

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of pulmonary rehabilitation on quality of life and activity tolerance of COPD patients

Protocol summary

Summary

Objective: determination the effect of pulmonary rehabilitation program on quality of life and activity tolerance in patients with chronic obstructive pulmonary disease, study: RCT, parallel, not blinded, convenient sampling. Inclusion criteria: 1) be younger than 75 years old, 2) they should be literate, 3) they should have healthy vision and hearing, 4) it should be possible to make phone calls directly to the patient's home. Exclusion criteria: 1) enter to the acute phase of severe or the patient dies during the study, 2) if patient does not adhere to the exercise program because of new physical limitations, 3) if patient does not do more than two sessions of exercise and breathing, 4) if the patient does not adhere to the nutritional recommendations in a week. sample size: 60. The number of patients participating in this study are 60 patients with chronic obstructive pulmonary disease admitted to hospital → Firoozgar and Imam Khomeini (RA). The patients have been randomly divided into two groups, intervention (n=30) and control (n=30) groups. The control group will receive only routine care and the intervention group will participate in pulmonary rehabilitation program for 8 weeks in addition to the usual care. Then rehabilitation program telephone follow-up will be done in-home for once a week. outcome: to improve the quality of life and activity tolerance in intervention conditions.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201203135987N4**

Registration date: **2013-04-16, 1392/01/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-04-16, 1392/01/27

Registrant information

Name

Shahrzad Ghiyasvandian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Expected recruitment start date

2012-08-12, 1391/05/22

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pulmonary rehabilitation on quality of life and activity tolerance of COPD patients

Public title

Effect of pulmonary rehabilitation on life of pulmonary diseases patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: all case studies will sign an informed consent, and also they should have the following conditions: 1) Be younger than 75 years old. 2) Not be in the acute phase of the disease. 3) Not have any known defect in the respiratory system caused by other diseases. 4) Not have motor impairment which prevents their exercise. 5) They should be literate. 6) They should have healthy vision and hearing system. 7) It should be possible to make phone calls directly to the patient's home. Exclusion criteria: In this study, if a patient has one of following characteristics, it will be excluded from the study: 1) Enter to the acute phase of severe or the patient dies during the study. 2) If patient does not adhere to the exercise program because of new physical limitations. 3) If patient does not do more than two sessions of exercise and breathing. 4) If the patient does not adhere to the nutritional recommendations in a week.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran University of Medical Sciences Ethics Committee

Street address

Tehran, Keshavarz blvd, Ghods st.

City

Tehran

Postal code

1419733171

Approval date

2012-08-12, 1391/05/22

Ethics committee reference number

1105/130/91/ص

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

Health-related quality of life

Timepoint

Pre test, 8 week after intervention

Method of measurement

sf-36 Questionnaire

Secondary outcomes

1

Description

Activity tolerance

Timepoint

Pre test, 8 week after intervention

Method of measurement

St. George's Questionnaire

Intervention groups

1

Description

Pulmonary rehabilitation program was provided on self-care training, nutritional advice, psychological interventions through education of techniques reduction stress, strategies for effective breathing, shortness of breath control strategies in crisis, clean up the air by coughing and effective strategies and exercise program. Care education program includes anatomy and physiology respiratory system, pathophysiology, drug therapy, oxygen therapy, nutritional advice and training for coping with stress. In addition to the face-to-face training was given to the cases of the study were given a booklet. Training materials pulmonary rehabilitation program by the researcher during the three sessions will run for 30 minutes. Patients three times a week for 8 weeks for 20 minutes each time from 5 minutes to 20 minutes, which gradually increased, training exercises were conducted. Follow up was conducted by the researcher once a week for a maximum of 15 minutes.

Category

Rehabilitation

2

Description

In the control group, Routine care which included without scheduling training the use of drugs, oxygen therapy and deep breathing can be performed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar Hospital

Full name of responsible person

Keyvan KHodayari

Street address

Beh Afarin Street, Karim Khan Zand Street.

City

Tehran

2

Recruitment center

Name of recruitment center

Imam Khomeyni Hospital

Full name of responsible person

Keyvan Khodayari

Street address

Tehran, Tohid Square.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Faculty of Nursing and Midwifery,
Tehran University of Medical Sciences

Full name of responsible person

Dr Azam Baheiraei

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Tehran, tohid sq, Faculty of nursing and midwifery,
University of Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research, Faculty of Nursing and Midwifery,
Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Keyvan KHodayari

Position

Master of Nursing

Other areas of specialty/work

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Other areas of specialty/work

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Email**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty