Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 21 2256 0418

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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

۱۴۴۹۶۱۴۵۳۵

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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74331-84799
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Postal code
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Phone
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Email
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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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Position
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Person responsible for updating data

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Email
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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