

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Name of organization / entity

Country

Iran (Islamic Republic of)

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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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Province

Isfahan

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 Questionnaire 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. Venlafaxine 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

Full name of responsible person

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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

Other areas of specialty/work

Psychiatrics

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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