Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 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 Tajtish 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, Shahrdari 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
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Physical Medicine & Rehabilitation department ,Shohadae Tajrish Hospital, Shahrdari St, Tajrish Sq, Tehran town
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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
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Physical Medicine and Rehabilitation Department, Shohadae Tajrish Hospital, Shahrdari St, Tajrish Sq, Tehran Town
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Person responsible for updating data

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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