

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the Effectiveness of Upper Limb Exercise and Respiratory Training on Outcome of COPD Patients in Selected Medical Centers of Qazvin Science Medicine University.

Protocol summary

Study aim

The comparison of the effectiveness of upper limb exercise and respiratory training on outcome of COPD patients

Design

Eligible patients (according to the inclusion criteria), then the patient will choose 75 blocks of a trio of three groups: upper limb exercise, breathing exercises and group controlling in the following, we will create five modes: (Upper extremity exercise, breathing exercises, control) (Breathing exercises, upper extremity exercise, control) (Control, respiratory exercises, exercise upper limbs) (Breathing exercises, upper extremity exercise, control) (Upper extremity exercise, control, respiratory exercises) and then, based on the table of random numbers each of these groups will be selected; for example, if the number is one, the first will select the combination or if the number two will be selected and combined the two came to the patient's respiratory exercises for a group of up to 25, 25 of the patient for group exercise of limbs the patient's upper and 25 for the control group.

Settings and conduct

Group exercise upper limbs for a month, three times a week (12 sessions) for 30 minutes per session, which will be in the presence of the researcher in the Center province hospital rehab. The second group, respiratory group, exercises daily for a month at home for 20 minutes and four times a day (morning, afternoon, evening, night) and will do the proper pattern of patients one minute workout and two minute break will be given training exercises conducted daily by a researcher tracking has enhanced call up to four weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria 1) All patients with copd referred to lung clinic of Qazvin Velayat Hospital with aged 30 to 90 years 2) Average and Sever COPD Diagnosis by a

Physician and Referring to the Researcher in a Written Format. The exit criteria: 1) exacerbation in such a way that fails to participate in the exercises. 2) advanced cardiovascular disease. 3) catching a nerve disorder that is in conflict with the muscle-have exercises.

Intervention groups

1. Upper Limb Exercise Group 2. Respiratory Training Group 3. Control Group

Main outcome variables

Improve the health level of patients with COPD and help them to enjoy the higher quality of life and consequently leading to life satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171006036584N1**

Registration date: **2018-01-07, 1396/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-07, 1396/10/17**

Update count: **0**

Registration date

2018-01-07, 1396/10/17

Registrant information

Name

Ommolbanin KESHAVARZ SARKAR

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3367 4365

Email address

o.keshavarzsarkar@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2018-01-21, 1396/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Upper Limb Exercise and Respiratory Training on Outcome of COPD Patients in Selected Medical Centers of Qazvin Science Medicine University.

Public title
Upper Limb Exercise and Respiratory Training on Outcome of COPD Patient

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with copd referred to lung clinic of Qazvin Ve Hospital aged 30 to 90 years Average and Sever COPD Diagnosis by a Physician and Referring to the Researcher in a Written Format.
Exclusion criteria:
exacerbation of the disease so that it misses the company exercises. advanced cardiovascular disease. catching a nerve disorder that is in conflict with the muscle-have exercises.

Age
From **30 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients (according to the inclusion criteria), then the patient will choose 75 blocks of a trio of three groups: upper limb exercise, breathing exercises and group controlling in the following five modes:: (Upper extremity exercise, breathing exercises, control) (Breathing exercises, upper extremity exercise, control) (Control, respiratory exercises, exercise upper limbs) (Breathing exercises, upper extremity exercise, control) (Upper extremity exercise, control, respiratory exercises) And then, based on the table of random numbers each of these groups will be selected. for example, if the number is one, the first will select the combination or if the number two will be selected and combined the two came

to the patient's respiratory exercises for a group of up to 25, 25 of the patient for group exercise of limbs The patient's upper and 25 for the control group.

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 Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blv, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2017-02-27, 1395/12/09

Ethics committee reference number

IR.QUMS.REC.1395.293

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

St. George's special quality of life questionnaire that is used for respiratory ailments. Rating of the questionnaire for every incumbent has from zero to 100, and the total inventory is defined in such a way that the number zero, indicates full health and gradually increase it to a lower quality of life.

Timepoint

measurement processes in this study would be at the beginning of the study, then after 30 days of

interventions and then the final measurement is done again.

Method of measurement

1. Demographic information form, 2. St. George's quality of life questionnaire 3. Performing 6-minute walk test 4. Self-reporting checklist 5. Upper extremity exercise checklist

Secondary outcomes

1

Description

6-minute walk test that documented in selected Medical Center (Velayat hospital) will be used. This form has 5 questions in the field of walking and finally the amount of mileage of the patient record.

Timepoint

Levels measured in this study was the first study in the first 30 days and then do the interventions are done, and then the final measurement is done again.

Method of measurement

The test would be carried out in Velayat Hospital (formerly in the Department of the Interior has been measuring men) within 6 minutes, will during the mileage rate and will be recorded by the researcher.

Intervention groups

1

Description

Intervention group: respiratory exercises on a regular basis that includes: a bud lips breathing and breathing is diaphragmy by three one-hour sessions on research during three consecutive days for a person and face to face training will be given to patients. After getting more information, respiratory exercises checklist to the target group will be given up to every day after doing exercises, in the appropriate section of mark. this group has 25 people and exercises daily for one month for 20 minutes and four times a day (morning, afternoon, evening, night) and patients will do a minute pattern of practice and two minute break will be given training exercises conducted daily tracking order by a researcher for the phone call up to four weeks. 2. upper extremity exercise group: 25 second sample in this group. After collecting the number of samples as previously mentioned research objectives with the briefing outlines and do the work for the patients of this group will be formed and after getting a written consent, completing a questionnaire, demographic information, St. George's quality of life questionnaire for all patients. 6-minute walk test in consecutive two days for this group such as the previous group will be conducted.

Category

Rehabilitation

2

Description

Control group: 25 patients will be put in the control

group. Similar to the intervention group, after explaining the research goals for each patient after completing the consent form, the demographic questionnaire and the questionnaire of the quality of life of St. George and 6-minute walk compared to complete. The usual care control group will be placed to avoid ethical problems. After completion of the study, the results of research will also presented to the control group. In the event of any change in personal life and work or any important changes either good or bad, such as the loss of a job or members of the family and marriage that makes changing the quality of life, it would be stated to the researcher. It should be noted at the end of the study in each group to compare the results St. George's quality of life questionnaire for all samples would be tested and also completed 6 minute walk.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Dr. Liela Yekefallah

Street address

Minoodar Blvd. Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3323 7267

Email

O.Keshavarzsarkar@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Liela Yekefallah

Street address

Shahid Bahonar Blv, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3323 7267

Email

O.Keshavarzsarkar@qums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Omolbanin Keshavarz Sarkar
Position
NURSE
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Velayat Hospital
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3323 7267
Fax
+98 28 1335 0056
Email
O.Keshavarzsarkar@qums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Liela Yekefallah
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address

Shahid Bahonar Blv, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3323 7267
Fax
+98 28 1335 0056
Email
leili_fallah@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Omolbanin Keshavarz Sarkar
Position
NURSE
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Bahonar Blv, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3367 4365
Fax
+98 28 1335 0056
Email
O.Keshavarzsarkar@qums.ac.ir

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
Given the multiple variables measured, and given that the data ultimately result in several articles, I do not plan to publish it.
Study Protocol
No - There is not 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
Not applicable
Data Dictionary
Not applicable

Title and more details about the data/document

The main results of the study are in the form of the article

When the data will become available and for how long

After completing the study and publishing the results as an article

To whom data/document is available

There is no limit to accessing for the results.

Under which criteria data/document could be used

To use its results for future studies.

From where data/document is obtainable

There is no limit to accessing for the results.

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

Send an email to the owner of the project to receive the documentation.

Comments

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