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 carriy 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

School of Nursing and Midwifery, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3228 7822

Email address

s.abbasi@nm.mui.ac.ir

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
anexiety

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
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research center of Isfahan University of Medical Sciences
Full name of responsible person
Saeed Pahlavanzadeh
Street address
Isfahan University Of Medical Sicences Hezarjarib Avenue
City
Isfahan
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
Saeed Pahlavanzadeh
Position
Msc of Psychiatric Nursing,Nursing and Midwifery Research Care Center, faculty member of psychiatri
Other areas of specialty/work
Street address
Hezarjarib, Isfahan
City
Isfahan
Postal code
Phone
+98 31 3792 2960
Fax
Email
pahlavanzadeh@nm.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of nursing and midwifery, Isfahan university of medical sciences, Isfahan
Full name of responsible person
Samira Abbasi
Position
Msc of psychiatric Nursing
Other areas of specialty/work
Street address
Hezarjarib Avenue,Isfahan
City
Isfahan
Postal code
Phone
+98 31 3228 7822
Fax
Email
s.abbasi@nm.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Samira Abbasi
Position
Msc of Psychiatric Nursing
Other areas of specialty/work
Street address
Isfahan university of medical sciences
City
Isfahan
Postal code

Phone
+98 31 3228 7822
Fax
Email
samiraabbasi6853@gmail.com s.abbasi@nm.mui.ac.ir
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