Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The effect of participatory care model training on mental health of patients with multiple sclerosis

Protocol summary

Study aim
Investigating the effect of participatory care model on mental health of patients with multiple sclerosis

Design
To be eligible for intervention, eligible individuals will be divided into two groups of control and test. Tools: Demographic Information Questionnaire and General Health Questionnaire. Demographic variables: age, gender, marital status, level of education, age of diagnosis, history of other illness and family status.

Settings and conduct
Blindness In analyzing the scores for the control and control groups, the group code was unknown to the analyst. Detachment of the code of the groups for the person performing the intervention with the evaluator, the target population of all MS patients, the research population of all MS patients referring to the MS Society of Tehran

Participants/Inclusion and exclusion criteria
entrance criteria: Definition of MS based on para clinical examinations , the ability to communicate verbally, minimizing literacy and reading. Exit criteria: the underlying mental and psychological illnesses, the patient's reluctance to continue Collaboration, lack of research tools.

Intervention groups
Clinical trials with two groups of test and control, available sampling method, after completing questionnaires in both groups, the intervention group will be participated and the participatory care model will be implemented in this group and in the control group No intervention will be done by the researchers.

Main outcome variables
Improvement and promotion of mental health of patients with MS, model effectiveness and cheapness and simplicity of the model for families and children.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180227038888N1**
Registration date: **2020-09-13, 1399/06/23**
Registration timing: **retrospective**

Last update: **2020-09-13, 1399/06/23**
Update count: **0**
Registration date
2020-09-13, 1399/06/23

Registrant information
Name
Saeed Nazari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-03-06, 1396/12/15
Expected recruitment end date
2018-04-30, 1397/02/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of participatory care model training on mental health of patients with multiple sclerosis

Public title
The Effect of Cooperative Care Model on Mental Health of MS Patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
• Definition of MS based on para clinical examinations active casework in the MS Society of Tehran The ability to communicate verbally Encouraging literacy at least write and read.
Exclusion criteria:
• Cognitive and mental illnesses (anxiety disorders, depression, obsessive-compulsive disorder, bipolar disorder, psychotic disorders)• Patient's unwillingness to continue cooperation or failure to complete research tools.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to intervene, qualified individuals will be divided into two groups of control and test by quasi-random method with a table.
Blinding (investigator's opinion)
Double blinded
Blinding description
Thus, in analyzing the scores for the control and control groups, the group code is unknown to the analyst. It is also blinded by a person who intervenes with a separate assessor.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of the University of Medical Sciences aja
Street address
No.77,Tehran pars Fatahi street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1654883859
Approval date
2018-02-25, 1396/12/06
Ethics committee reference number
IR.AJAUMS.REC.1396.115

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
Mental Health
Timepoint
The mental health is measured pre-test before intervention with the GHQ slider, and after the end of the intervention, the mental health is measured again with the GHQ questionnaire.
Method of measurement
General mental health questionnaire(GHQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study is a clinical trial study. Conditions are divided into two groups of control and test by semi-random method. Data collection tools include demographic information questionnaire and general health questionnaire. Using the demographic questionnaire, variables such as age, sex, marital status, level of education, age of diagnosis, history of other diseases and family status are collected. After completing the questionnaires in both groups, the experimental group is involved in an intervention that the participatory care model is implemented in this group and in the control group no intervention is performed by researchers.How to intervene and implement the participatory care model:1. Motivation

stage: The purpose of this stage is to motivate the client. This stage was performed by the research team (one neurologist, one clinical psychologist and two nurses. In this stage (the first session for 2 hours) the patients were explained about the research process in the intervention group. Patients were identified by taking a history and paraclinical examination, which led to a list of problems in the field of treatment and care in three areas of lack of health behaviors, lack of diet and inability to control the psychological problems of the disease. The active participation of research team members (according to their areas of responsibility) and patients was discussed.2. Preparation stage: In this stage (second session for one hour), the research team explained the nature of the visits (training and follow-up sessions), the goals and duration of the visits to the patients in the intervention group and the training schedule was presented to them.3. Involvement phase (implementation): This phase included three rounds of educational participation visits and two rounds of follow-up partnerships conducted by the research team.In the participatory educational phase, three visits were made (each visit lasting 50 to 70 minutes with a two-week interval between visits). The first visit was in the nature of disease and treatment, the second visit was in the field of diet and activity, the third visit was in the field of psychological issues. In each visit, the materials were simply presented to the patients by the research team (according to the areas of responsibility) in the form of lectures, PowerPoint, pamphlets and questions and answers. In the participation phase, two visits were followed (each visit for 40-50 minutes with an interval of two weeks). These visits, while examining the problems of the clients, the positive and negative results of the educational actions and previous actions were reviewed and reviewed, and the necessary instructions were provided to correct the objections.4. Evaluation stage: Stage evaluations were performed at the beginning and end of each visit by the research team. In the final evaluation (for 50-70 minutes) to assess the effect of implementing the participatory care model on patients' mental health, three months later, the GHQ-28 questionnaire was measured in the intervention group. Then the same method of assessment and evaluation was performed for the control group simultaneously.

Category
Rehabilitation

2

Description
Control group: The control group received routine care, and the researchers did not take any intervention on the control group

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Association MS Tehran

Full name of responsible person
Dr. Rahmatullah Hafezi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
Dr. Zahra Farsi

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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
Artesh University of Medical 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
Artesh University of Medical Sciences

Full name of responsible person
Saeed Nazari

Position
Ph.D. student

Latest degree
Master

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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
n order to access the topics mentioned above, we will only publish general information and, subject to observance of the information of the participants, there will be no access to the information of each individual participant in the study. The informed consent form, the clinical report report, and the study protocol after the completion of the project will be available at the Vice-Chancellor for Research and Technology of the University of Medical Sciences, and there will be no time limits.

When the data will become available and for how long
Starting data access will be possible 4 months after the results are printed

To whom data/document is available
For optimal and practical use of documentation for stepping up MS patients, there will be opportunities for academic and non-academic researchers.

Under which criteria data/document could be used
Except for the staff of the Vice-Chancellor of Research and Technology of the University of Medical Sciences, no other person will be allowed access to unidentifiable data. Requirements for submitting a request for access to data: 1. Researchers working in the treatment and rehabilitation of MS patients 2 MSs for exploitation and

use in the treatment and rehabilitation of MS patients

From where data/document is obtainable

Tehran, Fate mi Crossroads, Col. Etemadzadeh, aja University of Medical Sciences, Research and Technology

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

Referring to the Vice-Chancellor for Research and Technology of the University of Medical Sciences and the application form for consideration, which will be made available to the vice-president after examination by the deputy.

Comments