Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 23 3345 1336

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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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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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+98 23 3345 1336

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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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Person responsible for updating data

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Position
Student

Latest degree
Master

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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