

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of "Mindfulness-based stress reduction" on emotional regulation and mental health of pre-hospital emergency staff

Protocol summary

Study aim

Determining the effect of mindfulness based on stress reduction on emotional regulation and mental health of pre-hospital emergency staff of Kashan University of Medical Sciences 2021

Design

A randomized, parallel group, controlled trial

Settings and conduct

The study was designed to "The effect of mindfulness based on stress reduction on mental health and emotional regulation of pre-hospital emergency staff of Kashan University of Medical Sciences"

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Satisfaction to participate in the study 2. Do not have a known physical illness (self-report) 3. Do not have a known mental illness (self-report) 4- Not receiving mood-regulating drugs in the last 3 months 5. Not participating in similar mindfulness courses in the last 6 months 6- Having an associate's or bachelor's degree in pre-hospital emergencies 7- Employed and having at least 6 months of work experience as a pre-hospital emergency 8- Obtaining a score of 22 and above from the general health questionnaire and at the beginning of the study
Exclusion criteria: 1- Withdrawal from continuing cooperation 2. Absence from more than 2 sessions of mindfulness sessions 3- Lack of access to samples in the stages of monitoring mental health status and emotion regulation 4. Start taking mood-regulating drugs 5. Participate in similar courses based on mindfulness during the study

Intervention groups

The intervention group receives 8 sessions of MBSR in each week. Each session is 60 minutes and the treatment sessions are based on the Kabat Zin protocol. The control group just received pamphlets on mental health according to the NANDA International Association.

Main outcome variables

mental health emotional regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130721014086N15**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

Registration date

2022-01-19, 1400/10/29

Registrant information

Name

Mohammad Aghajani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 2001

Email address

aghajani_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of "Mindfulness-based stress reduction" on emotional regulation and mental health of pre-hospital emergency staff

Public title

The effect of "Mindfulness-based stress reduction" on emotional regulation and mental health of pre-hospital emergency staff

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study
Have an associate's or bachelor's degree in pre-hospital emergencies
Employed and having at least 6 months of work experience as a pre-hospital emergency

Exclusion criteria:

Withdrawal from continuing cooperation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are defined as block randomization in the form of 6 blocks using Sealed Envelope Ltd.2017 software available through the site www.sealedenvelope.com, with twelve blocks of 6 that are assigned to two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravadi, Kashan

City

Kashan

Province

Isfahan

Postal code

88715973474

Approval date

2022-01-03, 1400/10/13

Ethics committee reference number

IR.KAUMS.REC.1400.056

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

2

Description of health condition studied

Depression

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders

Primary outcomes

1

Description

Mental health

Timepoint

Before study and 1 month later

Method of measurement

General Health Questionare

Secondary outcomes

1

Description

Emotional regulation

Timepoint

Before study and 1 month later

Method of measurement

Difficulties in Emotion Regulation Scale

Intervention groups

1

Description

Intervention group: Intervention group: The 8 weekly sessions followed the standard MBSR protocol as developed by Kabat-Zinn (1990). Each session was 60 min. The overall content of the sessions were: 1) Introducing mindfulness 2) Sitting Meditation

3)Body Scan and walking meditation 4)yoga
5)Mindfulness of feelings and physical pain, meditation in every day of life 6)Self-reflection and self-management
7)Acceptance and changing 8)How can I take the best care of myself?

Category

Behavior

2

Description

Intervention group: Control group: patients receive usual treatments and educational pamphlets

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Medical Center of Kashan University of Medical Sciences

Full name of responsible person

Sanaz Lotfi

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88715973474

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

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8715988141

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research@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Aghajani

Position

lectuerer

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery, Km 3 Ghotbe Ravandi, Kashan

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Mohammad Aghajani
Position
lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Km 3 Ghotbe Ravandi, Kashan
City
Kashan

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

No more information

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available