Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Title: Effectiveness of Mindfulness-Based Stress Reduction (MBSR) Intervention on Psychological Symptoms, Quality of Life, Symptom Severity in Patients with Somatic Symptoms Disorder

Protocol summary

Study aim
Determining the effectiveness of mindfulness-based stress reduction intervention on psychological symptoms, quality of life, symptom severity in patients with somatic symptoms disorder

Design
The present study is a randomized clinical trial with control group.

Settings and conduct
Patients with impaired physical symptoms referred to Shariati Clinic and Noor Hospital of Isfahan University of Medical Sciences were interviewed by a psychiatrist.The patients in case of having inclusion and exclusion criteria and announcing consent to participate in the study are divided into two groups (Mindfulness-Based Stress Reduction Intervention or control) based on random numbers table. Both groups will receive 37.5-150 mg of venlafaxine for 8 weeks, and the intervention group will receive 8 sessions of psychotherapy to review physical stress symptoms, stress reduction techniques, and attention to everyday life events. Both groups complete the stress, anxiety and depression questionnaire, quality of life questionnaire, and Patient Health Questionnaire Physical Symptom before the study and 8 weeks later.

Participants/Inclusion and exclusion criteria
Diagnosis of somatic symptoms disorder based on diagnostic psychiatric criteria Having a minimum of elementary education Age between 20 to 50 years Have no history of suicide Has not received psychotherapy in the last 6 months Not have a major psychiatric disorder based on a psychiatric interview

Intervention groups
MBSR Group In addition to venlafaxine 37.5-150 mg, receive 8 sessions of psychotherapy to monitor the symptoms of physical stress, stress reduction methods, and attention to everyday life events. The control group received only 37.5-150 mg of venlafaxine.

Main outcome variables
Anxiety, Depression, Physical symptoms, Quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180909040974N2**
Registration date: **2020-08-01, 1399/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-01, 1399/05/11**
Update count: **0**

Registration date
2020-08-01, 1399/05/11

Registrant information
Name
Fatemeh Zargar
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-06, 1399/03/17
Expected recruitment end date
2020-09-05, 1399/06/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Title: Effectiveness of Mindfulness-Based Stress Reduction (MBSR) Intervention on Psychological Symptoms, Quality of Life, Symptom Severity in Patients with Somatic Symptoms Disorder

Public title

Mindfulness-Based Stress Reduction in Somatic symptom disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Documented diagnosis of Somatic Symptom Disorder based on Diagnostic and Statistical Manual of psychiatric disorders Educational level more than primary school, Age between 20-50 years, Patient's willingness to participate in this study

Exclusion criteria:

Diagnosis of other major psychiatry disorder based on clinical interview and Substance use disorder Participating in another psychotherapy

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

First, eligible patients will be simple randomly selected. Then they will be divided into two groups using random numbers created by computer software (SPSS software). So that, even numbers will be in the intervention group and odd numbers will be in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst is unaware of the group membership of the participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Department of Health Psychology, Hezar Jarib St.

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Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR.MUI.REC.1397.3.107

Health conditions studied

1

Description of health condition studied

somatic symptom disorder

ICD-10 code

F40.232

ICD-10 code description

Fear of other medical care

Primary outcomes

1

Description

Anxiety

Timepoint

Before and 8 weeks after intervention

Method of measurement

Questionnaire of anxiety, depression, stress scale (DASS)

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and 8 weeks after the intervention

Method of measurement

36-Item Short Form Health Survey

2

Description

Clinical symptoms

Timepoint

Before and 8 weeks after the intervention

Method of measurement
Patient Health Questionnare 15-item

Intervention groups

1

Description
Intervention group: The intervention group was treated with Venlafaxine, and they participated in eight 2-hour sessions of the Mindfulness Based Stress Reduction (MBSRD) program on a weekly basis. Venlafa xine was prescribed 37.5 to 150 mg daily for 8 weeks (VenabidER®, ABIDI Company, Tehran, Iran).
Category
Behavior

2

Description
Control group: the control group was treated with Venlafaxine alone. Venlafaxine was prescribed 37.5 to 150 mg daily for 8 weeks (Venabid ER®, ABIDI Company, Tehran, Iran).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Hospital
Full name of responsible person
Leila Rahafrouz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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Mojgan Mortazavi
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Grant name
Isfahan University of Medical Sciences Vice Chancellor for Research
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
Full name of responsible person
Leila Rahafrouz
Position
Non-Faculty Physician
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
specific participant data sets related to primary outcome measure are to be shared.
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Therapists working in hospital clinics
From where data/document is obtainable
Email: fatemehzargar@gmail.com
What processes are involved for a request to access data/document
Having a letter of introduction from work
Comments