Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Using of Pulmonary Rehabilitation at Home on Pulmonary Function, anxiety and depression in Patients with Covid 19

Protocol summary

Study aim
Determining the effect of Using of Pulmonary Rehabilitation at Home on Pulmonary Function, anxiety and depression in Patients with Covid 19 In Afzalipoor Hospital

Design
A clinical trial with 70 patients with Covid will be performed by simple random allocation using sealed and numbered envelopes, equally in the control and intervention groups.

Settings and conduct
Eligible patients in Afzalipour Hospital are divided into control and intervention groups. The control group will receive routine care. The intervention group will receive a pulmonary rehabilitation program.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with a history of non-invasive ventilation, having minimum literacy of reading and writing and having a caregiver at home. Non-Inclusion criteria: Having a motor or orthopedic disease, have a history of known mental illness or taking drugs that affect the psyche or any other chronic illness (including Chronic respiratory diseases, kidney, thyroid, cancer, and of drug addiction), have a history of severe physical illness (such as a pacemaker, left and right heart failure, uncontrolled hypertension, and patients with Deep Vein Thrombosis and Pneumo Thrombo Embolism), have a history of heart or chest surgery, the patient is a professional athlete, having Saturation of Peripheral Oxygen less than 90% at the time of discharge, patients with hypoxia with little activity and their heart rate exceed 120, A history of stressful events such as the deaths of first-degree relatives in the past six months and the inability to make telephone calls after the patient is discharged.

Intervention groups
Patients in the control group receive routine care. Patients in the intervention group receive a pulmonary rehabilitation program for 4 weeks

Main outcome variables
Spirometric indicators, anxiety and depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190702044074N1**
Registration date: **2021-08-04, 1400/05/13**
Registration timing: **prospective**

Last update: **2021-08-04, 1400/05/13**
Update count: **0**

Registration date
2021-08-04, 1400/05/13

Registrant information

Name
Fahime Hahsemi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3610 8307
Email address
hashemifh961@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-16, 1400/05/25

Expected recruitment end date
2021-11-06, 1400/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Using of Pulmonary Rehabilitation at Home on Pulmonary Function, anxiety and depression in Patients with Covid 19

Public title
The Effect of Using of Pulmonary Rehabilitation at Home on Pulmonary Function, anxiety and depression in Patients with Covid 19

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a history of non-invasive ventilation Have a minimum literacy of reading and writing Having a caregiver at home
Exclusion criteria:
Having a motor or orthopedic disease Have a history of known mental illness or taking drugs that affect the psyche or any other chronic illness (including Chronic respiratory diseases, kidney, thyroid, cancer, and of drug addiction) Have a history of severe physical illness (such as a pacemaker, left and right heart failure, uncontrolled hypertension, and patients with Deep Vein Thrombosis and Pneumo Thrombo Embolism) Have a history of heart or chest surgery The patient is a professional athlete. Having Saturation of Peripheral Oxygen less than 90% at the time of discharge. Patients with hypoxia with little activity and their heart rate exceed 120. A history of stressful events such as the deaths of first-degree relatives in the past six months. The inability to make telephone calls after the patient is discharged.

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients with Crohn's disease admitted to Afzalipour Hospital in Kerman, based on admission and discharge criteria, voluntarily and with random allocation, are divided into two groups of intervention and control. For randomization, we use the simple random allocation method using sealed and numbered envelopes. To do this, we first prepare 70 perfectly uniform envelopes and 70 sheets of white paper. We write the control group on 35 sheets of paper and the intervention group on the other 35 sheets. Then we put the sheets of paper inside the envelope so that they are not visible from the outside. Thoroughly mix the envelopes and then number them from 1 to 70 and put them in a regular box from 1 to 70. For each patient who volunteers to enter the study and has the inclusion criteria, we select an envelope from 1 to 70, respectively, and after opening the envelope, the group to which the patient belongs will be visible.

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 Kerman University of Medical Sciences

Street address
University of Medical Sciences, Haft Bagh Alavi Blvd, Kerman

City
kerman

Province
Kerman

Postal code
7616913555

Approval date
2021-06-15, 1400/03/25

Ethics committee reference number
IR.KMU.REC.1400.151

Health conditions studied

1

Description of health condition studied
Patients with Covid 19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Pulmonary Function

Timepoint
after intervention

Method of measurement
Spirometric index registration form

2

Description
Anxiety and depression score
Timepoint
Before intervention, after intervention
Method of measurement
Hospital Anxiety and Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Control group: At discharge, patients will be instructed that they will receive only routine post-discharge care for four weeks, and It will be emphasized that during this period, you should refrain from other treatments recommended by others, except those prescribed by your doctor.
Category
N/A

2

Description
Intervention group: At the time of discharge, the patients will be given a pulmonary rehabilitation program, which is collected as an educational pamphlet, and the patient will be instructed to perform the exercises in the presence of a family member. The entire respiratory rehabilitation program at home lasts 4 weeks, which includes; First 2 weeks (one day in between; one week even days - one week individual days, 2 sessions each day and each session for 10 minutes), Second 2 weeks (one day in between; one week even days - one week individual days, 2 sessions each day and each session for 15 minutes).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Fahime hashemi
Street address
No 5, Gelayol 7, Shahrak Afzalipour, Emam Reza Highroad, Kerman
City
Kerman
Province
Kerman
Postal code
7614914516
Phone
+98 51 3610 8307
Email
fahimehashemi0@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Abbas Pardakhti
Street address
University of Medical Sciences, Haft Bagh Blvd, kerman
City
Kerman
Province
Kerman
Postal code
761693555
Phone
+98 34 3132 5700
Email
Fahimehashemi0@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Fahime hashemi
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No 5, Gelayol 7, Shahrak Afzalipour, Emam Reza Highroad, Kerman

City
Kerman
Province
Kerman
Postal code
7614914516
Phone
+98 51 3610 8307
Email
Fahimehashemi0@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fahime hashemi
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No 5, Gelayol 7, Shahrak Afzalipour, Emam Reza Highroad, Kerman
City
Kerman
Province
Kerman
Postal code
7614914516
Phone
+98 51 3610 8307
Email
Fahimehahsemi0@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
fahime hashemi
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No 5, Gelayol 7, Shahrak Afzalipour, Emam Reza Highroad, Kerman
City
Kermak
Province
Kerman
Postal code
7614914516
Phone
+98 51 3610 8307
Email
fahimehashemi0@gmail.com

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 can be provided at the request of a specific person or organization
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
For all people
Under which criteria data/document could be used
It can be used after coordination with researchers and information about its use
From where data/document is obtainable
To the responsible author mentioned in the article
What processes are involved for a request to access data/document
Refer to the e-mail address of the responsible author in the research article
Comments