Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effectiveness of pulmonary rehabilitation in the rehabilitation center in comparison with tele rehabilitation on the prognosis of patients with Covid-19

Protocol summary

Study aim
Comparison of the average activities of daily living, the average quality of life, the findings of the 6MWT and Barthel Index before and after the intervention in the intervention and control groups.

Design
Clinical trial with control group, with parallel groups, randomized, on 52 patients. Data analysis is done using SPSS version 25 software.

Settings and conduct
A questionnaire including demographic information, quality of life, stress and depression and Barthel index is given to each patient. Then the patients are placed in one of the two groups of pulmonary rehabilitation in the rehabilitation center or tele rehabilitation. Patients in the first group are treated with a course of respiratory physiotherapy by visiting the rehabilitation center, and patients in the second group are treated with a respiratory physiotherapy program that is given to them in the form of a brochure. Patients are evaluated before the beginning of pulmonary rehabilitation and then 1 month and 3 months after rehabilitation. No blinding done.

Participants/Inclusion and exclusion criteria
Inclusion criteria : 1. Patients with a definite diagnosis of covid19 2. Age > 30 and < 60 years Exclusion criteria : underlying lung disease, neuromuscular diseases, heart disease

Intervention groups
The intervention group includes patients with covid-19 who receive respiratory rehabilitation intervention in the rehabilitation center. The comparison group includes patients with covid-19 who receive remote respiratory rehabilitation intervention.

Main outcome variables
Quality of life questionnaire score; Activities of daily living questionnaire score; Hospital anxiety and depression scale score; Bartel index score; The amount of distance traveled in the 6-minute walking test based on meters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220723055525N1**
Registration date: **2022-09-07, 1401/06/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-07, 1401/06/16**
Update count: **0**

Registration date
2022-09-07, 1401/06/16

Registrant information
Name
soheila shahbaz
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-29, 1401/05/07

Expected recruitment end date
2023-04-20, 1402/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of pulmonary rehabilitation in the rehabilitation center in comparison with tele rehabilitation on the prognosis of patients with Covid-19

Public title
Evaluation of the effectiveness of pulmonary rehabilitation on the prognosis of patients with Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with difinit diagnosis of COVID-19 according to PCR Age between 30 to 60 years Having symptoms of cough and dyspnea Moderate to severe pulmonary involvement according to CT scan (less than 50% pulmonary involvement according to CT scan) 3 weeks after positive PCR test No COPD disease No cardiac disease
Exclusion criteria:
COPD, asthma and any underlying lung disease Neuromuscular diseases that affect lung function History of ischemic heart disease, congestive heart failure and uncontrolled blood pressure Asymptomatic carriers Severe comorbidity Unwillingness to participate in the study Lack of access to the Internet and virtual programs
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization tool is version 2 of the Random Allocation software. Using the software, the order of the random chain is determined, and then the patients of the intervention and control groups are entered into the chain based on the order obtained through the software. For example, first blocks of 8 are prepared, each block of 8 includes 4 patients for the control group and 4 patients for the intervention group. In one block, the first four patients may be placed in the control group and the next four patients in the intervention group, and in another block, the patients may be divided one by one.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Artesh University of Medical Sciences
Street address
Imam Reza hospital, Etemad zade Ave, Fatemi Street, Amirabad
City
tehran
Province
Tehran
Postal code
1854614117
Approval date
2022-06-22, 1401/04/01
Ethics committee reference number
IR.AJAUMS.REC.1401.043

Health conditions studied

1

Description of health condition studied
Corona disease
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
quality of life
Timepoint
Before starting pulmonary rehabilitation and then 1 month and 3 months after rehabilitation
Method of measurement
Quality of life questionnaire

2

Description
activities of daily living
Timepoint
Before starting pulmonary rehabilitation and then 1 month and 3 months after rehabilitation
Method of measurement
Daily activity questionnaire

3

Description
psychological status in terms of anxiety and depression
Timepoint
Before starting pulmonary rehabilitation and then 1 month and 3 months after rehabilitation
Method of measurement
Hospital anxiety and depression scale

4

Description
Barthel index
Timepoint
Before starting pulmonary rehabilitation and then 1 month and 3 months after rehabilitation
Method of measurement
Barthel questionnaire

5

Description
6 minute walking test
Timepoint
Before starting pulmonary rehabilitation and then 1 month and 3 months after rehabilitation
Method of measurement
6 minute walking test results

Secondary outcomes

1

Description
Pulse rate
Timepoint
Before starting pulmonary rehabilitation and then 1 month and 3 months after rehabilitation
Method of measurement
Pulse oximeter device

2

Description
Oxygen saturation percentage
Timepoint
Before starting pulmonary rehabilitation and then 1 month and 3 months after rehabilitation
Method of measurement
Pulse oximeter device

Intervention groups

1

Description
Intervention group: Patients in the first group are treated with a course of respiratory muscle physiotherapy by visiting the rehabilitation center. These measures are performed on the day of the patient's visit and then repeated 1 month and 3 months later in 15-minute sessions. In this treatment method, strengthening of respiratory muscles is taught by performing movements. Equipment or medicine is not used during these sessions.
Category
Rehabilitation

2

Description
Control group: The patients of the second group are treated with a 15-minute respiratory physiotherapy program, which is taught how to do it by a brochure, and they are followed up on the day of referral, and then 1 month later and 3 months later in terms of home training. In this treatment method, strengthening of respiratory muscles is taught by performing movements. No equipment or medicine is used in this method.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Physical Medicine in Artesh Medical Sciences Hospital
Full name of responsible person
Soheila shahbaz
Street address
Imam Reza hospital, Etemad zade Ave, Fatemi Street, Amirabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Reza Mosaed
Street address
Imam Reza hospital, Etemad zade Ave, Fatemi Street, Amirabad
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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

soheila shahbaz

Position

Resident of physical medicine and rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Soheila

Position

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Person responsible for updating data

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Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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