

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effectiveness of cognitive-behavioral therapy in reducing anticipatory anxiety and death anxiety in patients with multiple sclerosis

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral therapy on reducing waiting anxiety and death anxiety in patients with multiple sclerosis

Design

Clinical trial work with a control group with parallel groups of a simple blind randomized phase 3 on 30 patients. A simple method has been used for randomization. That is, the first is included in the intervention group, the second is included in the non-intervention group, and so on.

Settings and conduct

The current research is a semi-experimental design of pre-test-post-test type with a control group. The statistical population of the present study consisted of 100 people from all patients with multiple sclerosis in Mazandaran province who had visited the MS clinic of Bo Ali Sina Hospital in Sari city between May 1401 and Shahrivar 1401 and met the criteria for entering the study. 30 people were randomly replaced in two experimental (15 people) and control (15 people) groups.

Participants/Inclusion and exclusion criteria

The criteria for entering the research included the following. The person has multiple sclerosis. At least 18 years old. Have at least a diploma. Do not have an acute psychiatric problem that may interfere with the intervention process—consent to participate in the research. Exclusion criteria from the research: Occurrence of intervening psychiatric illness during the research. Non-cooperation of the participant absence of more than two sessions and receiving psychological interventions at the same time

Intervention groups

The intervention group underwent 45-minute cognitive-behavioral therapy individually once a week for 8 sessions. However, no action was taken on the control group.

Main outcome variables

Waiting anxiety; death anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220506054750N1**

Registration date: **2024-01-29, 1402/11/09**

Registration timing: **retrospective**

Last update: **2024-01-29, 1402/11/09**

Update count: **0**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name

Ramin Raei varandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3339 3795

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

2022-04-21, 1401/02/01

Actual recruitment end date

2022-09-21, 1401/06/30

Trial completion date

2022-09-23, 1401/07/01

Scientific title

The effectiveness of cognitive-behavioral therapy in reducing anticipatory anxiety and death anxiety in patients with multiple sclerosis

Public title

Cognitive-Behavioral Therapy in MS

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All MS patients referred to the MS clinic of Bo Ali Sina Hospital in Sari from May 1401 to September 1401

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

3

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

Simple randomization: To ensure that all patients had an equal chance of receiving the new treatment under study, a coin toss was used for the participants to assign lions to the treatment group and lines to the no-treatment group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Biomedical Research, Islamic Azad University, Sari Branch

Street address

km 7 of Darya Road (Farahabad), Islamic Azad University, Khazar Square Sari branch, Sari, Mazandaran

City

Sari

Province

Mazandaran

Postal code

48164-194

Approval date

2022-04-17, 1401/01/28

Ethics committee reference number

IR.IAU.SARI.REC.1401.036

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**

anxiety

Timepoint

8 sessions and once a week

Method of measurement

Anticipatory Anxiety Questionnaire; Death Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: During 8 sessions, they underwent 45-minute cognitive-behavioral therapy individually once a week

Category

Rehabilitation

2**Description**

Control group: No action was taken

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

بیمارستان بوعلی سینا ساری

Full name of responsible person

Ramin Raei Verandi

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Pasdaran Blvd, Sari, Mazandaran Province,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
دکتر علی عباس زاده
Street address
km 7 of Darya Road (Farahabad), university complex
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mohammadbaghbanian@gmail.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
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
Mazandaran University of Medical Sciences
Full name of responsible person
Seyed Mohammad Baghbanian
Position
Associate professor
Latest degree

Subspecialist
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Person responsible for updating data

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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 result or the like, can be shared.

When the data will become available and for how long

"The access period starts 6 months after the publication of the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no other conditions for the use of data or documentation

From where data/document is obtainable

Sayed Mohammad Baghbanian - Bo Ali Sina Hospital, MS Clinic, Pasdaran Blvd., Sari - Tel: 00981133343348

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

The applicant can receive the documents through the email below and after presenting the ethics code of her study. mohammadbaghbanian@gmail.com

Comments