Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 dvice, 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
Arak

Province
Markazi

Postal code
3847176941

Phone
+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

Street address
No. 8833, MazidAbadi alley., laali Ave

City
Arak

Province
Markazi

Postal code
3814768833

Phone
+98 86 3328 7185

Fax

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
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 8833, MazidAbadi alley., laali Ave

City
Arak

Province
Markazi

Postal code
3814768833

Phone
+98 86 3328 7185

Fax

Email
homa.rst96@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