Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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

Street address
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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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 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