

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 Haghighejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4967

Email address

hhaghghi@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 scan 7 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 fourth 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

hhaghghi@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

hhaghghi@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 Haghhighinejad

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 Haghhighinejad

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 Haghhighinejad

Position

Assistant professor

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Fars

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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