

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The Effect of Pulmonary Rehabilitation on Depression, Anxiety, Fatigue and Quality of Life in COVID-19 Patients with one-month Follow-up

#### Protocol summary

##### Study aim

The effect of pulmonary rehabilitation on depression, anxiety, fatigue and quality of life in COVID-19 patients with one-month follow-up

##### Design

Clinical trial with parallel control group, randomized, on 40 patients

##### Settings and conduct

The COVID-19 wards of Imam Khomeini Hospital in Sari were selected as the sampling site. 40 patients were admitted to the study with satisfaction and based on random allocation will be divided into two groups of intervention and control. For each group, questionnaires were completed at regular intervals and 60 interventions, one minute daily will be done at home for 6 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with COVID-19 and under 75 years of age. No history for other chronic diseases such as heart, orthopedic and motor disorders, diabetes, multiple sclerosis and cancer that interfere with the rehabilitation program. Exclusion criteria: asthma and any underlying lung disease are neuromuscular diseases that affect lung function.

##### Intervention groups

1-Pulmonary rehabilitation group; 2- Control group. In the pulmonary rehabilitation group, the patient will be asked to perform 3 sessions per week, 60 minutes per session including (warm-up, aerobic exercise, strength training, balance training and cooling) for 6 weeks after discharge from the hospital according to the program protocol. Control group: this group will perform their usual treatments according to the doctor's instructions. Pulmonary rehabilitation will not be performed in these people for 6 weeks.

##### Main outcome variables

Assess the severity of shortness of breath during daily activities

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191125045496N3**

Registration date: **2021-01-25, 1399/11/06**

Registration timing: **retrospective**

Last update: **2021-01-25, 1399/11/06**

Update count: **0**

##### Registration date

2021-01-25, 1399/11/06

##### Registrant information

##### Name

Mostafa Behzad Khamslo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3310 9230

##### Email address

mostafabehzadkh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-09-21, 1399/06/31

##### Actual recruitment start date

2020-04-29, 1399/02/10

##### Actual recruitment end date

2020-09-15, 1399/06/25

##### Trial completion date

2020-10-01, 1399/07/10

##### Scientific title

The Effect of Pulmonary Rehabilitation on Depression, Anxiety, Fatigue and Quality of Life in COVID-19 Patients with one-month Follow-up

#### Public title

Evaluation of the Effect of Pulmonary Rehabilitation in COVID-19 Patients

#### Purpose

Health service research

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

COVID-19 Patients aged 35 to 75 years old No history of chronic diseases such as heart, orthopedic and motor disorders, diabetes, multiple sclerosis and cancer that interfere with the rehabilitation program The ability to use the technology or caregiver that made it possible for him to be quarantined

##### Exclusion criteria:

Asthma and any underlying lung disease are neuromuscular diseases that affect lung function. Lack of patient cooperation and lack of motivation Taking antidepressants and anti-anxiety drugs two months before the intervention

#### Age

From **35 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **40**

Actual sample size reached: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization method was performed based on random permutation blocks with 4 samples in each block and a random list of data was obtained using Random Allocation software.

#### 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 Mazandaran University of Medical Sciences

#### Street address

Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem Square

#### City

Sari

#### Province

Mazandaran

#### Postal code

4817875816

#### Approval date

2020-05-13, 1399/02/24

#### Ethics committee reference number

IR.MAZUMS..REC.1399.7588

### Health conditions studied

#### 1

##### Description of health condition studied

COVID-19

##### ICD-10 code

U07.1

##### ICD-10 code description

COVID-19, virus identified

### Primary outcomes

#### 1

##### Description

Quality of Life

##### Timepoint

At baseline (before intervention) and 6 weeks after intervention

##### Method of measurement

Short Form Quality of Life Questionnaire (SF-36)

#### 2

##### Description

Anxiety and Depression scale

##### Timepoint

At baseline (before intervention) and 6 weeks after intervention

##### Method of measurement

Hospital Anxiety Depression scale (HADS)

#### 3

##### Description

Fatigue scale

##### Timepoint

At baseline (before intervention) and 6 weeks after intervention

##### Method of measurement

Osmens Multidimensional Fatigue Inventory Questionnaire

### Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Pulmonary Rehabilitation Group: For this group, 3 training sessions and each session for 60 minutes of pulmonary rehabilitation program will be given face to face and individually. At the end of the third session, an educational illustrated booklet containing the educational content will be provided to patients and the patient After discharge from the hospital, they will be required to perform 3 sessions per week, each session lasting 60 minutes (warm-up, aerobic exercise, strength training, balance training, and cooling) for 6 weeks.

#### Category

Rehabilitation

### 2

#### Description

Control group: This group will perform their usual treatments according to the doctor's instructions. Pulmonary rehabilitation will not be performed in these people for 6 weeks.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital Sari

##### Full name of responsible person

Mostafa Behzad Khamslo

##### Street address

Imam Khomeini Hospital., Amir Boulevard., Sari Town

##### City

Sari

##### Province

Mazandaran

##### Postal code

4817875816

##### Phone

+98 11 3310 9231

##### Email

mostafabehzadkh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr. Majid Saiedi

##### Street address

Vice chancellor for research, Moallem Square,

Mazandaran University of Medical Sciences, Sari,  
Mazandaran, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Phone

+98 11 3448 4854

##### Fax

##### Email

pajoheshi@mazums.ac.ir

##### Web page address

<https://pajoheshi.mazums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Vice chancellor for research, Mazandaran University of  
Medical Sciences

#### Proportion provided by this source

20

#### 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Seyed Hamzeh Hosseini

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Psychiatrics

##### Street address

Imam Khomeini Hospital., Amir Mazandaran St., Sari  
Town

##### City

Sari

##### Province

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##### Postal code

4817875816

##### Phone

+98 11 3310 9231

##### Email

hosseinish20@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mostafa Behzad Khamslo

**Position**

Teaching

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

**Street address**

7 km of sea road, Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4817875816

**Phone**

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**Email**

mostafabehzadkh@yahoo.com

## Person responsible for updating data

### Contact

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Mazandaran University of Medical Sciences

**Full name of responsible person**

Mostafa Behzad Khamslo

**Position**

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**Latest degree**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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