Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effectiveness and sustainability of "Mindfulness-based Stress Reduction (MBSR)" education on Depression, Anxiety and Stress Scale (DASS-21) score in nurses and comparing it with control group.

Protocol summary

Study aim

Comparison of mean score changes in three sub-scales of DASS 21 questionnaire in nurses before the start of the study, after training and 3 months later in the trained and control groups. Investigating the relationship between the studied factors on the changes in three sub-scales mean score of DASS 21 questionnaire before the start of the study and after training in nurses.

Design

This is a two arm parallel groups randomized trial with block randomization (intervention and control groups). The randomization sequence carried out at an internet site. Based on calculated sample size, 68 person will participate in the study and will be followed after 3 months.

Settings and conduct

Sampling will be done in health and treatment organization of Fars Oil Industry. All eligible nurses who have therapeutic activity in Shiraz city will be included in the study. The statistician who analyses the data and the staff who collects completed questionnaires are blinded to participant allocation. Before and after training and three months later, the questionnaire are presented to participants in the workplace by an irrelevant staff.

Participants/Inclusion and exclusion criteria

Nurses who have therapeutic activity in the health and treatment organization of Fars Oil Industry and work in Shiraz city Willing to participate in the project Age less than 65 years old.

Intervention groups

For the intervention group, training sessions are planned one hour per week for 4 consecutive weeks. In each session the modified version of Mindfulness-Based Stress Reduction (MBSR) program (extracted from https://palousemindfulness.com/) will be presented to participants by a experienced psychiatrist in the field. As well as training videos will be provided to attendees. During this time the control group will receive no training.

Main outcome variables

Three sub-scale of DASS21 (Depression Anxiety and Stress Scale) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190604043813N3**
Registration date: **2021-01-11, 1399/10/22**
Registration timing: **prospective**

Last update: **2021-01-11, 1399/10/22**
Update count: **0**

Registration date

2021-01-11, 1399/10/22

Registrant information

Name

Hourvash Akbari Haghighinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4967

Email address

hhaghighi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-21, 1399/11/02

Expected recruitment end date

2021-02-20, 1399/12/02

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effectiveness and sustainability of "Mindfulness-based Stress Reduction (MBSR)" education on Depression, Anxiety and Stress Scale (DASS-21) score in nurses and comparing it with control group.

Public title
Effect of "Mindfulness-based Stress Reduction" (MBSR) on mood disorders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willing to participate in the project Having a therapeutic activity as a nurse in the health and treatment organization of Fars oil industry who work in Shiraz city
Exclusion criteria:
Age over 65 years
Age
To **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **68**
More than 1 sample in each individual
Number of samples in each individual: **3**
Before training, immediately after training, three months after training
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly allocated to one of the 2 groups in this trial by block randomization given a block size of 4. For this propose these steps must be followed: First the list of nurses staff of the organization will be provided, then by a randomization software at https://www.sealedenvelope.com/simple-randomiser/v1/lists, a blocked randomization list will be created given block size of 4 and list length of 68. Allocation is based on matching the number of two lists (randomization list and list which is provided by organization) so each case is assigned to a group A or B
Blinding (investigator's opinion)
Double blinded
Blinding description
The questionnaire will be delivered to participant in the workplace by a hospital staff who is unaware of group allocation .The results will enter in SPSS20 and analyze by a statistician who is unaware of the group allocation.
Placebo
Used
Assignment
Parallel
Other design features
Each one-hour session is a combination of training method including education by video (half an hour) and theoretical and practical training (half an hour).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Family Medicine Department, Namazi Hospital. Shiraz
City
Shiraz
Province
Fars
Postal code
7184983858
Approval date
2019-06-22, 1398/04/01
Ethics committee reference number
IR.SUMS.MED.REC.1398.218

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

2

Description of health condition studied
Anxiety
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

3

Description of health condition studied
Stress
ICD-10 code
ICD-10 code description

4

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

Primary outcomes

1

Description
DASS-21 (depression , anxiety, stress) questionnaire score
Timepoint
Before and after training and 3 months after training
Method of measurement
DASS-21 (depression , anxiety, stress) questionnaire score

Secondary outcomes

1

Description
Copenhagen burnout questionnaire score
Timepoint
Before and after training and 3 months after training
Method of measurement
Copenhagen burnout questionnaire score

Intervention groups

1

Description
Intervention group: The intervention group will be given 4 training sessions one hour per week for 4 consecutive weeks in which the Mindfulness-Based Stress Reduction (MBSR) program will be moderated by the respective assistant as well as instructional videos. During this time the control group received no training.The session schedule is as follows. The first session: half hour presenting the video "Power of mindfulness" and the second half hour lecture of Body scan7 myths of meditation, The second session: first half hour presenting the video "Don't try to be mindful" and The second half hour the lecture Why you find it hard to meditate , The third session the first half hour presenting the video "Raisin meditation" and the second half hour of brain-rewires, The forth session: half hour presenting the video Attention, intention attitude and the second half hour of Sitting Meditation and Your mind lecture . At the end of each session meditation is done for about 10 minutes. Exact titles and educational materials have been extracted from the site https://palousemindfulness.com/. An experienced psychiatrist in this field is responsible for training the intervention group.
Category
Treatment - Other

2

Description
Control group: No intervention will be done. Only the questionnaires will be completed before, after, and three months after training.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health and treatment organization of Farse Oil Industry
Full name of responsible person
Arman Mostaghni
Street address
Family medicine department, Namazi hospital.
City
Shiraz
Province
Fars
Postal code
7184983858
Phone
+98 71 3647 4967
Email
hhaghighi@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Family medicine department, Namazi hospital. Shiraz
City
Shiraz
Province
Fars
Postal code
7184983858
Phone
+98 71 3647 4967
Email
hhaghighi@sums.ac.it
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Hourvash Akbari Haghighinejad
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Family medicine department, Namazi hospital. Shiraz
City
Shiraz
Province
Fars
Postal code
7184983858
Phone
+98 71 3647 4967
Email
hhaghighi@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hourvash Akbari Haghighinejad
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Zand street, Namazi hospital, Family medicine department
City
Shiraz
Province
Fars
Postal code
7184983858
Phone
+98 71 3647 4967
Fax
Email
hhaghighi@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hourvash Akbari Haghighinejad
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Zand street, Namazi hospital, Family medicine department
City
Shiraz
Province
Fars
Postal code
7184983858
Phone
+98 71 3647 4967
Fax
Email
hhaghighi@sums.ac.ir

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
All potential data can be shared after the participant become unidentifiable.
When the data will become available and for how long
After article acceptance
To whom data/document is available
All who request to use data in other related research
Under which criteria data/document could be used
To use data in other related research only if the source of information be mentioned in the related research
From where data/document is obtainable
hhaghighi@sums.ac.ir
What processes are involved for a request to access data/document

Provided that the applicant explains the program and title of his research project, the cooperation of one of the researchers in this project in the research project of the applicant as one of the authors and also mentioning the source of information, information will be provided to him as soon as possible.

Comments