

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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

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Name of organization / entity

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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 Committee of Iran University of Medical Science

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

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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 implemented 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

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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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Person responsible for updating data

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Position

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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