

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Telerehabilitation on Pulmonary Functions in Discharged Patients with Covid-19; A Single-Blind Parallel-Randomized Controlled Trial

Protocol summary

Study aim

This study aims to evaluate the efficacy of pulmonary telerehabilitation vs. rehabilitation in patients with Covid-19.

Design

This study is a single-blind, two-armed parallel randomized controlled trial in which participants would be blinded.

Settings and conduct

The pulmonary telerehabilitation program will perform through WhatsApp (video call) platform. This program includes 2 sessions of one hour per week of pulmonary exercises, such as diaphragmatic breathing exercises, and hand massages. The third week after the intervention, pulmonary outcomes will be assessed. Regarding the control group, the same program will be performed for patients with Covid-19 who are candidates for the rehabilitation program. Onsite rehabilitation programs will be held at the physical medicine and rehabilitation research center, Shohadaye Tajrish Hospital, Tehran, Iran.

Participants/Inclusion and exclusion criteria

Inclusion: 1- Patients who were diagnosed with Covid-19 and discharged from the hospital. 2- Patients aged between 18 to 80 years. Exclusion: 1- Patients who are unwilling to continue their participation in the study. 2- Having chronic diseases. 3- Patients who have participated in any rehabilitation programs during the study.

Intervention groups

Patients in the intervention group will receive a telerehabilitation program through 2 sessions per week. on the other hand, patients enrolled in the control group will receive the onsite rehabilitation program, as same as the intervention group.

Main outcome variables

O2 saturation, the 36-Item Short Form Survey (SF-36),

Borg scale, and Heart rate before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220103053609N1**

Registration date: **2022-02-19, 1400/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-19, 1400/11/30**

Update count: **0**

Registration date

2022-02-19, 1400/11/30

Registrant information

Name

Mahsa Ghorbanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2219 6207

Email address

mahsaghorbanzadeh1992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of Telerehabilitation on Pulmonary Functions in Discharged Patients with Covid-19; A Single-Blind Parallel-Randomized Controlled Trial

Public title
Efficacy of Pulmonary Telerehabilitation in Patients with Covid-19

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
1- Patients who were diagnosed with Covid-19 and discharged from the hospital. 2- Patients who are desired to participate in the study. 3- Patients aged between 18 to 80 years. 4- Having accessibility to the Internet.
Exclusion criteria:
1- Patients who are unwilling to continue their participation in the study. 2- Having chronic diseases, such as pulmonary disease, kidney diseases, neurologic disease, high blood pressure, uncontrolled heart disease, rheumatic diseases, cognitive disorders and psychological problems, and musculoskeletal disease. 3. Patients who have undergone any physiotherapy. 4. Patients who have participated in any rehabilitation programs during the study.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this clinical trial study, 60 patients with a previous diagnosis of Covid-19 and discharged from the hospital randomly will be included in the study. For random allocation of individuals in the study groups (intervention or intervention group and comparison or comparison group), the method of random allocation with block method (Block Randomization) will be used. In this method, blocks with size of six (including three people in the intervention group and three people in the comparison group) with a ratio of 1: 1 will be used. Random Allocation software will be used to generate random sequences. For concealment, the random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified on the cards and these cards are placed inside the sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered

envelopes will be placed in a folder. Then, according to the order of entry of the eligible participants, the envelopes will be opened and the assigned group of the participant will be determined.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single blinded and blinding is done only on the analyzer without knowledge about two groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Tehran, Ghods Town (West), between South Flamek and Zarafshan, Iran TV St. - Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor
City
Tehran
Province
Tehran
Postal code
1998845739
Approval date
2021-07-14, 1400/04/23
Ethics committee reference number
IR.SBMU.MSP.REC.1400.215

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
Quality of life based on SF-36 score
Timepoint
Just before rehabilitation and 3 weeks later

Method of measurement

SF-36 questionnaire, Clinical Assessment, finger O2 Saturation monitor

Secondary outcomes

1

Description

Heart rate checked by pulse oxymeter

Timepoint

Just before intervention and 3 weeks later

Method of measurement

by pulse oxymeter

2

Description

Severity of dyspnea based on borge scale

Timepoint

Just before rehabilitation and 3 weeks later

Method of measurement

Borge scale

3

Description

Blood oxygen saturation checked by pulse oxymeter

Timepoint

Just before rehabilitation and 3 weeks later

Method of measurement

Puls oxymeter

Intervention groups

1

Description

Intervention group: Pulmonary telerehabilitation will be done through communication via video call with the help of WhatsApp program. In each session, about ten types of breathing exercises (for example, diaphragmatic breathing exercises, hand massage, rib breathing, etc.) are taught to the patient and then performed under the supervision of the therapist. This program is done for two weeks and one hour session every week and all these exercises are done daily by the patient until the end of third week, which is the time of the final follow-up.

Category

Rehabilitation

2

Description

Control group: Pulmonary rehabilitation will be done in rehabilitation center of Shohada Tajrish Hospital. In each session, about ten types of breathing exercises (for example, diaphragmatic breathing exercises, hand massage, rib breathing, etc.) are taught to the patient and then performed under the supervision of the therapist. This program is done for two weeks and one hour session every week and all these exercises are

done daily by the patient until the end of third week, which is the time of the final follow-up.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih daneshvari hospital

Full name of responsible person

Mahsa ghorbanzadeh

Street address

Unit 5, No 10, eastern Nazaru alley, Sadaf St, Weastern Sarv St, Saadatabad

City

Tehran

Province

Tehran

Postal code

1998845739

Phone

+98 21 2219 4207

Email

Mahsaghorbanzadeh1992@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President for Research and Technology

Street address

Unit 5, No 10, eastern nazari alley, Sadaf St, western sarv St, Saadat Abad

City

Tehran

Province

Tehran

Postal code

1998845739

Phone

+98 912 484 8648

Email

Mahsaghorbanzadeh1992@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahsa ghorbanzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Unit 5, No 5, eastern Nazari alley, Sadaf St, western Sarv St, Saadatabad
City
Tehran
Province
Tehran
Postal code
1998845739
Phone
+98 21 2219 4207
Email
Mahsaghorbanzadeh1992@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahsa ghorbanzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Unit 5, No 10, eastern Nazari alley, Sadaf St, western Sarv St, Saadatabad
City
Tehran
Province
Tehran
Postal code
1998845739
Phone
+98 21 2219 6207
Email
Mahsaghorbanzadeh1992@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahsa ghorbanzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Unit 5, No 10, eastern nazari alley, Sadaf St, western sarv St, Saadat Abad
City
Tehran
Province
Tehran
Postal code
198845739
Phone
+98 21 2219 6207
Email
Mahsaghorbanzadeh1992@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient data can be shared through files after identifying them.

When the data will become available and for how long

Access period 1 month after printing the results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Any use to help advance science is unrestricted.

From where data/document is obtainable

Email address to mahsa ghorbanzadeh
Mahsaghorbanzadeh1992@gmail.com

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

After sending an email to request, they can access the information within a month.

Comments

