Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Mindfulness Based Stress Reduction (MBSR) on Burden of Care in the Caregivers of hospitalized patients in Ebne Sina Hospital

Protocol summary

Study aim
Effectiveness of Mindfulness Based Stress Reduction (MBSR) on Burden of Care in the Caregivers of hospitalized patients in Ebne Sina Hospital

Design
This study is a randomized clinical trial.The participants are selected from among the main caregivers of the hospitalized patients of EbneSina Hospital based on inclusion and exclusion criteria, and are placed in two intervention and control groups (n=19 in each group).

Settings and conduct
The participants are selected from among the main caregivers of the hospitalized patients of EbneSina Hospital based on inclusion and exclusion criteria, and are placed in the intervention and control groups (n= 19 in each group). Data is collected via individual information form of the patient and the caregiver, the mental burden questionnaire, and the depression, anxiety and stress questionnaire, 21 questions version (DASS21) before and after the intervention. 8 weekly sessions of MBSR will be conducted for the intervention group, and no intervention for the control group. Finally, the data will be analyzed by SPSS software.

Participants/Inclusion and exclusion criteria
Participants: from among the main caregivers of patients admitted to EbneSina Hospital. Inclusion criteria: willingness to participate in the research; not having a substance use disorder, a major psychiatric disorder such as psychosis, and concurrent psychological treatments; minimum high school education. Exclusion criteria: willingness to leave whenever the subjects want; absence of more than 50% in meetings.

Intervention groups
Intervention group: stress reduction sessions will be conducted based on mindfulness. The content of the 8 MBSR sessions will be determined. Control group: no intervention will be done; however the intervention will be done for them at the end of study due to ethical principles.

Main outcome variables
Care pressure; depression; anxiety; stress

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230807059072N1**
Registration date: **2024-01-22, 1402/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-22, 1402/11/02**
Update count: **0**

Registration date
2024-01-22, 1402/11/02

Registrant information
Name
Zahra Sadat sangsefidi
Name of organization / entity
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Iran (Islamic Republic of)
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+98 51 3711 2701
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-21, 1402/09/30
Expected recruitment end date
2024-07-20, 1403/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Mindfulness Based Stress Reduction (MBSR) on Burden of Care in the Caregivers of hospitalized patients in Ebne Sina Hospital

Public title
Effectiveness of Mindfulness Based Stress Reduction (MBSR) on Burden of Care in the Caregivers of hospitalized patients in Ebne Sina Hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the research Not having a substance use disorder and not having a major psychiatric disorder such as psychosis Not receiving concurrent psychological treatments Minimum high school education

Exclusion criteria:
Willingness to leave whenever group members Absence of more than 50% of group meetings

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Random permuted blocks method is used for random allocation. In this method, 9 blocks of 4 will be randomly selected from the combination of letters A and B. These blocks are AABB, ABBA, BBAA, BAAB, ABAB, BABA. We will also have a block of 2 in the form of AB or BA. The selection of blocks will be based on the table of random numbers and the preparation of blocks by someone outside the research team. The prepared blocks will be written on separate sheets and placed in sealed envelopes and will be provided to the researcher at the time of sampling. Allocation of letters A and B to the intervention and control groups will also be done randomly before the randomization by someone outside the research team so that being aware of the randomization process does not distort the selection. To generate the random allocation sequence, the random table and the method mentioned above are used.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, blinding was done for the participants of both intervention and control groups. In addition, the person in charge of data collection, who is responsible for completing the CRFs.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Mashhad University of Medical Sciences, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177899191

Approval date
2023-07-21, 1402/04/30

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.174

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety

Timepoint
Before and after intervention

Method of measurement
by DASS 21

2

Description
Depression

Timepoint
Before and after intervention

Method of measurement
by DASS 21

3

Description
Stress
Timepoint
Before and after intervention
Method of measurement
by DASS 21

4

Description
Burden of Care
Timepoint
Before and after intervention
Method of measurement
by Zariet care pressure questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Formation of the group. Introduction and familiarization and explanation of the concept of automatic guidance. Introduction of the program and a brief description of the eight sessions to familiarize the group members with each other and advice on setting the goals and rules of the group. Familiarity with the educational concepts of stress reduction based on mindfulness and the need for mindfulness training. Explanation about automatic guidance. and meditating on eating raisins and then meditating on checking the body and conscious breathing for thirty minutes.
Category
Treatment - Other

2

Description
Control group: There is no training.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
EbneSina hospital
Full name of responsible person
Dr Farshad Shaybani
Street address
Mashhad . haraami ST.next to the vehicle of qods razaviprovinceEbneSina hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Farshad Sheybani
Street address
vakil abad.bahonar avenue
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Grant name
mashhad university of medical sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Sangsefidy
Position
Psychiatry resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
We did not have permission to publish data of participants.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
We did not have permission to publish data of participants.
When the data will become available and for how long
We did not have permission to publish data of participants.
To whom data/document is available
We did not have permission to publish data of participants.
Under which criteria data/document could be used
We did not have permission to publish data of participants.
From where data/document is obtainable
We did not have permission to publish data of participants.
What processes are involved for a request to access data/document
We did not have permission to publish data of participants.
Comments