

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Inspiratory muscle training in quality of life, aerobic capacity and pulmonary functional index in patients with COVID-19 in Masih-Daneshvari hospital

#### Protocol summary

##### Study aim

The Effect of Inspiratory muscle training in quality of life, aerobic capacity and pulmonary functional index in patients with COVID-19 in Masih-Daneshvari hospital

##### Design

control group, parallel, randomized groups, Simple randomization method

##### Settings and conduct

All patients who meet the entry criteria and have completed the consent form for participation in the project are invited to take the test. Tests include: Complete an individual information questionnaire; Quality of Life Questionnaire ; MMRC shortness of breath index; 6MWT; PIMAX and PEMAX tests After the tests, patients are randomly divided into two groups. The first group includes breathing exercises, including diaphragmatic breathing exercises, bud lip breathing, and limb exercises, and the exercise brochure is given to patients. In the second group, in addition to the above exercises, patients are also taught how to use the IMT device. Patients in both groups do the exercises for 4 weeks. (Twice a day) After 4 weeks, patients are called to the hospital for re-evaluation.

##### Participants/Inclusion and exclusion criteria

age: 20-60; PCR Test (Rt: - PCR); Negative Hospital discharge; Lack of oxygen dependence; 10 days has passed since the quarantine ; Absence of any underlying disease; PIMAX less than 60%

##### Intervention groups

inspiratory muscle training

##### Main outcome variables

6 minute walking distance; strength index

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200611047727N1**

Registration date: **2020-06-24, 1399/04/04**

Registration timing: **prospective**

Last update: **2020-06-24, 1399/04/04**

Update count: **0**

#### Registration date

2020-06-24, 1399/04/04

#### Registrant information

##### Name

Maryam Sadat Mirenayat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2610 5050

##### Email address

mirenayat@sbmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-07-22, 1399/05/01

#### Expected recruitment end date

2020-10-22, 1399/08/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effect of Inspiratory muscle training in quality of life, aerobic capacity and pulmonary functional index in

patients with COVID-19 in Masih-Daneshvari hospital

## Public title

The Effect of Inspiratory muscle training in patients with COVID-19

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

All male and female patients who have undergone the course of Qovid 19 disease and have referred to the follow-up clinic of Masih Daneshvari Hospital. The age of the clients is between 20 and 60 years Negative PCR Test (Rt: - PCR) Hospital discharge according to the national discharge protocol Lack of oxygen dependence The time between one week and 10 days has passed since the quarantine period Absence of any underlying disease including COPD, CHF and neuromuscular disease or motor disorders PIMAX less than 60%

### Exclusion criteria:

With any of the experts or unwillingness to continue participating in the project

## Age

From **20 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Method of randomization: simple Unit of randomization : individual Tools used in randomization : table of random numbers Included patients, in a simple randomized evaluation using even and odd numbers, would get codes for each treatment group. In case of odd numbers, the patient would be enrolled in the group one to receive high flow oxygenation at the first stage and following a washout period, take noninvasive ventilation. On the other hand, patients gotten even numbers would receive noninvasive ventilation for the first stage. Then, after a washout period, high oxygen therapy would be prescribed.

## 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 Shahidbeheshti University of Medical Sciences

##### Street address

Masih Daneshvari Hospital, Darabad, Bahonar Ave, Tehran Town, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1956944413

#### Approval date

2020-04-30, 1399/02/11

#### Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.088

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

B34.2

#### ICD-10 code description

Coronavirus infection, unspecified

## Primary outcomes

### 1

#### Description

Strenght Index

#### Timepoint

The first day and four weeks later

#### Method of measurement

Inspiratory muscle training

## Secondary outcomes

### 1

#### Description

Walking distance test six minutes

#### Timepoint

At the beginning of the study (before the intervention begins) and four weeks later

#### Method of measurement

Strenght Index

### 2

#### Description

SF12 scale

#### Timepoint

At the beginning of the study (before the intervention begins) and four weeks later

**Method of measurement**  
questionnaire

## Intervention groups

### 1

#### Description

Intervention group: In this group, patients are taught to perform breathing exercises for four weeks with the help of the respiratory muscle strengthening device. This device is designed in such a way that the patient puts a filter on his mouth. He takes a deep breath and tries to make the most of his abdominal muscles. The patient performs 30 repetitions with the device twice a day. Each week, the intensity of the device increases by one degree. Variables are measured on the first day and after four weeks.

#### Category

Rehabilitation

### 2

#### Description

Common treatment: This group teaches patients regular breathing exercises, including bud breathing, diaphragmatic breathing, and deep breathing, and provides exercise brochures to patients. They are asked to practice for four weeks each day. Do it twice and the intervention variables are measured on the first day and after the fourth week.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Maryam Mirenayat

##### Street address

Masih Daneshvari Hospital, Darabad, Bahonar Ave,  
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##### Phone

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##### Email

MirenayaT\_M@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Afshin Zarghi

##### Street address

Masih Daneshvari Hospital, Darabad, Bahonar Ave,  
Tehran Town, Iran

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1983969411

##### Phone

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##### Email

Mpajouhesh@sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Maryam Mirenayat

##### Position

Assistant Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Internal Medicine

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Atefeh Fakharian

**Position**  
Associate professor

**Latest degree**  
Subspecialist

**Other areas of specialty/work**  
Internal Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Saba Karimzade

**Position**  
Researcher

**Latest degree**  
Master

**Other areas of specialty/work**  
Physiology

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sabakarimzade@yahoo.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

Clinical trial data will be published as an article

### When the data will become available and for how long

Start access 6 months after printing results

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

Related scientific research

### From where data/document is obtainable

مرکز تحقیقات بیماری های مزمن تنفسی بیمارستان مسیح دانشوری  
تهران

### What processes are involved for a request to access data/document

Provide the initial file of the approved research plan

### Comments