# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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 recived 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 questionaire

**4**

**Description**
Quality of life
**Timepoint**
Before intervention, six weeks after start of intervention
**Method of measurement**
SF36, santgeorg respiratory questionaire

**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 telerehabilition 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**
Çontrol 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
**Street address**
Shahid Beheshti educational and Medical Complex; Shahid Beheshti Blvd
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## Sponsors / Funding sources

**1**

**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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Vice Chancellor for Research and Technology, 5 th floor, the central building, Iran University of Medical Sciences, between Sheikh Fazlollah nuri and Chamran highway, Hemmat highway, Tehran

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**Phone**
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**Email**
research@iums.ac.ir

**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**
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**Position**
Professor

**Latest degree**
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Physiotherapy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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 avialable 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**