

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effectiveness of group intervention focused on intolerance of uncertainty on psychological distress and quality of life in multiple sclerosis patients

Protocol summary

Study aim

Investigate the effectiveness of group intervention focused on intolerance of uncertainty on psychological distress and quality of life in multiple sclerosis patients

Design

Clinical trial with control group, randomized, phase 2 on 60 patients

Settings and conduct

Group therapy sessions focusing on the inability to tolerate uncertainty and cognitive-behavioral therapy were conducted online and through Skype software during 12 weekly sessions. At the end of the intervention and in the post-test and follow-up phase, all three groups again completed the research questionnaires online.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: definitive diagnosis of the disease by a neurologist, age range 18-55 years, informed consent to participate in the study, non-inclusion requirements include: undergraduate education and severe psychiatric disorders (psychotic disorders or bipolar disorder) based on DSM_5, Exclusion criteria included: recurrence of the disease, absence of more than three sessions in educational interventions and willingness to leave the study.

Intervention groups

Group intervention focused on intolerance of uncertainty, based on the protocol of Molton et al., Which was performed in 12 sessions of 2 hours per week. In these sessions, the role of uncertainty in MS, effective strategies to increase tolerance of uncertainty such as mindfulness meditation and acceptance and awareness of life values and following them were discussed. Cognitive-behavioral group therapy is based on the protocol of Free et al., Which was performed in 10 sessions of 2 hours per week. The content of the sessions includes identifying cognitive distortions about the disease and teaching cognitive techniques to challenge

these distortions and respond to negative thoughts by evaluating and finding more useful options.

Main outcome variables

psychological distress, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210414050967N2**

Registration date: **2022-03-12, 1400/12/21**

Registration timing: **retrospective**

Last update: **2022-03-12, 1400/12/21**

Update count: **0**

Registration date

2022-03-12, 1400/12/21

Registrant information

Name

Mohammadreza Pirmoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-29, 1399/10/09

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

2020-12-29, 1399/10/09
Actual recruitment end date
2021-04-03, 1400/01/14
Trial completion date
2021-10-06, 1400/07/14

Scientific title
The effectiveness of group intervention focused on intolerance of uncertainty on psychological distress and quality of life in multiple sclerosis patients

Public title
Effect of intervention focused on intolerance of uncertainty in multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of the disease by a neurologist Age range 18 to 55 years Have at least a diploma Having a medical record in the MS community Score between 0 and 5 on the Extensive Disability Status Scale (EDSS) Having the necessary facilities for online participation in various stages of research (laptop or Mobile with high-speed Internet connection)
Exclusion criteria:
Severe psychiatric disorders (psychotic or bipolar disorders) based on DSM_5 drug use disorder based on DSM-5 the presence of a physical illness that prevented them from attending treatment sessions.

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Considering the inclusion and non-inclusion criteria, 60 patients who wished to participate in the study (with written consent) were randomly substituted into three groups of 20 intervention (the group that received routine drug therapy and group intervention focused on intolerance of uncertainty), the first control (group receiving routine drug therapy and cognitive-behavioral group therapy as gold standard) and the second control (group receiving only routine drug therapy) were divided. The method of randomization was that first, codes were assigned to all three groups and then, by drawing lots, the order of the groups was determined as the intervention focused on intolerance of uncertainty, cognitive-behavioral therapy and waiting list. In the next step, the code was assigned to the sample people. In one pot, 60 codes (20 codes for each group) and in another pot, 60 people were sampled. Then, randomly, a piece of paper was taken out of each pot, and based on the code

that came out, the patient was placed in the group corresponding to the same code, until the codes were completed. Thus, 20 people were placed in each of the mentioned 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 Sciences

Street address
Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
۱۳۹۹۱۴۵۳۵

Approval date
2020-12-27, 1399/10/07

Ethics committee reference number
IR.IUMS.REC.1399.1073

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
psychological distress

Timepoint
Before and after the intervention (pre-test and post-test),
Three-month follow-up

Method of measurement
Depression, Anxiety, Stress Questionnaire (DASS-21)

2

Description

Quality of life

Timepoint

Before and after the intervention (pre-test and post-test),
Three-month follow-up

Method of measurement

MS Quality of life (MSQoL-54)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group therapy focused on the inability to tolerate uncertainty was based on the protocol of Molton et al., performed in 12 sessions of two hours on a weekly basis. It is designed considering some basic principles of cognitive-behavioral therapy as well as acceptance and commitment therapy. This treatment focuses on recognizing the controllable and uncontrollable aspects of MS, setting personal goals for accepting the disease regardless of uncertainty, as well as mindfulness exercises, and finding ways to live alongside personal values despite uncertainty about the future.

Category

Behavior

2

Description

Control group: Cognitive-behavioral group therapy was based on the protocol of Van den Akker et al., performed in 12 sessions of two hours on a weekly basis. This treatment focuses on identifying cognitive distortions associated with MS; challenging cognitive distortions associated with the disease; and cognitive reconstruction of these beliefs, practicing to reduce attention to symptoms through attention distraction techniques, regulating sleep pattern, empowering patients to develop social activities by teaching communication skills and encouraging and supporting patients to increase mental activities such as reading or working with a computer.

Category

Behavior

3

Description

Control group: The group that receives only the usual drug treatment in MS patients and does not receive any other intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran MS Society

Full name of responsible person

Hani Rahimi

Street address

Imam Khomeini Boulevard, 31 Alley

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Evaz

Province

Fars

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74331-84799

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Email

hani.psy86@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Street address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Iran University of Medical Science

Proportion provided by this source

1

Public or private sector

Private

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

Hani Rahimi

Position

دانشجوی دکترا

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hani Rahimi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

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Full name of responsible person

Hani Rahimi

Position

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Latest degree

Master

Other areas of specialty/work

Psychology

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data of this project will be available for researchers working in academic and scientific institutes.

Under which criteria data/document could be used

Any use of data must be done in coordination with the developer.

From where data/document is obtainable

Iran University of Medical Science

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

Applicants should first correspond with the responsible author by e-mail and if possible, the desired information will be provided.

Comments