

# 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)

##### Phone

+98 11 3339 3795

##### Email address

ramin.raee1373@gmail.com

##### 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,

**City**  
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4815838477  
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+98 11 3334 3348  
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smbaghbanian@yahoo.com

## 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  
of Islamic Azad University, Sari branch  
**City**  
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48164-194  
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+98 11 3303 2891  
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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  
**Other areas of specialty/work**  
Neurology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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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**