

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Assessment of the effect of mindfulness on general health and sleep quality of patients with Covid - 19

Protocol summary

Study aim

Determining the effect of mindfulness on general health and sleep quality in patients with Covid 19

Design

A clinical trial with a control group, with parallel groups, one-way blind, randomized, on 60 patients. Block randomization with 2, 4, and 6 blocks will be used.

Settings and conduct

This single-blind clinical trial study will be performed on patients with COVID-19 who are being treated in the Infectious Diseases Hospital of Shahid Beheshti Hospital in Yasuj after obtaining permission from the Ethics Committee. Patients will be allocated to two groups through block randomization. Patients in the intervention group will receive 5 sessions of mindfulness training for one hour daily. In this study, the evaluator who evaluates the outcome variables in the post-test stage is not aware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of Covid 19 by an infectious disease specialist and hospitalized in the ward, the patient is over 18 years of age, the patient is not intubated, the patient's blood oxygen saturation is not below 93%. Exclusion criteria: The patient refuses to continue cooperation in the study, the patient dies, the patient's age is less than 18 years.

Intervention groups

All patients with COVID-19 will be treated according to the national guidelines in the intervention group. Patients in the intervention group will receive 5 sessions of mindfulness training per hour per day and the control group will not receive training.

Main outcome variables

General health ; Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160815029377N3**

Registration date: **2022-06-04, 1401/03/14**

Registration timing: **prospective**

Last update: **2022-06-04, 1401/03/14**

Update count: **0**

Registration date

2022-06-04, 1401/03/14

Registrant information

Name

Mohammad Malekzadeh

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 74 3332 3379

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mohamad.malekzadeh@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of mindfulness on general health and sleep quality of patients with Covid - 19

Public title

The effect of mindfulness on general health and sleep quality of patients with Covid - 19

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirmation of Covid 19 infection by an infectious disease specialist and hospitalization in the ward The patient should be 18 years or older. The patient's blood oxygen saturation should be 93% or higher.

Exclusion criteria:

Patient dissatisfaction with cooperation in the study. If the patient is intubated

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization through blocks 2, 4, and 6. Random allocation will be done according to the two groups of intervention and control, the sample size of 60 people, and the size of the blocks. For example, if the size of the blocks is 2, we will have 2 modes AB and BA (A intervention group and B control group). For other block sizes, possible modes will be considered. Also, the site with the following address will be used for ease and accuracy of work. Sealed Envelope Ltd. 2021. Create a blocked randomisation list. [Online] Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/lists> [Accessed 4 Jun 2022].

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the evaluator who evaluates the outcome variables in the post-test stage is not aware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

The intervention group will be trained in 5 sessions of mindfulness for one hour daily and the control group will not receive training.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Yasuj University of Medical Sciences

Street address

Vice President of Research Yasuj University of Medical Sciences, Shahid Motahari Blvd, Yasuj.

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IR.YUMS.REC.1400.193

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Covid-19

Primary outcomes**1****Description**

General Health. In this study, the 28-item Goldberg General Health Questionnaire will be used to assess patients' general health.

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Through GHQ-28 questionnaire and comparison of scores of the two groups.

2**Description**

Sleep quality. The score that patients will receive from the Richard Campbell Sleep Quality Questionnaire.

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Through the Richard Campbell Sleep Quality Questionnaire. A higher score indicates better sleep quality.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 hospitalized patients with Covid-19 and are eligible for inclusion in the study. These patients receive 5 sessions each day for one hour in the presence of a mindfulness-trained nurse. Mindfulness exercises are mainly about living in the present moment, accepting yourself fundamentally with all your strengths and weaknesses, having a different perspective on dealing with obstacles, coping with illness, controlling unpleasant thoughts and feelings.

Category

Behavior

2

Description

Control group: Control group: This group includes 30 hospitalized patients with Covid-19 and eligible for inclusion in the study. There is no mindfulness intervention for this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Somayeh Ansari

Street address

Shahid Beheshti Hospital, Shahid Mohammad Montazeri Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Hossein Mari Oriad. Vice Chancellor for Research, Yasouj University of Medical Sciences.

Street address

Vice Chancellor for Research and Technology, Yasouj

University of Medical Sciences, Shahid Motahari Blvd.

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en@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Malekzadeh

Position

Associated Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers, doctors and nurses

Under which criteria data/document could be used

By viewing the published article in the journal.

From where data/document is obtainable

Contact mzh541@yahoo.com

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

Publish the article and submit a request.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Malekzadeh

Position

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Latest degree

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