

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 in women 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 8 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 50 years; 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

Fatemeh Zargar

Name of organization / entity

Tehran Psychiatric Institute, Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

382/821/93/3

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**

psychological 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 questionnaire (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

Contact

Name of organization / entity

Isfahan university in medical sciences

Full name of responsible person

Fatemeh Zargar

Position

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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