Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of life skills training on self - management and coping of patients with Multiple sclerosis

Protocol summary

Summary

The aim of this study is to examine the effect of life skills training on self-management and coping with MS. The sample size would be 80. The study involved two groups: experimental and control and The study not blinded. The samples will be recruited by convenience sampling and and allocated to each groups by block randomization. Data collection tools include three questionnaires: (Personal and medical information questionnaire and coping and self-management questionnaires) will be completed by subjects before intervention. Coping and self-management questionnaires will be again completed, eighth weeks after intervention. Intervention includes a 4 teaching sessions over 4 weeks (1 session per week) with each session lasting 30 minutes and number of sessions may be increased if necessary. At the same time, the booklet and CD will be given to experimental group. During the study, the sample will be excluded if doesn't attend at least one teaching sessions.In cases of acute illness or inability to attend training sessions, the potential participants would be excluded. The subjects in control group will receive usual care. primary outcome 1&2 involved :Coping and self-management.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022326726N1**
Registration date: **2016-10-31, 1395/08/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Iran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of life skills training on self - management and coping of patients with Multiple sclerosis

Public title

The effect of life skills training on self - management and coping of patients with Multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: a definite diagnosis of MS by a neurologist ability to read and write; ability to participate in training sessions; negative history of any exacerbation

of the disease over the past three months; not being pregnant; not changing the dose of drugs in use; the absence of chronic cardiopulmonary diseases and psychological disorders . Exclusion criteria: admission to hospital or recurrence of the disease; not attending at least one teaching session; developing a progressive type of MS; having excessive fatigue that makes the patient unable to receive the training; serious medical conditions.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Iran University of Medical Sciences

Street address
Besides Milad Tower, Hemmat Highway, Tehran

City
Tehran

Postal code

Approval date
2016-04-20, 1395/02/01

Ethics committee reference number
ir.iums.rec.1394.9311686009

Health conditions studied

1

Description of health condition studied
G35

ICD-10 code
G35

ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
Coping

Timepoint
The first day and a month after the last training session

Method of measurement
questionnaire

2

Description
self management

Timepoint
The first day and a month after the last training session

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Group test: 4 sessions over 4 weeks (1 session per week) with each session lasting 30 minutes for patients in the intervention group (the number of sessions may be added if necessary). The booklet and CD will be given to experimental group. Teaching manual has been prepared based on scientific content as follows: Session I: Multiple sclerosis, and its nature, life skills training concept and its applications, self-awareness skill, session II: Teaching empathy, interpersonal relationships and effective communication, session III: Reminders of previous content and skill training of coping with stress, emotion management, problem solving, session IV: browsing, teaching decision-making skills, creative thinking and critical thinking. In the session IV: Reminders of previous content and teaching decision making, innovative thinking and critical thinking skills. Teaching would be provided by the main researcher in the form of lecture, discussion and Q & A.

Category
Behavior

2

Description
The control group: received usual care and research tools will be given to them.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Society in Tehran
Full name of responsible person
Head of the Center
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research Iran University of Medical Sciences
Full name of responsible person
Vice chancellor for Research Iran University of Medical Sciences
Street address
Besides Milad Tower, Hemmat Highway, Tehran
City
Tehran
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 Iran 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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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