

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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Seyed Mohammad Jamaliyan

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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

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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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