Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of education on mindfulness-based stress coping skills on psychological distress in patients with Covid 19

Protocol summary

Study aim
Determining the effect of mindfulness-based stress coping skills training on psychological distress in patients with Covid 19

Design
A clinical trial with a control and test group, one-way blind, randomized, on 75 patients and coin toss method was used for randomization.

Settings and conduct
This study is a clinical trial that will be conducted to investigate the effect of mindfulness-based stress coping skills training on psychological distress in patients with Covid 19 in 1400. Patients with inclusion criteria available for Participating in the study will randomly (coin toss) enter one of the test or control groups. Then the demographic and 42 DASS questionnaires will be completed by the test and control group. The test group will receive mindfulness-related training in 8 sessions of 2 hours remotely and in the WhatsApp software platform. After the intervention, the 42 DASS questionnaire will be completed by both groups.

Participants/Inclusion and exclusion criteria
People over 18 years of age and under 60 years of age with Covid 19 disease whose hemodynamic condition is stable and the patient is on the verge of discharge within the next 24-48 hours.

Intervention groups
In this study, mindfulness-based intervention refers to mindfulness-related training, which is 8 sessions of 2-hour training that will be implemented remotely and in the context of mass communication software such as Whats-app.

Main outcome variables
Anxiety, depression and stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210715051896N1**
Registration date: **2022-06-03, 1401/03/13**
Registration timing: **retrospective**

Last update: **2022-06-03, 1401/03/13**
Update count: **0**

Registration date
2022-06-03, 1401/03/13

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-12, 1400/07/20

Expected recruitment end date
2021-11-21, 1400/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of education on mindfulness-based stress coping skills on psychological distress in patients with Covid 19

Public title
The effect of education on mindfulness-based stress coping skills on psychological distress in patients with Covid 19
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study The patient's hemodynamic condition is stable and the patient is on the verge of discharge from the hospital within the next 24-48 hours. Have the ability to use mass communication software. No history of psychiatric illness No other sudden events such as the loss of loved ones... in the last six months
Exclusion criteria:
Previous attendance at stress management training courses Death of the participant Readmission Identify neurological diseases Not actively participating in meetings and partially abandoning the intervention Not having sudden events such as the loss of loved ones and ... while studying
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In the present study, initial sampling will be available in order to reach the eligible participants so that the participants are first included in the list of patients admitted to the ward wards of Modares, Imam Hossein and Masih hospitals. Knowledge will be selected as available and randomly (coin toss) will enter one of the test or control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
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Valie Asr
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1985717443
Approval date
2021-08-29, 1400/06/07
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.108

Health conditions studied

1

Description of health condition studied
Covid_19 patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Distance learning of mindfulness-based stress coping skills can make a difference in psychological distress in patients with Covid 19.
Timepoint
Mindfulness training that will be taught to patients with Covid 19 during 8 sessions, for 8 weeks, and a 2-hour session each week.
Method of measurement
Biographical information questionnaires and DASS-42

Secondary outcomes

empty

Intervention groups

1

Description
The first session of mindfulness training will include communication and conceptualization, the practice of formal breathing meditation and physical examination, and a snack exercise with the presence of the mind. In fact, the goal of training is to meditate. People focus most of the day on external stimuli. In this exercise, they should focus on the body itself without mental presuppositions.In the second session of formal meditation practice, explanation about yoga and teaching some yoga exercises, practicing the presence of breathing mind during the day, saying things about mindfulness and meditation, increasing the level of awareness in daily activities such as eating and bathing will be done. In this session, people will be taught that we should not do strange things, but they can achieve

the integration of mind and body with a few simple exercises.In the third session of formal meditation practice, telling about eating with the presence of mind, explaining seven false myths about meditation, thoughts about thinking, completing pleasant events, continuing daily activities with intentional awareness will be done. In this session, people will learn to write down the good events of their lives at a certain point in time along with the feelings and emotions created, and also to take care of their daily thoughts but do not react to them.The fourth session includes practicing formal meditation, saying things about chaos or relaxation, training (stopping technique) to stand, taking a breath, spreading awareness and thinking about other possibilities, completing unpleasant events, and continuing daily activities with intentional awareness. will be. In this session, unlike the previous session, the focus will be on the bad events of life and the thoughts and emotions related to it will be recorded.The fifth session of the formal meditation practice was to talk about the effect of meditation on the gray matter, teaching kindness prayers, insightful dialogue, completing communication sheets, interacting with the continuation of daily activities with intentional awareness, especially of others. Mindfulness is not training but an experience, and according to the law of flexibility, the brain changes with the experience of the brain.In the sixth session of formal meditation practice, movement from the interpersonal world to the interpersonal world, conflict management styles, mindful anger management, anger process explanation, continuation of daily activities with intentional awareness and informal meditation practice report will be done. One of the sources of stress is interpersonal conflicts that are due to cognitive errors. When people become familiar with these errors, they can better understand each other's feelings and needs in conflict situations.In the seventh session of formal meditation practice, telling about the process of pain and getting rid of it, finding the right shelter with the technique of rain, the continuation of daily activities will be done with deliberate awareness. With awareness, one can move towards unwanted things such as pain and consciously seek pleasure and pleasure in it.The eighth session of formal meditation practice will be suggestions for daily practice, writing three long-term and short-term goals, continuing daily activities with intentional awareness.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Masih Daneshvari Hospital

Full name of responsible person
Dr. Ali akbar velayati

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2

Recruitment center

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Shahid Modares Hospital

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3

Recruitment center

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Sponsors / Funding sources

1

Sponsor

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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
Shahid Beheshti 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
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document

All data is shared after being unidentified

When the data will become available and for how long

Three months after the results are published

To whom data/document is available

It is accessible to all individuals and institutions

Under which criteria data/document could be used

With permission from the publisher via email

From where data/document is obtainable

Shahid Beheshti School of Nursing and Midwifery

What processes are involved for a request to access data/document

By contacting the e-mail of the consultant professor and researcher Community Verified icon

Comments