Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of mindfulness-based stress reduction (MBSR) therapy on subjective vitality and self-compassion in people with panic attacks

Protocol summary

Study aim
Determining the effectiveness of mindfulness-based stress reduction (MBSR) therapy on subjective vitality and self-compassion in people with panic attacks

Design
A randomized, controlled, parallel-group clinical trial on 30 people with panic attacks used a randomized block method to randomize participants.

Settings and conduct
The study is being conducted at the Empathy Psychology Clinic in Semnan and involves people with panic attacks. Participants will be randomly divided into two groups: an experimental group that receives mindfulness-based stress reduction (MBSR) therapy, and a control group that only follows the center's routine programs.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Participants must be between 20 and 50 years old, have received a diagnosis of panic disorder according to DSM-5, and have a history of taking related medications for between 3 and 12 months. Also, be willing to participate in mindfulness-based stress reduction therapy for 8 weeks and not use similar treatments. Exclusion criteria: Participants must not have severe psychiatric disorders, medication dose changes, and drug and alcohol use.

Intervention groups
In this study, the experimental group will participate in 8 weekly 90-minute sessions designed based on mindfulness-based stress reduction (MBSR) therapy. The content of these sessions includes mindfulness exercises, stress management, and increased awareness of mental states. The control group will receive only usual care and no specific therapeutic intervention will be provided to them.

Main outcome variables
Subjective vitality, self-compassion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250223064822N1**
Registration date: **2025-04-06, 1404/01/17**
Registration timing: **prospective**

Last update: **2025-04-06, 1404/01/17**
Update count: **0**

Registration date
2025-04-06, 1404/01/17

Registrant information

Name
Mohammad Rajabi dahbozordaki

Name of organization / entity
Islamic Azad University, Semnan Branch

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-21, 1404/02/01

Expected recruitment end date
2025-05-22, 1404/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of mindfulness-based stress reduction (MBSR) therapy on subjective vitality and self-compassion in people with panic attacks

Public title
The effect of mindfulness-based stress reduction therapy on mental vitality and self-compassion

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of panic attack disorder based on DSM-5 criteria and confirmation by a psychiatrist or clinical psychologist. Age range 20 to 50 years. Participants must have a minimum of 3 months and a maximum of 12 months of history of taking psychiatric medications related to panic disorder. Willingness to participate regularly in Mindfulness-Based Stress Reduction (MBSR) therapy sessions for 8 weeks. Not using similar treatments at the same time, such as cognitive therapy or other mindfulness-based interventions. Ability to understand treatment concepts and perform mindfulness exercises. Absence of severe physical illnesses that would prevent participation in therapy sessions or mindfulness exercises.

Exclusion criteria:
Having a severe psychiatric disorder or experiencing a recent acute psychological crisis, such as a suicide attempt. Use of unregulated psychiatric medications, changes in medication dosage in the past three months, or use of drugs and alcohol in the past six months.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 30 participants are randomly assigned to two intervention and control groups. The randomization unit in this study is the individual. Randomization is performed using the random block method with variable block sizes of 4 and 6 and an allocation ratio of 1:1. First, each participant is assigned a unique number from 1 to 30. Then, using Random Allocation Software (RAS) version 4.9, the sequence of allocation to the intervention and control groups is generated based on the random blocks. The randomization process is performed by an independent person who has no role in conducting the study. This person places the allocation list in numbered, sealed, and opaque envelopes. When each participant enters, the corresponding envelope is opened and the group allocation is determined. This method ensures that the allocation of individuals to groups is completely random, in compliance with the principle of allocation concealment, and without bias.

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 Semnan Azad University

Street address
Islamic Azad University, University Town, Semnan

City
Semnan

Province
Semnan

Postal code
3513137111

Approval date
2024-12-30, 1403/10/10

Ethics committee reference number
IR.IAU.SEMNAN.REC.1403.093

Health conditions studied

1

Description of health condition studied
Panic disorder

ICD-10 code
F41.0

ICD-10 code description
Panic disorder [episodic paroxysmal anxiety] without agoraphobia

Primary outcomes

1

Description
Subjective vitality

Timepoint
Before the start of the intervention and after completing 8 intervention sessions.

Method of measurement
Ryan and Frederick Subjective Vitality Questionnaire (1997)

2

Description

Self-Compassion

Timepoint

Before the start of the intervention and after completing 8 intervention sessions.

Method of measurement

Neff et al.'s Self-Compassion Questionnaire (2003)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will undergo Mindfulness-Based Stress Reduction (MBSR) therapy intervention, which will be held in 8 weekly 90-minute sessions. This intervention is designed to reduce stress, increase mental vitality, and improve self-compassion in people with panic attacks. Initially, participants will be introduced to the basic concepts of mindfulness, focusing on the present moment, and nonjudgmental acceptance. Then, exercises including body scanning, mindfulness meditation, conscious breathing, and gentle yoga will be provided to increase awareness of internal experiences and reduce automatic reactions to stress. In the following stages, participants will practice techniques such as accepting thoughts and feelings, changing their relationship with rumination, regulating emotions, and developing self-compassion. Finally, the learned skills for consciously facing anxiety, preventing the recurrence of panic attacks, and improving the quality of life in everyday situations will be reviewed and consolidated.

Category

Treatment - Other

2

Description

Control group: This group does not receive any intervention and serves only as a comparison. People in this group continue to receive their usual, standard care and do not receive any mindfulness-based stress reduction (MBSR)-related treatment or intervention during the study. The aim is to keep the control group conditions unchanged so that their results can be compared with those of the MBSR group. This method allows for a precise assessment of the effects of the treatment intervention on the subjective vitality and self-compassion of people with panic attacks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamdeli Psychology Clinic

Full name of responsible person

Ali Mohebi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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, Semnan branch

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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Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In this study, data and research-related documentation will be shared in accordance with ethical principles and confidentiality considerations. Individual data of participants will only be published after removing identifying information and in an anonymous form. Primary data, including results related to research variables (such as primary and secondary outcome variables), will be made available to eligible researchers in the form of structured datasets without personal information. In addition to quantitative data, methodological documentation of the research, including the study protocol, data collection methods, intervention implementation instructions, and tools used, will also be shared.
When the data will become available and for how long
Access to the data and documentation of this study will be possible six months after the publication of the final results. This time frame is intended to ensure complete data analysis and adherence to ethical principles in sharing information.
To whom data/document is available
The data and documentation of this research will be available only to researchers and experts in the relevant scientific field who work in academic institutions, research centers, and reputable scientific organizations. Access requests from independent researchers will also be considered if they submit a relevant research plan and receive approval from the research ethics committee. Access to data for people working in industry will only be possible if they cooperate with academic or research centers and comply with research ethics principles.
Under which criteria data/document could be used

The data and documentation of this study can only be used for scientific and research purposes related to the subject of the study and any commercial or promotional use is prohibited. Statistical analyses and meta-analyses are permitted in compliance with scientific and ethical principles. The use of data must be in such a way that the identity of the participants cannot be identified. Applicant researchers must submit a formal application, sign an ethical commitment letter, and receive approval from the research ethics committee. Reference to the original source is mandatory and sharing of data with third parties without official permission is prohibited. This framework ensures that the data are used responsibly to advance scientific knowledge.

From where data/document is obtainable

If you need data, please contact mohammadrajbi4545@gmail.com.

What processes are involved for a request to access data/document

Applicants must submit a written application including the research objective and methodology. After an initial review, if approved, the necessary forms will be completed and an ethics commitment will be signed. Applications will be assessed within 2-4 weeks and, if approved, de-identified data will be made available to the applicant via a secure platform. The applicant will be committed to ethical principles and appropriate citation in the publication of the results. The entire process usually takes 4-6 weeks.

Comments