Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of the breathing exercises on quality of life and symptoms of shortness of breath and fatigue in patients with Covid 19

Protocol summary

Study aim

Determining the effect of breathing exercises on quality of life and symptoms of shortness of breath and fatigue in patients with Covid-19

Design

A randomized controlled clinical trial with parallel, single-blind, randomized block-block groups on 72 patients

Settings and conduct

This study is a clinical trial that is performed after receiving the code of ethics and the clinical trial code. A list of all eligible individuals in the selected hospitals of the University of Tehran that have the highest admission of patients with Covid-19 will be prepared and randomized. Blocks are divided into two groups of control and intervention. Blinding will be done blindly by the samples.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: (1) Patients with Covid-19 (2) Age 18 to 60 years (3) Having a mobile phone (4) Have symptoms of shortness of breath or fatigue or every two weeks after discharge from the hospital. Inclusion criteria include: (1) Hospitalized in ICU Covid-19 (2) Patients with moderate to severe heart failure (Grade III or IV, New York Heart Association) (3) COPD or other respiratory and infectious diseases

Intervention groups

During 6 weeks, do daily breathing exercises based on 6 sheets of functional checklist that explains how to do these exercises in the breathing exercise checklist and in the form of bud lip breathing 5 to 10 times each time, diaphragmatic breathing 5 times each time. Up to 15 in each session at home twice a day (morning and evening) for 42 days without interruption is sent to the intervention group after 2 weeks of discharge from the hospital, in addition to providing educational content by calling patients by The researcher also runs for 6 weeks.

Main outcome variables

Shortness of breath, fatigue, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210717051910N1**
Registration date: **2021-07-30, 1400/05/08**
Registration timing: **prospective**

Last update: **2021-07-30, 1400/05/08**
Update count: **0**

Registration date

2021-07-30, 1400/05/08

Registrant information

Name

Golrokh Abdollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

2021-08-28, 1400/06/06

Actual recruitment end date

2021-09-28, 1400/07/06

Trial completion date

2022-01-21, 1400/11/01

Scientific title

Effect of the breathing exercises on quality of life and symptoms of shortness of breath and fatigue in patients with Covid 19

Public title

Effect of the breathing exercises on quality of life and symptoms of shortness of breath and fatigue in patients with Covid 19

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID-19 with respiratory symptoms with radiological manifestations as one or two-way multilobular infiltration in CT scan or chest x-ray whose disease has been confirmed by nasal swap test (RT-PCR SARS-CoV-2) You have symptoms of shortness of breath or fatigue or every two weeks after discharge from the hospital. Having a mobile phone Ages 18 to 60

Exclusion criteria:

Hospitalized in ICU Covid-19 Patients with moderate to severe heart failure (grade III or IV, New York Heart Association) Having COPD or other respiratory and infectious diseases

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Using simple randomization method using random table of numbers, subjects will be divided into two groups of intervention and control. Randomization units are one of the patients referred to the Corona ward. Randomization tool is also a random table of numbers. The researcher puts numbers on one of the random table numbers and moves to the right and bottom. Records the numbers and assigns them to different study groups whose numbers are already specified.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data collected from both groups will be provided to the data analyzer without specifying which control or esoterry groups were related.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Reserch Ethics Committees of school of nursing and midwifery & rehabilitation-Tehran University of M

Street address

School of Nursing and Midwifery, Nosrat St., Enghelab Square, Tehran University of Tehran

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Approval date

2021-07-27, 1400/05/05

Ethics committee reference number

IR.TUMS.FNM.REC.1400.088

Health conditions studied

1

Description of health condition studied

covid-19b

ICD-10 code

U07.2

ICD-10 code description

covid19, virus not identified

Primary outcomes

1

Description

shortness of breath

Timepoint

Measurement of shortness of breath will be done before the intervention and 6 weeks after the intervention.

Method of measurement

Borg Shortness of breath

2

Description

Fatigue

Timepoint

Fatigue will be measured before the intervention and 6 weeks after the intervention.

Method of measurement

FSS Fatigue Intensity Scale

3

Description

Quality of life

Timepoint

Quality of life will be measured before the intervention and 6 weeks after the intervention.

Method of measurement

Quality of Life Questionnaire SF-36

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During 6 weeks, after sending the video and training brochure of breathing exercises as well as checklists that show how to do breathing exercises which are explained in the checklist of breathing exercises and breathing in the form of bud lip 5 to 10 times each time, breathing The diaphragm is 5 to 15 times per session at home twice a day (morning and evening) for 42 days without interruption. It is sent to the intervention group after 2 weeks of discharge from the hospital, in addition to providing educational content to In the intervention group, telephone calls to patients are made by the researcher for 6 weeks. In this way, telephone calls are made twice a week in the first 4 weeks and once a week in the second 2 weeks with the intervention group. The time of the conversation is between 10-12 in the morning and the duration of each conversation is between 5-10 minutes and the content of the conversation will include self-introduction, questions about the patient's general health, and encouraging the patient to follow the recommendations made.

Category

Rehabilitation

2

Description

Control group: After completing the informed consent form to participate in the study and completing the desired questionnaires (demographic information questionnaire, SF-36 quality of life questionnaire, Borg shortness of breath scale and FSS fatigue severity scale) will be established and completed using a telephone call within 6 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Golrokh Abdollahi

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Shariati Hospital, North Kargar St., Tehran

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Recruitment center

Name of recruitment center

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Recruitment center

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4

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Name of recruitment center

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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Golrokh Abdollahi

Position
Postgraduate Nursing Student

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