Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of psycho-education on family caregiver burden with multiple sclerosis patients.

Protocol summary

Summary

Introduction The effect of psycho-education program on the family caregivers with multiple sclerosis. Multiple Sclerosis is a chronic and progressive common disorder of nervous system which causes perturbation in some people in their youth (more in their third decade). The progress of the disease is such that the lack of attention causes the people to be crippled and useless in their productive and energetic ages. Currently, most of the chronic cares (e.g. Multiple Sclerosis) are done at homes and by main caregivers. Given the diverse problems of the disease and its chronic progression, most of the patients and their families are not aware of the coping ways and do not receive proper supporting services. Lack of adequate training and support of primary caregivers of MS patients are the major factors in causing stress, anxiety and increase of burden. Therefore, the MS caregivers have to prepare themselves to support the patient and his/her family during the immense physical, psychological, and social crisis and address the requirements of patient and the family. Therefore, the treatment team members like psychiatric nurses can help these vulnerable people to overcome psychiatric pressures effectively not only by their caring and referral role but also through their supportive characteristic which helps the patients to improve their clinical status, together with their social, familial, and work adaptation. there are different types of family interventions to reduce the familial healthcare burdens like: family behavioral management, family group psychotherapy intervention, family therapy and etc. which motivated the researcher to benefit the family group psychotherapy technique to control and improve the healthcare burden. Following the recent changes in the treatment of chronic diseases recommends the past interventions and family group psychotherapy educations to control the health care burdens which these interventions are based on supportive and educational interventions. Research Methodology This study is based on a clinical trial in two groups and three stages. After demanding the recommendation letter from the department of Nursing and Midwifery of Isfahan University of Medical Sciences, the researcher referred to the management of neurology clinics to present the purpose of the study and to start the sampling. The neurology clinics of Alzahra University Hospital (related to Isfahan University of Medical Sciences) and also one of the neurology specialist's clinics in downtown (where is referred by MS patients and their family) are selected as scope of the study for the data collection. The data collection process is done from the family members who are the main caregivers and are responsible for all supports. The samples were selected randomly and then categorized into two groups named as experimental and control. The methodology of the study is quantitative approach and the survey study (two part questionnaire) is selected for the data collection. Sample of the Study The all family members of MS patients including male and female who refer to neurology clinics and meet the criteria of the study. sample of the study The sample size of the study is 32 persons which is the result of consultation with the specialists of statistics. The data collection instrument in this study is two questionnaires which the first one includes two parts (A and B). Part A is related to demographic information of caregiver including (sex, age, marital status, education level, employment, relation to the patient, and the duration of caregiving) and the patient including (age, sex, marital status, education level, employment, duration of sickness, severity of illness, and the rate of hospitalization one month after and before intervention). Part B contains the questions regarding the evaluation of burden of ZARIT caregiver which includes 22 items which the scales of each item are as follows: • Never 0 • Seldom 1 • Sometimes 2 • Usually 3 • Always 4 o The lowest score of healthcare burden is zero which means there is no burden. o The highest score is 88 which means the highest rate of burden. o The score between 61-88 means severe burden. o The score between 31-60 is the average burden. o The score under 30 is the slight

burden.

General information

Acronym
multiple sclerosis
IRCT registration information
IRCT registration number: **IRCT2012121911820N1**
Registration date: **2013-09-18, 1392/06/27**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2013-09-18, 1392/06/27

Registrant information
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Recruitment status
Recruitment complete
Funding source
Isfahan University of Medical Sciences & Researcher

Expected recruitment start date
2013-04-07, 1392/01/18
Expected recruitment end date
2013-08-09, 1392/05/18
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of psycho-education on family caregiver burden with multiple sclerosis patients.

Public title
The effect of psycho-education on caregiver burden
Purpose
Supportive
Inclusion/Exclusion criteria
All family members of MS patients including male and female who refer to neurology clinics and meet the criteria of the study are constructing the sample of the study. The criteria are as follows: 1.The MS patients with the expanded disability status score (EDSS) of 3-9.5. 2.Family caregiving is considered as the main support and holds all the responsibilities of the patient. 3.Interested to participate in the study. 4. Age more than 18 years old. 5.Able to communicate and comply with the rules of training sessions. 6.From each family member who is the main caregiver is participated in the study. 7.The caregiver is just taking care of one patient refractory in the family. 8.The duration of patient care is at least 3 months. 9.Capable of speaking, reading and writing in Farsi. 10.Have not participated in family education sessions (any research study in this field). 11.The main caregiver does not under psychotropic medication. The criteria of excluding: 1.The family caregiver is reluctant to cooperate in training sessions. 2.Existence of any problem that the caregiver is not able to participate in the study. 3.The caregiver has at most two absents in session records. 4.There are physical and psychological problems that cannot attend the sessions.
Age
From **18 years** old to **149 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
Isfahan University of Medical Sciences
Street address
Darvaze Shiraz, Isfahan
City
Isfahan
Postal code
8174673461
Approval date
2013-03-10, 1391/12/20
Ethics committee reference number
392255

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35-G37
ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
Family caregiver burden
Timepoint
Before- immediately and one month after the intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Stress and anxiety of caregivers
Timepoint
Before- immediately and one month after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention is a family group psycho-education based on a scheduled multi-session program with families and main caregivers to consider their needs and problems, and also to study the current articles which are gathered by the researcher, that finally is planned under the supervision of specialists and the lecturers for an educational-supportive intervention for the study group that based on the availability of caregivers there would be six sessions (each session 90 minutes) during six weeks (one week one session). The main caregivers are grouped in minimum 11 to maximum 17 persons which the contents of sessions are same for all groups. The intervention begins with some comments on MS and how it affects the life of patient and the family. Some details regarding the symptoms of MS and disorders which it causes in sensory and motion system and also the effects of these problems on patient and family are expressed. The family will gain some information regarding the potential factors in causing or aggravating of this disease like environmental-familial stresses, ambient temperature, nutrition, physical activities, and also genetics. The role of family communication skills, feeling expressions, coping with negative emotions, reduction of stress and anxiety techniques to caregivers, problem solving techniques, and the utilization of them towards the needs rectification of caregiving roles are provided by providing information for caregivers, which there will be an open discussion by the end of each session. Also, in order to strengthen of learning CDs and educational books are provided which would be the same for control group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The neurology clinics of Alzahra University Hospital (related to Isfahan University of Medical Sc
Full name of responsible person
Fariba Dalvi Esfahani- Master of Science in Psychiatric Nursing
Street address
Kashani st., Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences - University of Central Staff - Building No. 4 - Vice Chancel
Full name of responsible person
Fariba Taleghani
Street address
Isfahan University of Medical Sciences - Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences - University of Central Staff - Building No. 4 - Vice Chancel
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

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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