Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of Cognitive-behavioral therapy (CBT) in resilience, distress tolerance and enhancement of quality of life in patients with Multiple sclerosis

Protocol summary

Study aim
Determining the effectiveness of cognitive-behavioral therapy (CBT) on resilience, tolerance of distress and improvement of quality of life in patients with multiple sclerosis.

Design
A clinical trial with a control group was conducted in a non-random and available manner on 30 patients and they were assigned to two groups, a 15-member experimental group and a 15-member control group

Settings and conduct
After approving the proposal and obtaining the code of ethics and obtaining permission from the head of Bo Ali Sinai hospital in Sari, people with MS were invited to participate in this study. A number of 30 people were selected non-randomly from the MS clinic, and those people were randomly assigned to two groups of 15 people, control and experimental.

Participants/Inclusion and exclusion criteria
The sample entry conditions are: suffering (at least 6 months) from MS disease (in the relapsing phase) with the diagnosis of a neurologist; age between 20 and 50 years old; completion of an informed consent agreement regarding participation in the research project. Conditions for leaving the sample group It consists of: absence of more than two sessions in treatment; failure to complete homework for more than two sessions; failure to complete informed consent.

Intervention groups
After completing the questionnaires, the experimental group received cognitive behavioral therapy in 8 sessions. Then they completed the questionnaires again. The control group also completed the questionnaires but did not receive treatment, then they completed the questionnaires again after 2 months.

Main outcome variables
Resilience; distress tolerance and quality of life are the main outcome variables

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240616062145N1**
Registration date: **2024-08-08, 1403/05/18**
Registration timing: **retrospective**

Last update: **2024-08-08, 1403/05/18**
Update count: **0**

Registration date
2024-08-08, 1403/05/18

Registrant information

Name
Seyed fateme Ahmadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 4254 5593
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-02-17, 1402/11/28
Expected recruitment end date
2024-03-14, 1402/12/24
Actual recruitment start date
2024-02-21, 1402/12/02
Actual recruitment end date
2024-03-28, 1403/01/09

Trial completion date
2024-06-11, 1403/03/22

Scientific title
The effectiveness of Cognitive-behavioral therapy (CBT) in resilience, distress tolerance and enhancement of quality of life in patients with Multiple sclerosis

Public title
The effectiveness of Cognitive-behavioral therapy (CBT) in patients with Multiple sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering from MS for at least 6 months in the relapsing phase with the diagnosis of a neurologist Age between 20 and 50 years. No history of psychotic psychiatric disorders. Not suffering from vision and hearing problems so that the person cannot participate in the treatment process and complete the questionnaires. Lack of history of participating in psychological treatments in the past 6 months Completing the informed consent agreement regarding participation in the research project Not having a substance use disorder Not suffering from other disorders (such as acute disorders)

Exclusion criteria:
Absence of more than two sessions in treatment Not doing homework for more than two sessions Failure to complete informed consent

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Available selection and random assignment by lottery method in two blocks of experimental group and control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University of sari

Street address
Kilometer 7 of Darya Road (Farahabad), Khazar Square, Sari

City
Sari

Province
Mazandaran

Postal code
48164-194

Approval date
2023-09-12, 1402/06/21

Ethics committee reference number
IR.IAU.SARI.REC.1402.190

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
Resilience

Timepoint
The beginning of the study (before the start of the intervention), the end of the intervention.

Method of measurement
Connor and Davidson's Resilience Questionnaire

2

Description
Distress tolerance

Timepoint
The beginning of the study (before the start of the intervention), the end of the intervention.

Method of measurement
Simmons and Gaher Distress Tolerance Questionnaire

3

Description
Quality of Life

Timepoint
The beginning of the study (before the start of the intervention), the end of the intervention.

Method of measurement

Hobart and colleagues quality of life questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group received treatment based on Heimberg and Becker treatment protocol for 8 sessions of 45 minutes. Resilience questionnaire, distress tolerance questionnaire and quality of life questionnaire related to multiple sclerosis patients were used as measurement tools in pre-test and post-test.
Category
Behavior

2

Description
Control group: Using three questionnaires of resilience, stress tolerance and quality of life at a two-month interval without receiving any treatment.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
MS clinic, super specialty clinic, Bou Ali Sina Hospital, Sari city
Full name of responsible person
Seyed Fateme Ahmadi Mahali
Street address
MS Clinic, Bo Ali Sina Hospital, Pasdaran Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Ali Abbaszadeh Suri
Street address
km 7 of Darya Road (Farahabad), Khazar Square, Sari
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aqiau@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
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Full name of responsible person
Seyed Fateme Ahmadi Mahali
Position
Master student
Latest degree
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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

Only a part of the data, such as the information related to the main outcome or the like, can be shared.

When the data will become available and for how long

Access starts 6 months after results are published.

To whom data/document is available

Researchers working in academic and scientific institutions can access the data.

Under which criteria data/document could be used

We have not considered other conditions.

From where data/document is obtainable

Dr Maedeh Bagheri 09113546225
Mbagheri66.mb@gmail.com

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

The applicant can receive the documents by submitting the code of ethics and sending her request to the mentioned email.

Comments