

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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 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

Name

Mahnaz Seyedoshohadaee

Name of organization / entity

Iran University of Medical Sciences

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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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

Masters Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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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