

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of group cognitive behavioral therapy on stress, anxiety and depression in women with Multiple Sclerosis

#### Protocol summary

##### Summary

**Objective:** This study aimed to determine the effects of cognitive behavioral group therapy on stress, anxiety and depression in women with multiple sclerosis. **Methods:** This study is a clinical trial, single blind (about patients in the control group), Two groups and three phases. from all of the women attending the MS clinic of alzahra & Kashani hospitals in Isfahan in 1393, 70 women who meet the inclusion criteria would randomly selected and assigned to two groups : test and control groups. the Test group will attend in 8 weekly sessions of cognitive behavioral therapy, which will carry out for 90 minutes. the control group will participate in 3 sessions that organized by fellow researcher, and they will discuss and share their experiences . both groups will answer a questionnaire on stress, anxiety and depression (DASS-42) in three stages: before and immediately after the intervention and also one month after the intervention .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015012720833N1**

Registration date: **2015-03-06, 1393/12/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-03-06, 1393/12/15

##### Registrant information

##### Name

Samira Abbasi

##### Name of organization / entity

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##### Country

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##### Recruitment status

**Recruitment complete**

##### Funding source

Research center of Isfahan University of Medical Sciences

##### Expected recruitment start date

2014-10-07, 1393/07/15

##### Expected recruitment end date

2014-12-21, 1393/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of group cognitive behavioral therapy on stress, anxiety and depression in women with Multiple Sclerosis

##### Public title

The effect of cognitive behavioral therapy on stress, anxiety and depression

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: a definite diagnosis of multiple sclerosis by a neurologist and a minimum of six months from the time it is diagnosed; any relapse during the past month; willingness to participate in the study; Previous participate in meetings of complementary medicine such as relaxation therapy, cognitive therapy, and etc until six months before the study ; having mild stress, anxiety

and depression based on DASS-42 ; absence of mental and physical disease (acute and chronic) such as heart disease, kidney disease, severe depression, speech or hearing difficulties; any psychotropic drugs at least 3 months before treatment; non of medical staff (doctors, nurses, etc); lack of other complementary treatments such as physical therapy, acupuncture, yoga and psychotherapy sessions during the study; points 5.5- 0 expanded disability status scale (EDSS) Exclusion criteria: 1) lack of desire to continue cooperation in research; lack of attendance at meetings (an absence of more than two sessions) ; dealing with the crisis and the severe stress during the study.

**Age**

From **19 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Isfahan University of Medical Sciences, School of Nursing and Midwifery

**Street address**

isfahan, hezarjarib Ave.

**City**

isfahan

**Postal code****Approval date**

2014-09-06, 1393/06/15

**Ethics committee reference number**

393513

**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**

stress

**Timepoint**

Before the intervention, Immediately after the intervention, One month after the intervention

**Method of measurement**

DASS-42 questionnaire

**2****Description**

anxiety

**Timepoint**

Before the intervention, Immediately after the intervention, One month after the intervention

**Method of measurement**

DASS-42 questionnaire

**3****Description**

depression

**Timepoint**

Before the intervention, Immediately after the intervention, One month after the intervention

**Method of measurement**

DASS-42 questionnaire

**Secondary outcomes**

empty

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

Intervention in the test group: The treatment program will held eight weekly sessions of cognitive behavioral therapy and each session for 90 minutes.

**Category**

Treatment - Other

**2****Description**

Intervention in the control group: the control group will participate in 3 sessions that will organize by fellow researcher, and women will discuss and share their experiences.

**Category**

Other

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

Azahra hospital

**Full name of responsible person**

Dr.Masoud Etemadifar

**Street address****City**

Isfahan

2**Recruitment center****Name of recruitment center**

kashani hospital

**Full name of responsible person**

Dr.Shaigan nejad

**Street address****City**

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**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Research center of Isfahan University of Medical Sciences

**Full name of responsible person**

Saeed Pahlavanzadeh

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Isfahan University Of Medical Sciences Hezarjarib Avenue

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research center of Isfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan University Of Medical Sciences

**Full name of responsible person**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*