

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of mindfulness-based stress reduction on fatigue severity, functional disability and emotion dysregulation among patients with multiple sclerosis

Protocol summary

Study aim

The effectiveness of mindfulness-based stress reduction on fatigue severity, functional disability and emotion dysregulation among patients with multiple sclerosis

Design

Randomization (random number table), without placebo control, single arm trial. The sample size of this study is 50 individuals: divided into 2 groups of 25 people.

Settings and conduct

Neyshabour society for support of patients with MS.

Participants/Inclusion and exclusion criteria

50 patients with Multiple Sclerosis referred to Neyshabour society for support of patients with MS. Inclusion criteria: Age of 20 to 55 years; Diagnosis of MS by a specialist; Having reading and writing skills; Passed at least 12-6 months from the onset of MS disease. Exclusion criteria: History of using psychiatric drugs; Mental retardation; Mental illness; History of drug abuse.

Intervention groups

Control group: Only for comparison with intervention group, no treatment is performed. Intervention group: 25 patients referring according to treatment protocol of mindfulness-based stress reduction (MBSR) are treated in 8 sessions. In order to be effective of before and after the intervention, and 2 months after the intervention, the measurements are carried out.

Main outcome variables

Fatigue Severity; Functional inability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N33**

Registration date: **2018-07-19, 1397/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-19, 1397/04/28**

Update count: **0**

Registration date

2018-07-19, 1397/04/28

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-13, 1396/11/24

Expected recruitment end date

2018-08-15, 1397/05/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of mindfulness-based stress reduction on fatigue severity, functional disability and emotion dysregulation among patients with multiple sclerosis

Public title

The effectiveness of mindfulness-based stress reduction on fatigue severity, functional disability and emotion

dysregulation among patients with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 20 to 55 years
Diagnosis of MS by a specialist
Having reading and writing skills
Passed at least 12-6 months from the onset of MS disease

Exclusion criteria:

History of using psychiatric drugs
Mental retardation
Mental illness
History of drug abuse

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization; Individual; Random Number Tables.
Randomized permutation blocks (block 2). Using Excel software to generate random number tables.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Neyshabur University of Medical Sciences

Street address

Neyshabur University of Medical Sciences, Moalem Square, Neyshabur

City

Neyshabur

Province

Razavi Khorasan

Postal code

9318614139

Approval date

2018-04-15, 1397/01/26

Ethics committee reference number

IR.NUMS.REC.1397.4

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

Fatigue Severity

Timepoint

Before and after intervention and 2 months after intervention

Method of measurement

Fatigue Severity Questionnaire (Fatigue Severity Scale (FSS))

2

Description

Functional inability

Timepoint

Before and after intervention and 2 months after intervention

Method of measurement

World Health Organization Disability Assessment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Only for comparison with intervention group, no treatment is performed.

Category

Diagnosis

2

Description

Intervention group:

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neyshabour society for support of patients with MS

Full name of responsible person

Narges Ensan

Street address

Fazl Ibn Shazan Clinic, Fazl Street, Ferdowsi Street.

City

Neyshabur

Province

Razavi Khorasan

Postal code

9313833333

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Email

are20935@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Semnan University

Full name of responsible person

Eshagh Rahimian

Street address

Semnan University, Damghan 5 km Road, Semnan

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3514799442

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Email

are20935@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research of Semnan University

Proportion provided by this source

100

Public or private sector

Public

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

Semnan University

Full name of responsible person

Eshagh Rahimian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Narges Ensan

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available