

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

Country

Iran (Islamic Republic of)

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Email address

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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

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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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Fatemi crossroad, Col. Etemadzadeh University of medical sciences aja

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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

In 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