Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 COVOID-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

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Iran (Islamic Republic of)

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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
Kohgilouyeh-va-Boyrahmad
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, Yasuj University of Medical Sciences.

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Vice Chancellor for Research and Technology, Yasuj University of Medical Sciences, Shahid Motahari Blvd.

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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
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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Person responsible for scientific

inquiries

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Person responsible for updating data

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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