

# 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)

##### Phone

+98 74 3332 3379

##### Email address

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.

##### City

Yasuj

##### Province

Kohgiluyeh-va-Boyer-Ahmad

##### Postal code

7591794857

##### Phone

+98 74 3322 1813

##### Email

somayeh.ansari1983@gmail.com

## 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.

##### City

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##### Province

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##### Phone

+98 74 3334 6078

##### Fax

+98 74 3334 6079

##### Email

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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##### Email

mzh541@yahoo.com

## Person responsible for scientific

## **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**

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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**

Associated Professor

**Latest degree**

Ph.D.

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