

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of diaphragmatic breathing training on dyspnea and anxiety of patient with Covid-19.

#### Protocol summary

##### Study aim

Determining the effect of diaphragmatic breathing training on dyspnea and situational anxiety in corona patients.

##### Design

This study is an interventional study. First, among all patients with covid-19 hospitalized on the day of discharge, sampling is performed using available sampling and taking into account the inclusion criteria. The samples will be divided into two groups of control and intervention with random allocation (quadruple blocking).

##### Settings and conduct

This study will be performed in the corona ward of Amir Al-Momenin Hospital in Arak. Intervention group will be wanted to do diaphragmatic breathing for 10 minutes and participants are asked to do this exercise one day after discharge, for one week, once in the morning and once at night each time for 10 minutes. The questionnaires of positional anxiety and shortness of breath and oxygen saturation will be completed by both groups before the intervention, immediately after the intervention and again a week later. The control group will also receive only routine care.

##### Participants/Inclusion and exclusion criteria

Entry requirements: 1) corona patients who hospitalized. 2) Spo2 less than 93% . 3) The patient expresses a feeling of shortness of breath. 4) Minimum age 18 years. 5) Fluency and understanding of Persian language. 6) No history of taking anti-anxiety and anti-depressant drugs. 7) No history of chronic coronary and pulmonary disease.

##### Intervention groups

The day of discharge intervention group will be individually trained by the researcher in diaphragmatic breathing training then they will do it for 10 minutes. One they after discharge they will wanted to do this train 10 minutes for tow times in morning and night till one week. The control group will also receive only routine care.

#### Main outcome variables

Anxiety, dyspnea, and spo2 are dependent variables.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211107052988N1**

Registration date: **2021-11-16, 1400/08/25**

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

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

##### Registration date

2021-11-16, 1400/08/25

##### Registrant information

##### Name

Homa Rastegari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3328 7185

##### Email address

homa.rst96@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-07, 1400/08/16

##### Expected recruitment end date

2022-01-06, 1400/10/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of diaphragmatic breathing training on dyspnea and anxiety of patient with Covid-19.

**Public title**

Effect of diaphragmatic breathing training on dyspnea and anxiety of patient with Covid-19.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All of the covid-19 patient in Amir-Al-momenin hospital in Arak city on the day of discharge. SPO2 less than 93%. Expressing feeling of shortness of breath. Minimum age 18 years old. Fluency and understanding of Persian language. No history of taking anti-anxiety and anti-depressant drugs. No history of having chronic coronary and pulmonary disease.

**Exclusion criteria:**

Reluctance to continue cooperation. Do not do breathing exercises for one shift or more. Incidence of acute and severe respiratory distress. Existence of mental and cognitive problems.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **78**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be divided into two groups of control and intervention with random allocation (quadruple permuted block). In this way, in each block of 4, two allocations to the intervention group and two allocations to the control group are considered And there are 6 cases in total, then the lottery is done by placement and each group that is selected, the sequence of participants (intervention and control) is determined.

**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 Arak university of Medical Sciences

**Street address**

Sardasht, Payambar Azam University Complex, office building

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2021-10-25, 1400/08/03

**Ethics committee reference number**

IR.ARAKMU.REC.1400.189

**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**

Situational Anxiety

**Timepoint**

Before the intervention, immediately after the intervention and one week after.

**Method of measurement**

Spielberg Situational Anxiety Questionnaire

**2****Description**

dyspnea

**Timepoint**

Before the intervention, immediately after the intervention and one week after.

**Method of measurement**

Borg scale for dyspnea, puls oximetry device, modified medical research council scale for dyspnea.

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

The "intervention group" on the day of discharge will be individually trained by the researcher in diaphragmatic breathing. They will then be asked to do this exercise for 10 minutes and the relevant questionnaires will be completed before and after this period. The "intervention group" is then asked to do this exercise for 10 minutes from the morning one day after discharge for one week, once in the morning and once in the evening, and again after a week the relevant questionnaires. Will be completed and compared and analyzed.

#### Category

Rehabilitation

### 2

#### Description

Control group: The "control group" in this study will receive only routine care and will not receive diaphragmatic training. However, they will complete the questionnaires 3 times together with the intervention group and will finally be compared and analyzed.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir-Al-Momenin Hospital

##### Full name of responsible person

Homa Rastegari

##### Street address

Sardasht, Basij Square, Amir-Al-Momenin hospital.

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3417 3601

##### Email

it-amiralmomenin@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Seyed Mohammad Jamaliyan

##### Street address

Sardash, Payambar Azam university complex, Arak

university of medical sciences

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3417 3524

##### Email

nursing.school@arakmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Homa Rastegari

##### Position

Master's student of medical-surgical nursing

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Sardasht, Payambarazam University complex, nursing school

##### City

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##### Province

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3847176941

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+98 86 3417 3524

##### Email

homa.rst96@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

**Full name of responsible person**

Homa Rastegari

**Position**

Master's student in medical-surgical nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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No. 8833, MazidAbadi alley., laali Ave

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**Email**

homa.rst96@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Homa Rastegari

**Position**

Master's student in medical-surgical nursing

**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