Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 randomely 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 siza 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 weaks later
Method of measurement
by pulse oxymeter

2

Description
Severity of dyspnea based on borge scale
Timepoint
Just before rehabilitation and 3 weaks later
Method of measurement
Borge scale

3

Description
Blood oxygen saturation checked by pulse oxymeter
Timepoint
Just before rehabilitation and 3 weaks 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

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Phone

+98 21 2219 4207

Email

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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

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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

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Other areas of specialty/work

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Postal code

198845739

Phone

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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