

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2701

Email address

sangsefidiz981@mums.ac.ir

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 gods
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zahra_sangsefidy@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Farshad Sheybani

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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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Ibn Sina Hospital, next to Astan Quds Razavi, At the end of Har Ameli St.

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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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