Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of quality of life therapy on well-being, illness perception and disease severity in multiple sclerosis patients

Protocol summary

Study aim
Investigate the effectiveness of quality of life therapy on well-being, illness perception and disease severity in multiple sclerosis patients

Design
Clinical trial with treatment, and control group with random assignment.

Settings and conduct
Patients from Tehran who have the characteristics required to participate in the study will be invited.Participants are randomly assigned following block randomization in quality of life treatment and control groups. Then, questionnaires and consent form are provided to the participants. Patients participate in 10 sessions last 45 minutes. After the treatment will be completed, patients will fill the questionnaires again, and the follow-up process will be conducted three months later. The control treatment group do not received any psychological treatment, and they just fill the questionnaires.

Participants/Inclusion and exclusion criteria
Participants are 30 patients in whom the Multiple Sclerosis is initially diagnosed. Inclusion Criteria include: The patient has Multiple Sclerosis disorder based on Magnetic resonance imaging (MRI), Patient's education should be up to diploma, and exclusion criteria include: Patient has another medical diagnosis based on medical records. patient has a psychological disorder assessed by structured interview (SCID-I). Receiving psychological intervention simultaneously.

Intervention groups
Intervention group: In this study, we use the individual quality of life therapy protocol. Patients participate in ten sessions.The therapist works with the patient to select two to five areas of life, then clarify the attitudes of the area, standards of fulfillment for the area, and the relative importance placed on the area for overall happiness. Control group: patients who did not receive psychological treatment.

Main outcome variables
Quality of life, illness perception, and disease severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181221042068N2**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-23, 1398/09/02**
Update count: **0**

Registration date
2019-11-23, 1398/09/02

Registrant information

Name
Afsaneh Akhani

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
2019-10-23, 1398/08/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of quality of life therapy on well-being, illness perception and disease severity in multiple sclerosis patients

Public title
Quality of life therapy in multiple sclerosis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The patient has Multiple Sclerosis disorder based on Magnetic resonance imaging (MRI) Patient's education should be up to diploma

Exclusion criteria:
Patients has another medical diagnosis based on medical records. a psychological disorder assessed by structured interview (SCID-I) Receiving psychological intervention simultaneously

Age
To **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are randomly assigned following block randomization in quality of life treatment and control groups.

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
Ethics Commitee of Iran University of Medical Science

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2017-12-08, 1396/09/17

Ethics committee reference number
IR.IUMS.REC 1396.30686

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Illness perception

Timepoint
At the beginning of the study, 70 days and Six months later

Method of measurement
The Brief Illness Perception Questionnaire

2

Description
Quality Of Life

Timepoint
At the beginning of the study, 70 days and Six months later

Method of measurement
36-Item Short Form Survey (SF-36)

3

Description
Level of Disability

Timepoint
At the beginning of the study, 70 days and Six months later

Method of measurement
Expanded Disability Status Scale (EDSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, we use the individual quality of life therapy protocol. This program is as follows: Patients participate in ten sessions. The therapist works with the patient to select two to five areas of life, then clarify the attitudes or perceptions of the area, standards of fulfillment for the area, and the relative importance placed on the area for overall happiness, then Cognitive-behavioral strategies are implement within each targeted area.

Category

Lifestyle

2

Description

Control group: patients who did not receive psychological treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Afsaneh Akhani

Street address

Hazrate Rasoole Akram Hospital, Maziar Mansoori st, Satarkhan Av, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakuti

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Akhani

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Latest degree

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable