

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### evaluation the effect of virtual pulmonary rehabilitation on the outcome and quality of life of COVID 19 patients after recovery from the acute phase

#### Protocol summary

##### Study aim

To identify the effect of virtual pulmonary rehabilitation on the outcome and quality of life of COVID19 patients after recovery from the acute phase

##### Design

Clinical trial with control group, with parallel groups, randomized on 70 patients, for randomization, permutation blocks with 4 samples in each block using Random Allocation software was used.

##### Settings and conduct

Breathing exercises in the form of educational videos will be provided to the intervention group in a virtual way using the training site, and patients should do the exercises for 8 weeks 5 days a week, three times a day and three repetitions each time.

##### Participants/Inclusion and exclusion criteria

Definite diagnosis of covid 19 with PCR Hospitalization during the acute phase of the disease Lung involvement with a typical pattern of covid 19 in chest X ray or chest CT scan Being clinically stable Being able to understand and perform the virtual respiratory exercises as given to them in the study Age over 18 and less than 60 years

##### Intervention groups

Virtual pulmonary rehabilitation in the form of breathing exercise for intervention group

##### Main outcome variables

The perceived dyspnea severity during daily activities, The severity of dyspnea, General health-related quality of life, Psychological state and mood disorder

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200930048892N1**  
Registration date: **2020-10-18, 1399/07/27**

Registration timing: **prospective**

Last update: **2020-10-18, 1399/07/27**

Update count: **0**

##### Registration date

2020-10-18, 1399/07/27

##### Registrant information

###### Name

Fariba Erfani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 5383 8166

###### Email address

erfanif70@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-20, 1399/07/29

##### Expected recruitment end date

2021-02-17, 1399/11/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

evaluation the effect of virtual pulmonary rehabilitation on the outcome and quality of life of COVID 19 patients after recovery from the acute phase

##### Public title

evaluation the effect of virtual pulmonary rehabilitaion

on covid 19 patients

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Definite diagnosis of covid 19 with PCR Hospitalization during the acute phase of the disease Lung involvement with a typical pattern of covid 19 in chest X ray or chest CT scan Being clinically stable Being able to understand and perform the virtual respiratory exercises as given to them in the study Age > 18 and < 60 years

### Exclusion criteria:

COPD, asthma and any other respiratory disease Neuromuscular disorders that affect lung function History of ischemic heart disease, congestive heart failure and uncontrolled hypertension Asymptomatic carriers Sever comorbid conditions Disagree to participate in the study Lack of access to the internet and virtual applications

## Age

From **18 years** old to **60 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

Randomization method was performed based on random permutation blocks with 4 samples in each block and a random list of data was obtained using Random Allocation software. Independent T test and paired T test will be used for statistical analysis of the data. Blindness will be done for people who measure the outcomes and people who analyze the data

## 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 Shiraz University of Medical Sciences

##### Street address

Medical School. Imam Hossein Square.Zand Stree .Shiraz Cityt

## City

shiraz

## Province

Fars

## Postal code

7134845794

## Approval date

2020-10-02, 1399/07/11

## Ethics committee reference number

IR.SUMS.MED.REC.1399.364

## Health conditions studied

### 1

#### Description of health condition studied

COVID 19

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The perceived dyspnea severity during daily activities

#### Timepoint

Before intervention and 8 weeks after study

#### Method of measurement

Medical Research Council Scale

### 2

#### Description

The severity of dyspnea

#### Timepoint

Before intervention and 8 weeks after study

#### Method of measurement

Modified Borg Scale

### 3

#### Description

General health-related quality of life

#### Timepoint

Before intervention and 8 weeks after study

#### Method of measurement

Short-Form 36 (SF-36)

### 4

#### Description

psychological state and mood disorder

#### Timepoint

Before intervention and 8 weeks after study

#### Method of measurement

The Hospital Anxiety and Depression Scale (HADS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: virtual pulmonary rehabilitation in the form of breathing exercise

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Faghihi hospital

##### Full name of responsible person

Seyed Mohammad Kazem Tadayyon

##### Street address

Zand Blvd, Shiraz City

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3235 1087

##### Email

faghihihsp@sums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Ali Asghar hospital

##### Full name of responsible person

Parnian Nikmanesh

##### Street address

Meshkin fam street

##### City

Shiraz

##### Province

Fars

##### Postal code

7143918796

##### Phone

+98 71 3228 8907

##### Email

aliasghar@sums.ac.ir

### 3

#### Recruitment center

##### Name of recruitment center

Shahid Chamran hospital

##### Full name of responsible person

Seyed Rouhollah Mousavi

##### Street address

Chamran Blvd, Shiraz City

##### City

Shiraz

##### Province

Fars

##### Postal code

7194815644

##### Phone

+98 71 3624 0101

##### Email

chamhosp@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Abbas Rezaeian zade

##### Street address

Zand Blvd. Shiraz University of Science, Shiraz City

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

##### Phone

+98 71 3230 5410

##### Email

info@sums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Fariba Erfani

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Physical Medicine

**Street address**

No 16, Nasr Blvd, Taleghani Street , Neyriz

**City**

Neyriz

**Province**

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**Postal code**

7491944388

**Phone**

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**Email**

erfanif70@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fariba Erfani

**Position**

Resident

**Latest degree**

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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