

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of respiratory exercises on quality of life in covid-19 patients

Protocol summary

Study aim

The effect of respiratory exercises on quality of life in patients after covid-19

Design

In this research by available sampling method, all qualified patients after corona referred to this center will be selected. The sample size according to previous studies using the formula and 0.05 alpha, were obtained 35.

Settings and conduct

After completing demographic questionnaire (11 questions), blood oxygen level, heart rate (by pulse oximeter), SF-36 QOL and Borg scale, in the first week treatment will be performed by therapist (2 days a week, each session 45-60 min) in the hospital containing; lung massage and exercises, then in the second week, by providing educational brochures it will be performed at home by patients daily and at the end of week questionnaires will be completed again.

Participants/Inclusion and exclusion criteria

Inclusion criteria; survived corona patients between 3 and 18 weeks of hospitalization, between 18 and 75 years old, referred to PM&R department of Shohadae Tajrish Hospital, written consent, not giving other pulmonary rehabilitation treatment Exclusion criteria; having problems for preventing pulmonary massage including active wounds, fractures and skin disorders, having uncontrolled cardiovascular problems, chronic pulmonary d., kidney, neurological d., hypertension, acute rheumatoid, psychological diseases

Intervention groups

This semi-experimental pre-test and post-test type clinical trial is conducted as repeated measurements (before and 2 weeks after treatment) to investigate the effect of respiratory exercises on QOL of patients (women and men) after corona

Main outcome variables

Respiratory exercises, blood oxygen, heart rate, dyspnea, QOL, gender, age, weight, height, marital status, education level, job status, disease after corona,

medications, time interval from corona conflict to initial assessment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211201053238N1**

Registration date: **2022-01-10, 1400/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-10, 1400/10/20**

Update count: **0**

Registration date

2022-01-10, 1400/10/20

Registrant information

Name

Leila Angooti Oshnari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4470 5120

Email address

leylaa1768@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

2021-12-11, 1400/09/20

Actual recruitment end date

2022-02-09, 1400/11/20

Trial completion date

2022-02-09, 1400/11/20

Scientific title

The effect of respiratory exercises on quality of life in covid-19 patients

Public title

The effect of respiratory exercises on quality of life in covid-19 patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients must be referred to the department of physical medicine and rehabilitation in Shohade Tajrish Hospital Patients must be recovered from corona (after 3 weeks and under 18 weeks) and after hospitalization Patients must be between the ages of 18 and 75 Patient satisfaction must be obtained to participate in the research None of the patients should have been treated for pulmonary rehabilitation

Exclusion criteria:

None of the patients have problems against pulmonary massage, including; active wounds, fractures and skin disorders in the chest area Patients do not have a history of uncontrolled cardiovascular problems, chronic pulmonary, renal, neurological, hypertension, acute rheumatological, psychological phases leading to not doing exercise

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **35**

Actual sample size reached: **35**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In order to prevent the patient from traveling a lot and the difficulty of going to medical centers and reducing costs, the patient will have only 2 face-to-face sessions in the first week with an interval of one day to ensure learning breathing exercises and limbs and continuing doing exercises and trainings with training brochures related to the implemented training sessions and follow-up and evaluation at home at the end of the second week will be done by phone.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Physical Medicine and Rehabilitation Department, Shohadae Tajrish Hospital, Shahr-dari St, Tajrish Sq, Tehran Town

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2021-12-12, 1400/09/21

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.531

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07. 1 (CO

ICD-10 code description

COVID-19, virus identified: COVID-19 has been confirmed by laboratory testing irrespective of severity of clinical signs or symptoms. Use additional code, if desired, to identify pneumonia or other manifestations. Coronavirus disease (COVID-19) is an inf

Primary outcomes

1

Description

Quality of life

Timepoint

Before and 2 weeks after intervention

Method of measurement

The RAND 36-item health survey (SF-36 health survey)

Secondary outcomes

1

Description

Level of Blood Oxygen

Timepoint

Before and 2 weeks after intervention

Method of measurement

Pulse Oximeter instrument

2

Description

Heart Rate

Timepoint

Before and 2 weeks after intervention

Method of measurement

Pulse Oximeter instrument

3

Description

Level of Dyspnea

Timepoint

Before and 2 weeks after intervention

Method of measurement

Borg Scale

Intervention groups

1

Description

In this semi-experimental clinical trial, intervention will be performed in the first week (2 days a week, Sundays and Tuesdays) and each session for 45-60 minutes in clinic by the researcher with the following content: Performing lung massages for 2 minutes and doing ten types of breathing exercises and limbs that will be repeated three times a day and each movement 10 times at home. By providing an educational brochure related to the training sessions performed to the patient, in the second week, the exercises will be performed at home by the patient and researcher will be contact with the patient by phone in order to control the training and resolve the problems.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadae Tajrish Hospital

Full name of responsible person

Leila Angooti Oshnari

Street address

Physical Medicine & Rehabilitation department
,Shohadae Tajrish Hospital, Shahrdari St, Tajrish Sq,
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Email

leylaa1768@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Mansour Rayegani

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rayegani@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Angooti Oshnari

Position

Physical Occupational Therapist

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Mansoor Rayegani
Position
Professor
Latest degree
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The reasons for not publishing raw data is to prevent the misuse of data in other studies also, the ethicality of publishing details about the participants

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data details can only be shared after analyzing and publishing the results in a paper

When the data will become available and for how long

Access will be available after the results are printed

To whom data/document is available

Only researchers in this study will have access to data

Under which criteria data/document could be used

In case of alignment of future documents or to compare the results of future studies with the recent study

From where data/document is obtainable

Correspondence with e-mail address included in the future article by following: leylaa1768@yahoo.com Leila Angooti

What processes are involved for a request to access data/document

Finally, one week after receiving the email, the requesting email of the printed documents can be made available to researchers

Comments