Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Mindfulness-Based Stress Reduction Therapy on Perceived Stress, Anxiety Sensitivity, Emotion Regulation Difficulties, and Oxidative Stress Factors (Oxidant/Antioxidant) in Patients with Chronic Obstructive Pulmonary Disease (COPD)

Protocol summary

Study aim
To assess the effectiveness of Mindfulness-Based Stress Reduction (MBSR) on anxiety sensitivity, perceived stress, emotion dysregulation and plasma oxidative and antioxidative biomarkers

Design
The sample includes 30 eligible participants, non-randomly assigned to intervention and control groups based on smoking status, then matched for age, gender, and other variables.

Settings and conduct
Participants are recruited using convenience sampling. Assignment to groups is based on smoking status. Both groups are assessed,Then the intervention group receives 8 weekly MBSR sessions; while the control group does not. After treatment both groups are assessed and compared againe.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. confirmed diagnosis of COPD by a pulmonologist. 2. Age between 18 to 60 years. 3.Providing written informed consent . 4. No current major depressive or anxiety disorders. 5. No history of psychological treatment within the past year. 6. No history of arthritis in the medical history. 7. No history of metabolic disorders 8. Not using supplements that affect oxidative and antioxidative fbiomaekers. Exclusion Criteria: 1. Missing more than two MBSR session. 2. Incomplete questionnaires. 3. Use of psychiatric medications. 4. Changes in medication or treatment during the study. 5 Occurrence of acute or emergency medical conditions during the the study, especially during MBSR sessions.

Intervention groups
Participants in the intervention group will attend 8 weekly 90-minute srssions of MBSR coductted by a licensed psychologist. And participants in the control group will not receive any psychological intervention.

Main outcome variables
reduction in anxiety sensitivity, perceived stress, emotion regulation, oxidative/antioxidative biomarkers and to determine the overral effectiveness of MBSR as a therapeutic approach

General information

Reason for update
chainging the sampling location

Acronym
MBSR

IRCT registration information
IRCT registration number: **IRCT20250713066470N1**
Registration date: **2025-07-21, 1404/04/30**
Registration timing: **prospective**

Last update: **2025-12-25, 1404/10/04**
Update count: **1**

Registration date
2025-07-21, 1404/04/30

Registrant information

Name
Sara Habibi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3637 9497

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habibisara422@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-06, 1404/06/15
Expected recruitment end date
2025-09-23, 1404/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Mindfulness-Based Stress Reduction Therapy on Perceived Stress, Anxiety Sensitivity, Emotion Regulation Difficulties, and Oxidative Stress Factors (Oxidant/Antioxidant) in Patients with Chronic Obstructive Pulmonary Disease (COPD)

Public title
The Effect of Mindfulness-Based Stress Reduction (MBSR) on Anxiety Sensitivity, Perceived Stress, Emotion Dysregulation, and Blood Oxidative and Antioxidative Markers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having chronic obstructive pulmonary disease based on the diagnosis of the lung specialist Participants aged between 18 to 60 years Having a written informed consent to participate in the study Participants must have no diagnosis of major depressive disorder or any anxiety disorders Participants must have no prior history of receiving psychological interventions (especially mindfulness-based interventions) by a psychologist or psychiatrist Participants must have no prior diagnosis of arthritis in the medical history Participants must have no history of metabolic disorders, including diabetes or hypertension in their medical history Participants must not use vitamin D,C,E supplements or any other dietary suuplements that influence plasma oxidative and antioxidant factor levels
Exclusion criteria:
Participants with absence from more than two treatment sessions Participants who incompletely compllete the questionnaris Use of psychiatric medications Any changes in medication use or treatment during the study Participants will be excluded if they develop an acute or emergency medical condition during the implement of the study
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features
participants will be divided into two groups: the experimental group will receive a psychological intervention (mindfulness based stress reduction) while the control group will not receive any psychological treatment. this designe aims to evaluate the effectiveness of the intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of medical sciences Ethnics Committee
Street address
Kashan University of Medical Sciences, Hekmat 56 Street, Qotb Ravandi Boulevard, Kashan, Isfahan Province, Iran
City
Kashan
Province
Isfehan
Postal code
8715981151
Approval date
2025-07-03, 1404/04/12
Ethics committee reference number
1404054

Health conditions studied

1

Description of health condition studied
chronic obstructive pulmonary disease
ICD-10 code
J44.9
ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
THE perceived stress score in the Cohen perceived stress scale
Timepoint

At the beginning of the study (before the intervention) and at the end of the study (after the intervention)

Method of measurement

Cohen perceived stress scale

2

Description

The anxiety sesitivity score in the Floyd anxiety sensitivity scale

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (after the intervention)

Method of measurement

Floyd anxiety sensitivity inventory

3

Description

The emotion dysregulation score in the 16-item Difficulties in Emotion Regulation Scale

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (after the intervention)

Method of measurement

The 16-item Difficulties in Emotion Regulation Scale (DERS-16) by Bjureberg

4

Description

Levels of oxidative and antioxidant blood factors (MDA, TOS, TAC, Thiol groups) measured using diagnostic assy kits

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (after the intervention)

Method of measurement

Assy kits for TAC, MDA, TOS, Thiol groups

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 8-week mindfulness-based stress reduction (MBSR)

Category

Treatment - Other

2

Description

Control group: The control group does not receive any intervention or treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinic in Shiraz

Full name of responsible person

Sara Habibi

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Kashan University of Medical Sciences, Hekmat 56 Street, Qotb Ravandi Boulevard, Kashan, Isfahan Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Gholamali Hamidi

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Sara Habibi

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

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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

No - There is not 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

Only de-identified summary data related to the primary outcomes (such as scores on perceived stress, anxiety sensitivity, and emotional dysregulation questionnaires) may be made available upon reasonable request. No personal or identifying data will be shared.

When the data will become available and for how long

The data will be available starting 6 months after the publication of the results and will be accessible for at least one year, with the possibility that the duration may change depending on future decisions.

To whom data/document is available

Access to the data and study documents will be granted only to qualified researchers who submit a reasonable request and agree to comply with ethical and confidentiality requirements.

Under which criteria data/document could be used

Access to de-identified participant data and study documents will be granted only to qualified researchers upon reasonable request and after signing a data use agreement. Data will be shared solely for the purpose of verifying published results or conducting additional analyses related to the original study objectives. Any other use, such as commercial use or sharing with unauthorized third parties, is prohibited. Researchers must comply with all applicable ethical guidelines and maintain confidentiality. Data access requests will be reviewed by the study's principal investigator or ethics committee to ensure compliance with these conditions.

From where data/document is obtainable

Access to data will be provided upon reasonable request via the corresponding author of the published article or the principal investigator at the Kashan University of Medical Sciences. Contact details will be provided in the published paper

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

Applicants must submit a formal written request or email including their full name, institutional affiliation, purpose of data use, and the type of analysis they intend to perform. Requests will be reviewed by the principal investigator, and if approved, the data will be shared within 2 to 4 weeks. Data will only be shared under conditions ensuring confidentiality and limited to the declared purpose of use.

Comments