Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of a preventive self-care protocol based on mindfulness on reducing perceived stress and improving work-life balance in women working in hospital healthcare staff

Protocol summary

Study aim
The effectiveness of a preventive self-care protocol based on mindfulness on reducing perceived stress and improving work-life balance in women working in hospital healthcare staff.

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 50 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
The statistical population will include all the women working in the medical staff in the affiliated hospitals of Ahvaz University of Medical Sciences in the specified time period. In the sample selection stage, available sampling method is used. After selecting the samples to the size of 50 people, based on the research entry and exit criteria, the participants will be randomly assigned to two groups: "preventive self-care protocol based on mindfulness" (intervention group) and "waiting list" (control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women working in healthcare, having at least 1 year of clinical experience in a hospital, scoring above average on the perceived stress questionnaire. Exclusion criteria: Participation in similar mindfulness or yoga courses in the last 6 months, unwillingness to participate in sessions.

Intervention groups
Intervention group: receiving the mindfulness-based self-care preventive intervention; Control group: not receiving any intervention.

Main outcome variables
Perceived stress, Work-life balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260617069854N1**
Registration date: **2026-07-04, 1405/04/13**
Registration timing: **prospective**

Last update: **2026-07-04, 1405/04/13**
Update count: **0**

Registration date
2026-07-04, 1405/04/13

Registrant information

Name
Maryam Doraki

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-11, 1405/04/20

Expected recruitment end date
2026-07-27, 1405/05/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of a preventive self-care protocol

based on mindfulness on reducing perceived stress and improving work-life balance in women working in hospital healthcare staff

Public title
The effectiveness of mindfulness intervention on mental health and work-life balance of working women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women working in healthcare Achieving a score above average on the perceived stress questionnaire Having at least 1 year of clinical experience in a hospital
Exclusion criteria:
Participation in similar mindfulness or yoga courses in the last 6 months Unwillingness to attend meetings
Age
From **25 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The statistical population will include all women working in the medical staff in hospitals affiliated to the University of Medical Sciences during the specified time period. In the sample selection stage, the convenience sampling method will be used. After selecting a sample size of 50 people, based on the study's entry and exit criteria, participants will be randomly assigned to two groups: "Mindfulness-Based Self-Care Preventive Protocol" (intervention group) and "Waiting List" (control group). Randomization will be performed using the random block method with variable sizes (4 and 6 people) by an independent statistician who is not involved in the implementation process. The random allocation list will be generated using the RAND function in Excel software and then placed in opaque, sealed, and numbered envelopes so that the researcher and participants are not aware of the allocation sequence (allocation concealment). The envelope will be opened and the allocation group will be informed only when each participant enters the study. To ensure the equality of basic variables (such as anxiety level, age, and work experience), their distribution in the two groups will be examined during the statistical analysis stage.
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 Islamic Azad University of Ahvaz Branch
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
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Ahvaz
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Postal code
6134937333
Approval date
2026-06-16, 1405/03/26
Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.280

Health conditions studied

1

Description of health condition studied
Job burnout
ICD-10 code
Z73.0
ICD-10 code description
Burn-out

Primary outcomes

1

Description
Perceived stress
Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
Method of measurement
The method of measurement will be the Cohen et al. (1983) Perceived Stress Scale.

2

Description
Work-life balance
Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
Method of measurement
The measurement method will be using the Fisher et al. (2009) work-life balance questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindfulness-based preventive self-care protocol. Duration of each session: 90 minutes. Total number of sessions: 8 sessions. Sequence of sessions: Twice a week. Therapeutic tools used: This intervention focuses on teaching and practicing mindfulness-based self-care skills with the aim of increasing present-moment awareness, reducing stress reactivity, regulating emotions, and enhancing work-life balance. The main tools used in this protocol include conscious breathing exercises, body scanning, mindfulness of thoughts and emotions, nonjudgmental acceptance, exercises to pay attention to the body and emotions, mindfulness exercises in daily activities, and rebuilding self-care behavioral patterns. The content of the various sessions is based on the following: Session 1: Pre-test implementation, introduction of the protocol, and explanation of the concepts of mindfulness and self-care. Session 2: Training in conscious breathing exercises and increasing attention to the present moment. Session 3: Training in the body scanning technique to identify and release physical tensions. Session 4: Training in observing thoughts without judgment and managing emotional reactions. Session 5: Training in the skill of accepting and managing stress in difficult situations. Session 6: Practicing mindfulness in daily activities and the workplace (treatment staff). Session 7: Developing self-care strategies to improve work-life balance. Session 8: Conclusion, providing final suggestions, conducting a post-test, and determining the follow-up time.

Category

Treatment - Other

2

Description

Control group: The control group will not receive any intervention during the research, but will receive the intervention after data collection to prevent factors that threaten the internal validity of the research, such as compensatory competition from the control group or demoralization.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Maryam Duraki

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Esfand Street, Daneshgah Town, Golestan Boulevard

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Sponsors / Funding sources

1

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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

Private

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

Maryam Duraki

Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable