Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The impact of respiratory Tele-rehabilitation on pulmonary function and quality of life in patient with COVID-19

Protocol summary

Study aim
Determine of the impact of respiratory Tele-rehabilitation on pulmonary function and quality of life in patient with COVID 19

Design
Clinical trial with control group, double-blind, randomized on 60 patients. The randomization site will be used for randomization.

Settings and conduct
The covid-19 wards of Imam Reza Hospital were selected as the sampling location. 60 patients will enter to study with consent and based on random allocation will be divided into two groups of intervention and control. For each group, questionnaires will compelet at regular intervals and interventions will be done during 4 weeks in home of patient via sky room software, daily in 30 minutes sections.

Participants/Inclusion and exclusion criteria
Willingness to participate in study, acceptable visual, auditory and alertness. Ability to understand and speak Persian. Having online communication facilities such as convenient internet and one of the communication devices such as laptop, tablet or smartphone. Ability to use online technology or caregiver to access it during quarantine. Patients who have been diagnosed with covid 19 and have a lung lesion based on the results of CXR or CT scan with the approval of an infectious disease specialist. Discharge after treatment. Social isolation. Having a cardiac echo at the time of admission that indicates heart health. Age between 18 and 80 years

Intervention groups
Intervention group: The intervention as respiratory tele-rehabilitation will be performed as a video conferencing program for 30 minutes daily for 4 weeks. Control group: In this group, patients will receive only routine discharge training and rehabilitation training pamphlet and motivational spirometry, and will be followed up daily by telephone.

Main outcome variables
Pulmonary function; Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200711048077N1**
Registration date: **2020-11-16, 1399/08/26**
Registration timing: **prospective**

Last update: **2020-11-16, 1399/08/26**
Update count: **0**

Registration date
2020-11-16, 1399/08/26

Registrant information

Name
Fateme Rangani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3864 3672

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The impact of respiratory Tele-rehabilitation on pulmonary function and quality of life in patient with COVID-19

Public title
Evaluation of respiratory Tele-rehabilitation in patient with COVID-19

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Acceptable visual, auditory and alertness to participate in study Ability to understand and speak Persian Having online communication facilities such as internet and one of the smart devices such as laptop, tablet or smartphone. Ability to use online technology or caregiver to access it during quarantine. Patients who have been diagnosed with covid 19 and have a lung lesion based on the results of a CXR or CT scan with the approval of an infectious disease specialist Discharge after treatment Observance of social isolation Having a cardiac echo at the time of admission that indicates heart health

Exclusion criteria:
Having deformity in the chest mental disorder Any severe illness that impairs the movement of patients such as severe heart disease, severe musculoskeletal pain, vascular aneurysms, severe neurological diseases Pregnancy vestibular disorders

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of study will done by generating a random sequence with randomization.com for each research unit in two groups alternatively. The envelope method in the package is used to hide the random sequence. In this way, a random sequence is written on small cards as code A or B and is kept in a closed envelope. Whenever a research unit is found to meet the inclusion criteria, it is opened in an envelope and entered the group based on the first card. Becomes relevant. This will continue until the required number of research units are assigned to both groups

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will be informed that generally there will be two different groups in the study, in one different pulmonary rehabilitation exercises will be performed online and in the other one pulmonary rehabilitation training will be given via pamphlet. Patients are then informed that they will be randomly assigned to one of two groups. The data collected from both groups will be provided to the data analyzer without specifying which control or test group it belongs to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of mashhad university of medical sciences

Street address
No. 10, Hafte-e-Tir 5, Hafte-e-Tir Blvd, Vakil abad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9178846674

Approval date
2020-09-15, 1399/06/25

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.052

Health conditions studied

1

Description of health condition studied
Coronavirus 2019

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Quality of life score in SF-36 questionnaire

Timepoint
At the beginning of the study (before the intervention) and at the end of the second week and at the end of the fourth week after the intervention

Method of measurement
SF-36 questionnaire

2

Description
Pulmonary function
Timepoint
At the beginning of the study (before the intervention) and at the end of the second week and at the end of the fourth week after the intervention
Method of measurement
By examining the six-minute walk test and measuring the maximum inspiratory pressure (MIP) and the percentage of blood oxygen saturation (SPO2)

Secondary outcomes

1

Description
six-minute walking test (6mwt)
Timepoint
At the beginning of the study (before the intervention) and at the end of the second week and at the end of the fourth week after the intervention
Method of measurement
The patient walks a 30-meter flat path in six minutes and the distance is measured.

2

Description
Maximum inspiratory pressure (MIP)
Timepoint
At the beginning of the study (before the intervention) and at the end of the second week and at the end of the fourth week after the intervention
Method of measurement
En IMT K1 POWER BREATH device

3

Description
peripheral capillary oxygen saturation
Timepoint
At the beginning of the study (before the intervention) and at the end of the second week and at the end of the fourth week after the intervention
Method of measurement
Pulse Oximeter

4

Description
Fatigue and dyspnea score
Timepoint
At the beginning of the study (before the intervention) and at the end of the second week and at the end of the fourth week after the intervention
Method of measurement
Borg scale 6-20

Intervention groups

1

Description
Intervention group: For four weeks, every day for 30 minutes once a day for two set with 10 minutes of rest and hydration. The program includes one-minute diaphragmatic breathing exercises, 5-minute incentive spirometry exercises, 30-second sit to stand squats, 30-second standing marching, 30-second seated arm reaches, 30-second standing heel raises, 30-second sidestepping, 30- second Wall pushups. Individuals practice in groups of five on the Skyroom platform. Every day after training, the amount of fatigue and dyspenea based on the BORG scale, the number of exercises performed and problems during training in a special checklist for each The person is registered.
Category
Other

2

Description
The usual training is done during discharge. They are given a training pamphlet on encouraging respiratory rehabilitation and spirometry exercises. Their condition is monitored daily by telephone. They are asked to record fatigue and shortness of breath and the number of exercises in the checklist.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Ali khorsand vakilzadeh
Street address
Emam reya hospital Square, Ebn-e-sina Ave, Daneshgah Ave
City
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Razavi Khorasan
Postal code
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Email
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https://emamreza.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Ghorashi Building, next to Hoveyzeh Cinema, Daneshgah Ave

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Razavi Khorasan

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9138813944

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vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Fateme Rangani

Position
Master student

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

Full name of responsible person
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Position
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Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
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Latest degree
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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

In this study, all participants' data (demographic information, pulmonary function factors and questionnaire scores) will be available after being identified.

When the data will become available and for how long

Access period starts 3 months after the results are published.

To whom data/document is available

Researcher working in academic institutions

Under which criteria data/document could be used

Academic researchers will be able to submit requests for data, and all quantitative and qualitative inferential and analytical analyzes of the data will be allowed.

From where data/document is obtainable

Fatemeh Rangani. Ranganif981@mums.ac.ir

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

The applicant must write a formal application to the corresponding author, announcing his/her application. After approval and coordination with the Vice Chancellor for Research, the study data will be sent to the applicant formally and confidentially.

Comments