraz University of Medical Science, Zand Street, Shiraz, Fars, Iran.

City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shiraz University of Medical Science
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
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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