

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### the effects of pranayama on the respiratory function in discharged covid-19 patients

#### Protocol summary

##### Study aim

Investigating the effect of pranayama on the respiratory function of recovered patients from covid-19

##### Design

Before starting the interventions, all independent and dependent variables related to individual characteristics and the main and secondary outputs of the present study will be measured. Then, the participants of the intervention group will perform pranayama exercises on a regular basis, during 12 sessions. All spirometry measurements in this study will be performed according to standard recommendations. Each patient will perform breathing exercises using a standard spirometry to measure forced expiratory flow in the first second, vital capacity, FEV1/FVC ratio should be evaluated.

##### Settings and conduct

Pranayama breathing is performed 10 rounds of 10 s during 6 weeks and 3 times a week {at homes} and the parameters are checked with spirometry and 6-minute walk methods at Vali E asr Fasa Hospital.

##### Participants/Inclusion and exclusion criteria

A definite diagnosis of covid-19 and discharge from the hospital over 18 has not suffered from any other acute illness except for covid-19 in the past 6 months. The patient does not have Chronic obstructive pulmonary disease or other respiratory diseases. The participant's forced expiratory volume in 1s must be above 70% discharged from the hospital for a week.

##### Intervention groups

Participants will be selected from among the discharged patients of Covid-19 from Valiasr Hospital. Then, the process of conducting the intervention and reviewing the results will be explained to the qualified people and the participants will enter the study while completing the written informed consent. To measure the desired goals in this study, we need to divide the participants into two control and intervention groups. The subjects will be randomly divided into seven blocks of ten in two groups.

##### Main outcome variables

Respiratory function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220805055622N1**

Registration date: **2022-09-23, 1401/07/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-09-23, 1401/07/01**

Update count: **0**

##### Registration date

2022-09-23, 1401/07/01

##### Registrant information

##### Name

marzie shahriary

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3743 3525

##### Email address

marzieshahriary1@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

the effects of pranayama on the respiratory function in discharged covid-19 patients

### Public title

the effects of pranayama on the respiratory function in discharged covid-19 patients

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

The patient has been discharged from the hospital for a week. over 18 years of age In the past 6 months, he has not suffered from any other acute illness except for Covid-19. The patient does not have Chronic obstructive pulmonary disease or other respiratory diseases. The participant's forced expiratory volume in 1s must be above 70%. (The recovered patient does not have severe respiratory restriction and is able to participate in the study) The patient has been discharged from the hospital for a week

#### Exclusion criteria:

Have underlying cardiovascular diseases including severe ischemia or hemorrhagic stroke Suffer from neurodegenerative diseases Get infected with Covid-19 again and show symptoms of the disease

### Age

From **18 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

We divide people into individual blocks{7 blocks of 10} , which include the following variables. Age-Sex-Education-Occupation-History of Disease-Body Mass Index {Method of measuring these 6 items is a questionnaire} experimental group {measurement method is randomization} 6-min walk distance {chronometer} Forced expiratory volume in 1-inspiratory capacity-inspiratory time to total breathing cycle time- Forced vital capacity-FEV1/FVC {measurement method is Spirometry} Variable role: independent, dependent, contextual, and confounding Variable type: continuous quantity, discrete quantity, rank quality, nominal quality Measurement scale: nominal, ordinal, interval, relative

### 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 fasa university of medical sciences

##### Street address

Ebn sina blv.fasa university of medical science

##### City

Fasa

##### Province

Fars

##### Postal code

74616\_86688

#### Approval date

2022-07-31, 1401/05/09

#### Ethics committee reference number

IR.FUMS.REC.1401.049

## Health conditions studied

### 1

#### Description of health condition studied

covid-19

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Measurement of respiratory volume

#### Timepoint

6 week

#### Method of measurement

Spirometry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group :The intervention group should perform pranayama breathing 3 times a week for 6 weeks and the effect of this exercise will be measured using spirometry and 6 minutes walk .Exercises are provided to people in the form of brochures and educational videos. The executive protocol is as follows: First, sit on all fours on the floor in a comfortable position, so that the back is straight and not hunched

over. The position of the eyes can be half open or closed. Breathing begins and all the focus and awareness of the person is directed to his breathing. Correct breathing method: inhale for 4 seconds, hold for 2 seconds and exhale for 4 seconds. According to the ability of each person, the duration of inhaling and exhaling should increase and the duration of inhaling should be longer than inhaling [if possible and without any pressure]. 10-12 times of this breathing. Another exhalation. A deep breath is taken from both nostrils. The right nostril is closed with the thumb and the exhalation comes out from the left nostril. The thumb still remains on the right nostril. Now one breath is done through the left nostril. The breath is held and the little finger is placed on the left nostril and the thumb is removed and exhaled through the right nostril. This breathing period should be done 8 to 10 times according to the person's capacity. This breathing should be done 3 times a week for 6 weeks. In case of dizziness or headache, you should immediately stop the exercise and rest in a state like prostration. After 6 weeks, spirometry and 6 minute walk are performed again and the results are compared with the control group.

**Category**

Rehabilitation

**2****Description**

Control group: At the beginning of the study, the control group performs spirometry and 6 minute walk at the same time as the intervention group. In the continuation of the study, this group does not perform any breathing exercises. At the end of the study, after 6 weeks, this group is again performs spirometry and 6 minute walk and the result is measured with the intervention group.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Vali e Asr Hospital

**Full name of responsible person**

Marzie Shahriary

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Ebn Sina Blv

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**Email**

Marzieshahriary1@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Dr Yaser Mansuri

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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**

Fasa 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**

Fasa University of Medical Sciences

**Full name of responsible person**

Marzie Shahriary

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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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