

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of the breathing exercises on quality of life and symptoms of shortness of breath and fatigue in patients with Covid 19

#### Protocol summary

##### Study aim

Determining the effect of breathing exercises on quality of life and symptoms of shortness of breath and fatigue in patients with Covid-19

##### Design

A randomized controlled clinical trial with parallel, single-blind, randomized block-block groups on 72 patients

##### Settings and conduct

This study is a clinical trial that is performed after receiving the code of ethics and the clinical trial code. A list of all eligible individuals in the selected hospitals of the University of Tehran that have the highest admission of patients with Covid-19 will be prepared and randomized. Blocks are divided into two groups of control and intervention. Blinding will be done blindly by the samples.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include: (1) Patients with Covid-19 (2) Age 18 to 60 years (3) Having a mobile phone (4) Have symptoms of shortness of breath or fatigue or every two weeks after discharge from the hospital. Inclusion criteria include: (1) Hospitalized in ICU Covid-19 (2) Patients with moderate to severe heart failure (Grade III or IV, New York Heart Association) (3) COPD or other respiratory and infectious diseases

##### Intervention groups

During 6 weeks, do daily breathing exercises based on 6 sheets of functional checklist that explains how to do these exercises in the breathing exercise checklist and in the form of bud lip breathing 5 to 10 times each time, diaphragmatic breathing 5 times each time. Up to 15 in each session at home twice a day (morning and evening) for 42 days without interruption is sent to the intervention group after 2 weeks of discharge from the hospital, in addition to providing educational content by calling patients by The researcher also runs for 6 weeks.

##### Main outcome variables

Shortness of breath, fatigue, quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210717051910N1**

Registration date: **2021-07-30, 1400/05/08**

Registration timing: **prospective**

Last update: **2021-07-30, 1400/05/08**

Update count: **0**

##### Registration date

2021-07-30, 1400/05/08

##### Registrant information

##### Name

Golrokh Abdollahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7784 2192

##### Email address

abdolahygoiii@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-23, 1400/06/01

##### Expected recruitment end date

2021-09-22, 1400/06/31

##### Actual recruitment start date

2021-08-28, 1400/06/06

##### Actual recruitment end date

2021-09-28, 1400/07/06

##### Trial completion date

2022-01-21, 1400/11/01

##### Scientific title

Effect of the breathing exercises on quality of life and symptoms of shortness of breath and fatigue in patients with Covid 19

#### Public title

Effect of the breathing exercises on quality of life and symptoms of shortness of breath and fatigue in patients with Covid 19

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with COVID-19 with respiratory symptoms with radiological manifestations as one or two-way multilobular infiltration in CT scan or chest x-ray whose disease has been confirmed by nasal swap test (RT-PCR SARS-CoV-2) You have symptoms of shortness of breath or fatigue or every two weeks after discharge from the hospital. Having a mobile phone Ages 18 to 60

##### Exclusion criteria:

Hospitalized in ICU Covid-19 Patients with moderate to severe heart failure (grade III or IV, New York Heart Association) Having COPD or other respiratory and infectious diseases

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Data analyser

#### Sample size

Target sample size: **72**

Actual sample size reached: **72**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Using simple randomization method using random table of numbers, subjects will be divided into two groups of intervention and control. Randomization units are one of the patients referred to the Corona ward. Randomization tool is also a random table of numbers. The researcher puts numbers on one of the random table numbers and moves to the right and bottom. Records the numbers and assigns them to different study groups whose numbers are already specified.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The data collected from both groups will be provided to the data analyzer without specifying which control or esoterry groups were related.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Reserch Ethics Committees of school of nursing and midwifery & rehabilitation-Tehran University of M

##### Street address

School of Nursing and Midwifery, Nosrat St., Enghelab Square, Tehran University of Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

#### Approval date

2021-07-27, 1400/05/05

#### Ethics committee reference number

IR.TUMS.FNM.REC.1400.088

## Health conditions studied

### 1

#### Description of health condition studied

covid-19b

#### ICD-10 code

U07.2

#### ICD-10 code description

covid19, virus not identified

## Primary outcomes

### 1

#### Description

shortness of breath

#### Timepoint

Measurement of shortness of breath will be done before the intervention and 6 weeks after the intervention.

#### Method of measurement

Borg Shortness of breath

### 2

#### Description

Fatigue

#### Timepoint

Fatigue will be measured before the intervention and 6 weeks after the intervention.

#### Method of measurement

FSS Fatigue Intensity Scale

### 3

#### Description

Quality of life

#### **Timepoint**

Quality of life will be measured before the intervention and 6 weeks after the intervention.

#### **Method of measurement**

Quality of Life Questionnaire SF-36

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: During 6 weeks, after sending the video and training brochure of breathing exercises as well as checklists that show how to do breathing exercises which are explained in the checklist of breathing exercises and breathing in the form of bud lip 5 to 10 times each time, breathing The diaphragm is 5 to 15 times per session at home twice a day (morning and evening) for 42 days without interruption. It is sent to the intervention group after 2 weeks of discharge from the hospital, in addition to providing educational content to In the intervention group, telephone calls to patients are made by the researcher for 6 weeks. In this way, telephone calls are made twice a week in the first 4 weeks and once a week in the second 2 weeks with the intervention group. The time of the conversation is between 10-12 in the morning and the duration of each conversation is between 5-10 minutes and the content of the conversation will include self-introduction, questions about the patient's general health, and encouraging the patient to follow the recommendations made.

##### **Category**

Rehabilitation

#### **2**

##### **Description**

Control group: After completing the informed consent form to participate in the study and completing the desired questionnaires (demographic information questionnaire, SF-36 quality of life questionnaire, Borg shortness of breath scale and FSS fatigue severity scale) will be established and completed using a telephone call within 6 weeks.

##### **Category**

N/A

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Shariati Hospital

###### **Full name of responsible person**

Golrokh Abdollahi

###### **Street address**

Shariati Hospital, North Kargar St., Tehran

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1411713135

###### **Phone**

+98 21 8490 1000

###### **Email**

shariatihosp@tums.ac.ir

#### **2**

##### **Recruitment center**

###### **Name of recruitment center**

Imam Khomeini Hospital Complex

###### **Full name of responsible person**

Golrokh Abdollahi

###### **Street address**

Imam Khomeini Hospital Complex, Dr. Gharib St., Tehran

###### **City**

تهران

###### **Province**

Tehran

###### **Postal code**

۱۴۱۹۷۳۳۱۴۱

###### **Phone**

+98 21 6698 2000

###### **Email**

Imamhospital@tums.ac.ir

#### **3**

##### **Recruitment center**

###### **Name of recruitment center**

Amir Alam Hospital Complex

###### **Full name of responsible person**

Golrokh Abdolahi

###### **Street address**

Enghelab St. - Saadi St. - Amir Alam Hospital Complex

###### **City**

تهران

###### **Province**

Tehran

###### **Postal code**

1744793779

###### **Phone**

+98 21 6670 6666

###### **Email**

hamiralam@sina.tums.ac.ir

#### **4**

##### **Recruitment center**

###### **Name of recruitment center**

Ziaian Hospital

###### **Full name of responsible person**

Golrokh abdollahi

###### **Street address**

Qazvin Street, Abuzar Street, Ziaian Hospital

###### **City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1366736511  
**Phone**  
+98 21 5517 6814  
**Email**  
ziaeian@tums.ac.ir

## 5

### Recruitment center

**Name of recruitment center**  
Baharloo Hospital  
**Full name of responsible person**  
Golrokh Abdollahi  
**Street address**  
Tehran - Railway Square - Beehdari Street - Baharloo Hospital.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1339735382  
**Phone**  
+98 21 5565 8500  
**Email**  
baharloo@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammad Ali Sahraian  
**Street address**  
Imam Khomeini Street, Hassan Abad Square, Sina Hospital  
**City**  
tehran  
**Province**  
Tehran  
**Postal code**  
1136746911  
**Phone**  
+98 21 6670 6142  
**Email**  
Sahraian1350@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tehran 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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Golrokh Abdollahi  
**Position**  
Postgraduate Nursing Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Narmak Street Afshari Kahkvand Alley No. 4 Unit 8  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1645913539  
**Phone**  
+98 21 7784 2192  
**Email**  
Abdolahygoiii@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Golrokh Abdollahi  
**Position**  
Postgraduate Nursing Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Narmak Street Afshari Alley Avansian No. 4 Unit 8  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1645913539  
**Phone**  
+98 21 7784 2192  
**Email**  
Abdolahygoiii@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Golrokh Abdollahi

**Position**

Postgraduate Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Narmak Street Afshari Alley Avansian No. 4 Unit 8

**City**

Tehran

**Province**

Tehran

**Postal code**

1645913539

**Phone**

+98 21 7784 2192

**Email**

Abdolahygolii@gmail.com

## 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