Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of group training of hope therapy approach on quality of life and meaning of life of patients with MS and their family caregivers in Rafideh Rehabilitation Hospital

Protocol summary

Study aim
Overall Objective: To determine the effectiveness of hope therapy group training on increasing the quality of life and meaning of life of patients with MS referred to Rafideh Hospital in Tehran and their family caregivers

Design
Study design: included MS patients. The sample size was about 60 people. 15 patients and 15 caregivers were in two groups

Settings and conduct
Type of study: This research will be done by quasi-experimental method (quasi-experimental) and pre-test and post-test with control group.

Participants/Inclusion and exclusion criteria
1- Patients with inflammation between the ages of 20 to 70 years 2- Conscious consent to participate in research 3- At least six months have passed since their diagnosis

Intervention groups
Intervention group 1: Patients with MS: Hope therapy training protocol for MS patients Intervention group 2: Caregivers of patients with MS: Protocol of hope therapy training for caregivers of MS patients

Main outcome variables
Quality of life and meaning of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201119049440N1**
Registration date: **2020-12-04, 1399/09/14**
Registration timing: **retrospective**

Last update: **2020-12-04, 1399/09/14**
Update count: **0**

Registration date
2020-12-04, 1399/09/14

Registrant information

Name
moslem arian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5612 2224

Email address
mo.arian@uswr.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-09-22, 1398/06/31

Actual recruitment start date
2019-07-23, 1398/05/01

Actual recruitment end date
2019-09-22, 1398/06/31

Trial completion date
2019-09-22, 1398/06/31

Scientific title
The effectiveness of group training of hope therapy approach on quality of life and meaning of life of patients with MS and their family caregivers in Rafideh Rehabilitation Hospital

Public title
The effectiveness of group training in hope therapy approach on quality of life and meaning of life

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Criteria for admission of the patient: with MS Informed consent Get a low or average score in the meaning of life and quality of life questionnaire Criteria for patient exit: dissatisfaction and withdrawal Achieve high scores in the questionnaires of meaning of life and quality of life Criteria for caregiver entry: Family member of a patient with MS and being the primary caregiver Informed consent Get a medium or low score in the Meaning and Quality of Life Questionnaire Criteria for leaving the caregiver: dissatisfaction or withdrawal from continuing the research Get a high score in the Meaning and Quality of Life Questionnaire
Exclusion criteria:
Get a high score on the Quality of Life Questionnaire Get a high score on the meaning of life questionnaire Receive parallel psychological treatment or interventions

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
First, inclusion and exclusion criteria in patients with MS and their caregivers were evaluated. Then, meaning of life and quality of life questionnaires were distributed. Then 30 patients and 30 caregivers Average or low scores were obtained in these two questionnaires. The names of these 30 patients were written on paper. The name paper was separated and placed in a basket. Then we took a piece of paper each time and put it in the test basket or control basket. This process continued for 30 patients until 15 patients were included in the experimental basket and 15 patients in the control group. The researcher used the lottery method when selecting the names, and therefore there was no bias or intentionality in assigning individuals to the two groups. Exactly the same procedure was performed for 30 patient caregivers. In fact, the randomization was simple and by lottery. Due to the low number of samples, this was done manually.

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
University of Social Welfare and Rehabilitation Sciences
Street address
Tehran, Evin, Daneshjoo Blvd., Koodkiar dead end
City
Tehran
Province
Tehran
Postal code
1985713871

Approval date
2019-06-28, 1398/04/07

Ethics committee reference number
IR.USWR.REC.1398.047

Health conditions studied

1

Description of health condition studied
Meaning of life and quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Meaning of life: This variable, which is designed by the meaning of life questionnaire of Steger et al., Has two subscales: meaning presence and meaning search. This variable was evaluated before and after the implementation of the protocol to measure the changes resulting from the implementation of the protocol in the two intervention groups.

Timepoint
A pre-test is taken before the protocol is implemented and after the protocol is implemented (which takes one month). So the test is taken. That is, this variable is measured twice.

Method of measurement
questionnaire

2

Description
Quality of life: This variable has been evaluated with the MSIS-29 Quality of Life Questionnaire, which includes two subscales of physical and mental quality of life. This variable was evaluated before and after the implementation of the protocol to measure the changes resulting from the implementation of the protocol in the two intervention groups.

Timepoint
A pre-test is taken before the protocol is implemented

and after the protocol is implemented (which takes one month). So the test is taken. That is, this variable is measured twice.

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

experimental group 1: or group of patients with MS: For this group, a group training protocol of hope therapy was provided. This treatment protocol is designed for eight two-hour sessions that are performed for the group of MS patients and their family members with the necessary adjustments and adaptations. For example, patient assignments and family member assignments are different. Also, each session consists of 4 sections. In the first section, which lasts approximately 83 minutes, group members discuss the topics of the per session, review the assignment of the previous session, and encourage members to help each other solve homework problems. In the second section, which lasts approximately 83 minutes, group members are taught a new hope-related skill that includes three dimensions: goals, directions, and agent thinking. Apply these skills in their lives, discuss and encourage them to articulate their problems and help each other learn how to use these skills to solve their problems. During this part of group therapy, the therapist leads the group to discuss the skill as the main topic of the group. Finally, in the final ten minutes of the group, members are given a homework assignment for the next session, with the goal of having the members of the group apply hope-related skills in their daily lives. At the beginning of the group, as a general task, members are asked to choose a specific goal to work in group meetings to apply the skills learned on that specific goal in each session Control group 1: A group of MS patients remained in a non-intervention state and after the intervention and post-test and to observe ethics. They received several training sessions.

Category

Behavior

2

Description

Intervention group 2: or experimental group 2 (group of caregivers of patient with MS): For this group, a group training protocol of hope therapy was provided. This treatment protocol is designed for eight two-hour sessions that are performed for the group of MS patients and their family members with the necessary adjustments and adaptations. For example, patient assignments and family member assignments are different. Also, each session consists of 4 sections. In the first section, which lasts approximately 83 minutes, group members discuss the topics of the per-session, review the assignment of the previous session, and encourage members to help each other solve homework problems. In the second section, which lasts approximately 83 minutes, group members are taught a new hope-related skill that includes three dimensions: goals, directions, and agent thinking. Apply these skills in their lives, discuss and encourage them to articulate their problems and help each other learn how to use these skills to solve their problems. During this part of group therapy, the therapist leads the group to discuss the skill as the main topic of the group. Finally, in the final ten minutes of the group, members are given a homework assignment for the next session, with the goal of having the members of the group apply hope-related skills in their daily lives. At the beginning of the group, as a general task, members are asked to choose a specific goal to work in group meetings to apply the skills learned on that specific goal in each session. Control group 2: The caregiver of patients with MS remained in a non-intervention state and after the intervention and post-test and to observe ethics. They received several training sessions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafideh Hospital

Full name of responsible person

Research Committee of University of Social Welfare and Rehabilitation Sciences

Street address

Qeytariyeh - Shahid Baradaran Soleimani St. - Nemati Alley - Rafideh Rehabilitation Hospital.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr. Homeira Sajadi

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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

University of social welfare and rehabilitation sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Moslem Arian

Position

PhD student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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University of social welfare and rehabilitation sciences

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Moslem Arian

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Documentation is provided in the article

When the data will become available and for how long

Documentation is provided in the article

To whom data/document is available

By publishing an article, everyone in this field can use the article

Under which criteria data/document could be used

Documentation is provided in the article

From where data/document is obtainable

Documentation is provided in the article

What processes are involved for a request to access data/document

Documentation is provided in the article

Comments