

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 Khamislo

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

Mazandaran

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

+98 11 3310 9230

Email

mostafabehzadkh@yahoo.com

Person responsible for updating data

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

+98 11 3310 9230

Email

mostafabehzadkh@yahoo.com

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