Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of mindfulness exercises on moral distress among nurses working in the intensive care units

Protocol summary

Study aim
The effect of implementing mindfulness exercises on moral distress among nurses working in the intensive care units of Imam Reza educational and medical center in Larestan in 2025

Design
A clinical trial with two groups (intervention and control) will be conducted on 56 participants who are selected using convenience sampling. Using a random number table, the participants will be randomly assigned to either the intervention group or the control group.

Settings and conduct
The study will be conducted in the intensive care units of Imam Reza Educational and Medical Center in Larestan. The study population consists of 56 nurses. Blinding type: No blinding will be applied in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Holding a bachelor's degree or higher; ability to attend all sessions; having at least 6 months of work experience in intensive care units. Exclusion criterion: Simultaneous participation in an intervention program during the implementation of the research

Intervention groups
Intervention group: After completing the questionnaires, participants will take part in eight 60-minute mindfulness training sessions based on the Kabat-Zinn model. The sessions include mindful breathing, body scan, meditation, mindful movement, and non-judgmental awareness. Control group:The control group will not receive any intervention.

Main outcome variables
Moral distress score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251028067796N1**
Registration date: **2025-12-12, 1404/09/21**
Registration timing: **prospective**

Last update: **2025-12-12, 1404/09/21**
Update count: **0**

Registration date
2025-12-12, 1404/09/21

Registrant information

Name
Hamidreza Ghavami

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-16, 1404/09/25

Expected recruitment end date
2025-12-30, 1404/10/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of mindfulness exercises on moral distress among nurses working in the intensive care units

Public title
The effect of mindfulness exercises on moral distress

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a bachelor's degree or higher Ability to attend all meetings Having at least 6 months of work experience in the intensive care unit (ICU)

Exclusion criteria:

Simultaneous participation in an intervention program during the implementation of the research

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

After preparing the list of eligible nurses and assigning a unique number to each individual, the randomization process was carried out using a random number table. A starting point in the table was first selected at random. Then, the numbers in the table were read sequentially, and each number was assigned to one of the two groups based on whether it was even or odd; even numbers were allocated to the control group and odd numbers to the intervention group. Numbers that fell outside the range of assigned codes were ignored, and the reading continued until the required sample size was achieved.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Isfahan (Khorasgan) Branch

Street address

Islamic Azad University, Isfahan (Khorasgan) Branch, Daneshgah Boulevard, Arghavaniyeh, East J Street, Isfahan

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Province

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Postal code

743183886

Approval date

2025-09-07, 1404/06/16

Ethics committee reference number

IR.IAU.KHUISF.REC.1404.496

Health conditions studied

1

Description of health condition studied

Moral distress among nurses working in the intensive care units

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The moral distress score in the Hamric questionnaire

Timepoint

Before the intervention and immediately after the completion of the intervention sessions

Method of measurement

Hamric Moral Distress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the demographic questionnaire and Hamric’s Moral Distress Questionnaire will be completed for the intervention group. Then, the intervention will be implemented as an in-service training program titled “Mindfulness Exercises Training,” consisting of 7 to 8 in-person sessions of 60 minutes each (using PowerPoint presentations). The session content includes mindfulness exercises based on Jon Kabat-Zinn’s model (mindful breathing, body scan, sitting meditation, mindful movement, awareness of the present moment in daily activities, acceptance, and non-judgment). After completing the sessions, the Moral Distress Questionnaire will be administered again to the intervention group, and the results of the intervention and control groups will be compared and evaluated.

Category

Behavior

2

Description

Control group: First, the demographic questionnaire and Hamric’s Moral Distress Questionnaire will be completed for the control group. After the intervention is completed,

the educational content provided to the intervention group will also be presented to the control group in order to observe ethical considerations and allow these participants to benefit from the in-service training program as well.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Educational and Medical Center, Laristan

Full name of responsible person
Hamidreza Ghavami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Ahmad Shajari

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Islamic Azad University Complex, Shohada-ye Gomnam Boulevard, Alam Square, Safaieh, Yazd

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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
Islamic Azad University

Full name of responsible person
hamidreza ghavami

Position
Master’s degree student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No additional information is available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available