# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Jul 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)
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**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
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
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University of Medical Sciences, Haft Bagh Blvd, kerman
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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**
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
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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 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**