

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effectiveness of Mindfulness-based Stress Reduction (MBSR) on occupational burnout and comparing it with control group in hospital non-medical staffs

Protocol summary

Study aim

Comparison of the mean differences of burnout in non-therapeutic staff in 3 dimension of burnout (personal burnout, work-related burnout, and client-related burnout) before , after training of mindfulness-based stress reduction (MBSR) and 3 months later in the trained and control groups

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, 50 person will participate in the study and will be followed for 3 months.

Settings and conduct

Sampling will be done in Alzahra Heart Hospital of Shiraz. All eligible non-medical staff who work with visitors 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

Non-medical staff of Shiraz Alzahra Heart Hospital who have eligible criteria. Willingness to participate in project; Having non-therapeutic activity; Having a working relationship with visitors Exclusion criteria: age under 18 and over 70 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 will be presented to participants by the relevant assistant. As well as training videos will be provided to attendees. During this time the control group will receive no training.

Main outcome variables

Copenhagen Burnout Questionnaire scores with three sub-scales (personal burnout, work-related burnout, and client-related burnout); DASS (Depression Anxiety and Stress Scale) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190604043813N1**
Registration date: **2019-10-19, 1398/07/27**
Registration timing: **retrospective**

Last update: **2019-10-19, 1398/07/27**

Update count: **0**

Registration date

2019-10-19, 1398/07/27

Registrant information

Name

Hourvash Akbari Haghighinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4967

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hhaghighi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-06, 1398/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of Mindfulness-based Stress Reduction (MBSR) on occupational burnout and comparing it with control group in hospital non-medical staffs

Public title

Evaluating the effectiveness of "Mindfulness-based Stress Reduction" (MBSR) on occupational burnout

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Willing to participate in the project Having non-therapeutic activity Having a working relationship with patients / caregiver

Exclusion criteria:

Age over 70 years old Age under 18 years old

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **3**

-

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 2. For this propose these steps must be followed: First the list of non-medical staff of the hospital will be provided, then by a randomization software at <https://www.sealedenvelope.com/simple-randomiser/v1/lits>, a blocked randomization list will be created given block size of 2 and list length of 50. Allocation is based on the results of the software in a way that the number of each item in the list which was provided by the hospital will be matched with the list created by software so each case is assigned to group A or group 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 into the SPSS 20

software by a statistician who is unaware of the group allocation.

Placebo

Not used

Assignment

Parallel

Other design features**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

2018-10-08, 1397/07/16

Ethics committee reference number

IR.sums.med.rec.1397.276

Health conditions studied**1****Description of health condition studied**

Occupational burnout

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Copenhagen burnout questionnaire score

Timepoint

Before and after training and 3 months later

Method of measurement

Copenhagen burnout questionnaire score

Secondary outcomes**1****Description**

Changes of Copenhagen burnout questionnaire score

Timepoint

Before and after training and 3 month later

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 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 was done for about 10 minutes.

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

Alzahra heart Hospital

Full name of responsible person

hamid ghazipour

Street address

Family medicine department, Namazi hospital. Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Hourvash Akbari Haghighejad

Position

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Community and Family medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

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

if the applicant accept to mention the source of information in his research, the data will be provided as soon as possible after the applicant has described the program and the title of his research project.

Comments