Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

“Examining the effect of Mindfulness-Based Stress Reduction (MBSR) on anxiety, stress, and depression in psychiatric patient

Protocol summary

Study aim
Determining the effect of Mindfulness-Based Stress Reduction (MBSR) program on the levels of anxiety, stress, and depression in psychiatric patients

Design
Simple randomization will be used to allocate participants into two groups: an intervention group and a control group, with 48 participants in each group.

Settings and conduct
In this study, eligible patients will first be identified among inpatients at Razi Psychiatric Teaching Hospital. The inclusion and exclusion criteria will be carefully assessed to ensure the selection of a homogeneous and appropriate sample for the study. After eligible patients have been identified, written informed consent will be obtained from the participants. The objectives, procedures, benefits, and requirements of the study will be fully explained to them to ensure that they participate with complete awareness. The study will be conducted using a single-blind design.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Age over 18 years - Diagnosis of a psychiatric disorder by a psychiatrist - Ability to attend weekly sessions Exclusion criteria: - Patients experiencing an exacerbation of acute psychiatric disorders or suffering from an acute physical illness - Any stressful life event

Intervention groups
The intervention group will receive the MBSR intervention in addition to usual care and treatments. The intervention will be delivered in semi-structured group sessions, consisting of eight 2-hour sessions. The control group will receive only usual care and treatments throughout the study period, and no MBSR intervention will be provided. Outcome assessments will be conducted at the same time points as in the intervention group.

Main outcome variables
Mindfulness-Based Stress Reduction (MBSR)

General information

Reason for update

Acronym
MBSR

IRCT registration information
IRCT registration number: **IRCT20260721070278N1**
Registration date: **2026-09-13, 1405/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-13, 1405/06/22**
Update count: **0**

Registration date
2026-09-13, 1405/06/22

Registrant information

Name
Mohammad Hosseini ashtiani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2026-09-23, 1405/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
"Examining the effect of Mindfulness-Based Stress Reduction (MBSR) on anxiety, stress, and depression in psychiatric patient

Public title
"Examining the effect of Mindfulness-Based Stress Reduction (MBSR) on anxiety, stress, and depression in psychiatric patient

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 or older Diagnosis of a psychiatric disorder by a psychiatrist Ability to attend weekly sessions

Exclusion criteria:
Patients with exacerbation of acute psychiatric disorders or acute physical illness Any stressful life event

Age
From **18 years** old

Gender
Male

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting up to 94 eligible participants through purposive sampling and obtaining written informed consent, participants will be randomly allocated to the intervention and control groups using simple randomization with a 1:1 allocation ratio. The unit of randomization is the individual participant. The random allocation sequence will be generated using SPSS statistical software. Based on the generated random sequence, each participant will be assigned to either the intervention or the control group after completion of the baseline assessment. To ensure allocation concealment, the randomization sequence will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). After enrollment and baseline assessment, the corresponding envelope will be opened in sequence to reveal the participant's group assignment.

Blinding (investigator's opinion)
Single blinded

Blinding description
In a single-blind study, information that could skew the results of the experiment is hidden from the participant, but the person conducting the experiment is aware of it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address
Islamic Azad University, Tehran Medical Sciences Branch Khalili Dead End, South Roudaki St., Khaghani St., Shariati St. Tehran, Iran.

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Approval date
2026-05-27, 1405/03/06

Ethics committee reference number
IR.IAU.TMU.REC.1405.020

Health conditions studied

1

Description of health condition studied
Psychiatric patients

ICD-10 code
F20–F29

ICD-10 code description
Schizophrenia, schizotypal and delusional disorders

Primary outcomes

1

Description
Changes in participants' anxiety scores on the DASS-21 questionnaire.

Timepoint
Measurement of anxiety scores at baseline (before the initiation of the intervention) and after completion of Session 8 (the final session), which took place two months after the start of the intervention.

Method of measurement
The anxiety subscale of the 21-item Depression, Anxiety and Stress Scales (DASS-21) consists of 7 items. The anxiety subscale is rated on a four-point Likert scale ranging from 0 (not at all) to 3 (very much). The minimum and maximum possible scores for each subscale are 0 and 21, respectively.

2

Description
Changes in participants' stress scores on the DASS-21

questionnaire.

Timepoint

Measurement of stress scores at baseline (before the initiation of the intervention) and after completion of Session 8 (the final session), which took place two months after the start of the intervention.

Method of measurement

The stress subscale of the 21-item Depression, Anxiety and Stress Scales (DASS-21) consists of 7 items. The stress subscale is rated on a four-point Likert scale ranging from 0 (not at all) to 3 (very much). The minimum and maximum possible scores for each subscale are 0 and 21, respectively.

3

Description

Changes in participants' depression scores on the DASS-21 questionnaire.

Timepoint

Measurement of depression scores at baseline (before the initiation of the intervention) and after completion of Session 8 (the final session), which took place two months after the start of the intervention.

Method of measurement

The depression subscale of the 21-item Depression, Anxiety and Stress Scales (DASS-21) consists of 7 items. The depression subscale is rated on a four-point Likert scale ranging from 0 (not at all) to 3 (very much). The minimum and maximum possible scores for each subscale are 0 and 21, respectively.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention GroupIn addition to receiving usual psychiatric treatments, participants in the intervention group will receive Mindfulness-Based Stress Reduction (MBSR) in semi-structured group sessions. The intervention will consist of eight 2-hour sessions and will be delivered by the researcher, who has completed a university-based specialized MBSR training course according to the relevant protocol.The sessions will be conducted as follows:Introduction to mindfulness: Familiarization with the concept of mindfulness and its relationship with stress and automatic thoughts; practice of mindful breathing.Awareness of the body and physiological sensations: Practice of body scan meditation.Mindful movement and gentle yoga: Focusing on breathing and bodily sensations during movement.Awareness of thoughts and emotions: Observing thoughts as transient events rather than absolute reality.Mindful responses to stress: Replacing automatic reactions with mindful pausing and observation.Mindful communication: Practicing active listening, nonjudgmental speaking, and loving-kindness meditation.Integrating mindfulness into daily life: Applying mindfulness to eating, walking, and interactions with others; reviewing common barriers.Course summary: Reviewing the personal mindfulness journey, conducting a full meditation practice, and planning for continued practice.

Category

Other

2

Description

Control group: Participants in the control group will receive only usual psychiatric care throughout the study, including pharmacotherapy, routine clinical visits, and other daily services. Outcome assessments will be conducted at the same time points as those for the intervention group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Teaching and Treatment Center (Aminabad)

Full name of responsible person

Hossein Akhavan Zanjani

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Razi Psychiatric Teaching and Treatment Center, Shahid Rastegar Boulevard, Taqiabad Three-Way Junction, Shahr-e Rey, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad 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
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Full name of responsible person
Mohammad Hosseini Ashtiani
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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
Undecided - It is not yet known if there will be a plan to make this available

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

Informed Consent Form
Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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