Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 71 3647 4967

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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 Aage 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/lists, 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 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 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
City
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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
Street address
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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

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Full name of responsible person

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Position

Assistant professor

Latest degree

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Community and Family medicine

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Person responsible for updating data

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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