

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect of pulmonary tele-rehabilitation with and without progressive muscle relaxation training on exercise capacity, anxiety and depression in COVID-19 patients after hospital discharge: a randomized clinical trial

Protocol summary

Study aim

The effect of pulmonary rehabilitation with progressive muscle relaxation exercise on patient suffering from COVID-19 after hospital discharge

Design

Clinical trial with control group, two parallel groups, double blind, randomized, phase three, among 52 participants, permuted block randomization method will be used for random allocation. (trial phase dose not apply for this study)

Settings and conduct

Study place: Internal ward of Shahid Beheshti Hospital in Qom. Blinding: double blind (participants and assessor blindness), Evaluator and patients in the study will be blinded during the entire process. The evaluator will be unaware of the study objectives and the randomized distribution of patients to study groups and will not have access to the randomization sequence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 confirmed with PCR test and discharged from hospital (at least six days after the onset of symptoms); patients who have the ability read and write in Persian and access to the Internet and video call service. Exclusion criteria: Severe heart condition such as uncontrolled arrhythmias, Chronic pulmonary and kidney condition, severe neurological condition, uncontrolled diabetes or hypertension; Smoker; Athlete; pregnant women

Intervention groups

In the intervention group, pulmonary telerehabilitation will be received with progressive muscle relaxation exercises. Pulmonary rehabilitation includes breathing exercises, aerobic and resistance exercises. The relaxation exercise is based on Jacobsen's summarized method. The active control group receives only pulmonary telerehabilitation. The duration of the

intervention in each group is six weeks and the exercises are supervised by the physiotherapist through video call twice a week.

Main outcome variables

Exercise capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140810018754N12**

Registration date: **2021-03-15, 1399/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-15, 1399/12/25**

Update count: **0**

Registration date

2021-03-15, 1399/12/25

Registrant information

Name

Javad Sarrafzadeh

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-08, 1399/11/20

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of pulmonary tele-rehabilitation with and without progressive muscle relaxation training on exercise capacity, anxiety and depression in COVID-19 patients after hospital discharge: a randomized clinical trial

Public title

Effect of pulmonary tele-rehabilitation and progressive muscle relaxation training in COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

COVID-19 confirmed with polymerase chain reaction test (PCR) Discharged from hospital (at least six days after the onset of symptoms) Patients who have to the ability to read and write in Persian Patients who access to the Internet and video call service

Exclusion criteria:

Severe heart condition such as uncontrolled arrhythmias Chronic pulmonary and kidney condition Severe neurological condition such as guillan-barre, stroke and multiple sclerosis Uncontrolled diabetes or hypertension Smoker Athlete Pregnant women

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation is done by permuted block randomization method. The size of the blocks is twice the number of groups (four). The intervention group will be considered as A and the control group as B. We will have six blocks [AABB], [BBAA], [BABA], [ABAB], [BAAB] and [ABBA], numbered from one to six. Fourteen random numbers is needed to put the blocks together based on the sample size and the size of the blocks. Google random number generation will be used to get 14 random numbers (from one to six) and put the blocks together.

Blinding (investigator's opinion)

Double blinded

Blinding description

Evaluator and patients in the study will be blinded during the entire process. The evaluator will be unaware of the study objectives and the randomized distribution of patients to study groups and will not have access to the randomization sequence.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

5th floor, Iran University of Medical Sciences, Hemmat highway, between Sheikh Fazlollah Nuri and Chamran highways, Tehran

City

Tehran

Province

Tehran

Postal code

1449615435

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

IR.IUMS.REC.1399.1119

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**

exercise capacity

Timepoint

before intervention, up to two and six week after intervention

Method of measurement

Six minute walk test

Secondary outcomes

1

Description

Dyspnea

Timepoint

Before intervention, up to two and six week after start of intervention

Method of measurement

0-10 dyspnea Borg scale

2

Description

Axiety

Timepoint

Before intervention and six weeks after start of intervention

Method of measurement

Hospital anxiety and depression scale

3

Description

Sleep quality

Timepoint

Before intervention, six weeks after start of intervention

Method of measurement

Petersborg sleep quality questionnaire

4

Description

Quality of life

Timepoint

Before intervention, six weeks after start of intervention

Method of measurement

SF36, santgeorg respiratory questionnaire

5

Description

fatigue severity

Timepoint

Before intervention, six weeks after start of intervention

Method of measurement

fatigue severity scale

6

Description

exercise capacity

Timepoint

Before intervention, six weeks after start of intervention

Method of measurement

repeated chair rise test during 30 seconds

7

Description

depression

Timepoint

Before intervention and six weeks after start of intervention

Method of measurement

Hospital anxiety and depression scale

Intervention groups

1

Description

Intervention group: pulmonary telerehabilitation with progressive muscle relaxation exercise. pulmonary rehabilitation includes breathing exercises, aerobic and resistance exercises. The relaxation exercise is based on Jacobsen's summarized method. The duration of the intervention is six weeks and the exercises are supervised by the physiotherapist through video call twice a week.

Category

Rehabilitation

2

Description

Control group: pulmonary telerehabilitation includes breathing exercises, aerobic and resistance exercises. The duration of the intervention is six weeks and the exercises are supervised by the physiotherapist through video call twice a week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital affiliated to Qom University of Medical Sciences

Full name of responsible person

Mohammadreza Ghadir

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Shahid Beheshti educational and Medical Complex;
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Sponsors / Funding sources

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malakouti, Vice chancellor for research

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Web page address

http://vcr.iums.ac.

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Javad Sarrafzadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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 data or results of the present study will be presented in an article or some articles that will be published, also will be available through correspondence with the corresponding author.

When the data will become available and for how long

After completing the present study and publishing the resulting article or articles

To whom data/document is available

All researchers in the field of the present study

Under which criteria data/document could be used

With the same goal as the present study and with mention of the present study as the reference. All intellectual property rights of the present study belongs to the Iran University of Medical Sciences.

From where data/document is obtainable

The corresponding author of the article or articles derived from this study

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

Written request from the author responsible for the present review after the publication of the resulting article or articles

Comments