Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Impact of Mindfulness-based Stress Reduction on Sleep Quality in Women Suffering from Multiple Sclerosis in Ahwaz

Protocol summary

Summary

Objectives: The aim of this research is evaluation of effectiveness of Mindfulness Based Stress Reduction (MBSR) on psychological symptoms, quality of sleep and quality of life inwomen with Multiple Sclerosis in Ahwaz city. Setting and conduct: Statistical population includes all MS patients that are member of MS association of Ahwaz. Forty women with MS are chosen using available sampling method and they are assigned to two groups randomly (Mindfulness Based Stress Reduction and the control group). All of the groups will receive usual medication too. The Mindfulness Based Stress Reduction group is participated in therapy sessions. Participants of both groups will fill out Depression, Anxiety and Stress Scale (DASS), Petersburg Quality of Sleep (PSQG) and quality of life (SF-36) in three stages of pretest, post test and two month follow up. Major Inclusion and Exclusion criteria: inclusion criteria: being female;having at least 20 years and a maximum of 50years; having multiple sclerosis diagnosis by neurologist; having at least third-level education in guided school; agreement to participate in research according to informed consent and not receiving psychological treatment for at least a month before the study. Exclusion criteria:suffering from a diagnosed psychiatric illness; absence of more than three sessions and MS relapse. Intervention: the Mindfulness Based Stress Reduction group will receive eight weekly treatments. control group do not receive any psychotherapy. Main outcome measures: Depression, Anxiety and Stress, Quality of Sleep and quality of life

General information

Acronym

Mindfulness-based Stress Reduction on Multiple Sclerosis

IRCT registration information

IRCT registration number: **IRCT201507087227N5**

Registration date: **2015-08-08, 1394/05/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-08, 1394/05/17

Registrant information

Name

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Name of organization / entity

Tehran Psychiatric Institute, Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2013-12-01, 1392/09/10

Expected recruitment end date

2014-07-11, 1393/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Mindfulness-based Stress Reduction on Sleep Quality in Women Suffering from Multiple Sclerosis in Ahwaz

Public title
Effectiveness of Mindfulness Based Stress Reduction on psychological Symptom, Sleep and Quality of Life in Women with Multiple Sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: women aged 20 to 50 who are diagnosed with multiple sclerosis by neurologists; at least third-level education in guided school; and absence of any other psychotherapy for three months. Exclusion criteria: suffering from a diagnosed psychiatric illness; absence of more than three sessions and MS relapse.
Age
From **20 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
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
Azad University, Khorasgan branch
Street address
Isfahan, Azad University, Khorasgan branch
City
Isfahan
Postal code
Approval date
2014-09-01, 1393/06/10
Ethics committee reference number
382/821/93/ه

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
Sleep Quality
Timepoint
pre-test, post- test and 2 months after starting intervention
Method of measurement
Pittsburgh sleep quality questionnaire

2

Description
psychologial symptoms
Timepoint
pre-test, post- test and 2 months after starting intervention
Method of measurement
Depression, Anxiety and Stress Scale

3

Description
quality of life
Timepoint
pre-test, post- test and 2 months after starting intervention
Method of measurement
quality of life questinnaire (36 items)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mindfulness based stress reduction
Category
Behavior

2

Description
control group: drug therapy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Multiple Sclerosis Association of Ahwaz
Full name of responsible person
Nastaran Majdinasab
Street address
School of Rehabilitation, Golestan Hospital, Ahwaz
City
Ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
investigator
Full name of responsible person
Hoda Kolahkaj
Street address
700, Hossein Abad, Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
investigator
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

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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