Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of breathing exercises training on arterial oxygen saturation and anxiety in COVID-19 Patients

Protocol summary

Study aim
Determining the effect of breathing exercises training on arterial oxygen saturation and anxiety in COVID-19 patients

Design
A clinical trial with the control group, randomized, 70 Covid-19 patients

Settings and conduct
Kamkar-Arabnia hospital in Qom city After completing the written consent of the patients, information is collected from the samples of the intervention and control groups by means of a Beck Anxiety Inventory and a checklist of clinical information on O2Sat and respiration rate. Then, the training program of breathing exercises and relaxation runs for the intervention group, during 15-minute daily sessions for 4 weeks at home and virtually. The subject of these sessions is active coughing exercises, diaphragmatic breathing, and budding lips, chest volume-enhancing exercises, and resistance exercises of the respiratory muscles. During these four weeks, the research team will follow the intervention group. The control group will not receive any training intervention. In both groups, one week after the intervention, a post-test will be taken.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Going through the acute stage of the disease, male and female patients aged 20 to 75 years, having full consciousness, having the desire to participate in training, have not previously received any training on breathing exercises, and have not participated in any other training program during this study. Exclusion criteria: Having heart, kidney, liver, gastrointestinal, and peripheral edema problems, uncontrolled diabetes, and blood pressure, and exacerbation of the disease and death of the patient during the study.

Intervention groups
Intervention group: Training program of breathing exercises and relaxation. Control group: no receive any training intervention.

Main outcome variables
Arterial blood oxygen saturation; respiration rate; and anxiety level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160716028948N2**
Registration date: **2021-12-29, 1400/10/08**
Registration timing: **prospective**

Last update: **2021-12-29, 1400/10/08**
Update count: **0**

Registration date
2021-12-29, 1400/10/08

Registrant information

Name
Tahereh Ramezani

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-31, 1400/10/10

Expected recruitment end date
2022-01-30, 1400/11/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of breathing exercises training on arterial oxygen saturation and anxiety in COVID-19 Patients

Public title
Effect of breathing exercises training in arterial oxygen saturation and anxiety of COVID-19 Patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having a minimum Hemoglobin 11 gr/dl Having body temperature between 36.5°C to 37.5°C Having minimum systolic blood pressure 100 mmHg Going through the acute stage of the disease Having full consciousness and awareness of time, place and person Having the desire to participate in training Have not previously received any training on breathing exercises and have not participated in any other training program during this study.
Exclusion criteria:
Having heart, kidney, liver, gastrointestinal, and peripheral edema problems Having uncontrolled diabetes and blood pressure Exacerbation of the disease and death of the patient during the study
Age
From **20 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
By referring to the Medical Record Unit of Qom educational hospital, the files of hospitalized COVID-19 patients will be extracted and samples will be selected by simple random sampling (using lottery) based on inclusion criteria. Then, each person is given a number and based on random numbers table, the subjects will be placed in two groups of control and intervention. In this way, from the table, the two digits on the left side of the number chosen randomly are considered as the number of the person and and patients will be placed in two groups of control and intervention every others.
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 Qom University of Medical Sciences
Street address
No. 83, alley 4, Jahad daneshgahi street, Safashahr street, Qom, Iran
City
Qom
Province
Ghoum
Postal code
37169-93456
Approval date
2021-07-14, 1400/04/23
Ethics committee reference number
IR.MUQ.REC.1400.149

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19,virus identified

Primary outcomes

1

Description
Arterial blood oxygen saturation (O2Sat)
Timepoint
The effect of breathing exercises training on Arterial blood oxygen saturation (O2Sat) in Covid-19 patients, before and one week after the intervention
Method of measurement
Arterial blood oxygen saturation (O2Sat) checklist

2

Description
Respiratory rate (RR)
Timepoint
The effect of breathing exercises training on respiratory rate in Covid-19 patients, before and one week after the intervention
Method of measurement
Respiration rate checklist

Secondary outcomes

1

Description
Anxiety
Timepoint
Before and one week after the intervention
Method of measurement
Beck Anxiety Inventory

Intervention groups

1

Description
Intervention group: After completing the written consent by the patients, information is collected from the samples of the intervention and control groups by the Beck Anxiety Inventory and a checklist of clinical data on O2Sat and respiration rate. Then, the training program of breathing exercises runs according to the protocol of breathing exercises and relaxation for the intervention group, during 15-minute daily sessions for four weeks at home and virtually (internal messengers such as Eitaa) through the training content provided by trained experts. The subjects in these sessions receive active coughing exercises (3 sets, 10 repetitions), diaphragmatic breathing and budding lips (30 voluntary breathing in various positions including supine position, prone position, side-lying position, and quadruped position), chest volume-enhancing exercises according to the therapist's instructions (the patient performs horizontal opening, bending, turning and external rotation of the arms at the same time with each breathing cycle) and resistance exercises of the respiratory muscles by the patient himself. These exercises will be in a range of simple to difficult and based on the patient's condition. Also, during these four weeks, the research team will be sure that the intervention protocol movements are performed correctly by the patients. One week after the intervention, the level of anxiety and O2Sat in the hospital will be measured again using a pulse oximetry device and a questionnaire by the same researcher who measured and recorded the outcome variables before the breathing exercises.
Category
Rehabilitation

2

Description
Control group: No educational intervention is done on the control group and they are received only usual care. Also, data are collected from the samples of the control group before and one week after the intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamkar-Arabnia hospital in Qom city
Full name of responsible person
Dr Javad Khodadadi
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Sponsors / Funding sources

1

Sponsor
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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
Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person
Dr Zahra Taheri-kharameh

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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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