

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Physical and Psychological Effects of Pulmonary Rehabilitation Program in Patients with Chronic Obstructive Pulmonary Disease

Protocol summary

Study aim

Determining the physical and psychological effects of pulmonary rehabilitation program in patients with chronic obstructive pulmonary disease

Design

One- group before- after clinical Trial without blinding

Settings and conduct

Selecting 47 patients with chronic obstructive pulmonary disease referring to lung clinic or hospitalized in the lung/ general internal medicine ward at Shariati hospital affiliated to Tehran university of medical sciences.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: diagnosis of Chronic Obstructive Pulmonary Disease (COPD) according to GOLD criteria (I to IV); and Occurrence of exacerbation. Exclusion Criteria: Contraindication for pulmonary rehabilitation; No compliance with the program; psychiatric disorders; with uncontrolled cardiovascular diseases; disability for doing the program.

Intervention groups

Implementation of pulmonary rehabilitation program including training of breathing exercises at home and aerobic exercise program according to the American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR) including respiratory muscle training, respiratory techniques and the way to discharge lung secretions, twice a week about 30 to 60 minutes for eight weeks according to patient`s tolerance by sport medicine specialist in pulmonary rehabilitation clinic at Shariati hospital affiliated to Tehran university of medical sciences.

Main outcome variables

Assessment of pulmonary function, ability of walking, shortness of breath, health- related quality of life, anxiety and depression before and 1 week after finishing the pulmonary rehabilitation program.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170210032476N2**

Registration date: **2018-03-09, 1396/12/18**

Registration timing: **retrospective**

Last update: **2018-03-09, 1396/12/18**

Update count: **0**

Registration date

2018-03-09, 1396/12/18

Registrant information

Name

Mahin Nomali

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6692 7171

Email address

m-nomali@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-01-29, 1395/11/10

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2017-02-03, 1395/11/15

Trial completion date

empty

Scientific title

Physical and Psychological Effects of Pulmonary Rehabilitation Program in Patients with Chronic Obstructive Pulmonary Disease

Public title

Effects of Pulmonary Rehabilitation Program in Patients with Chronic Obstructive Pulmonary Disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients that are with the Diagnosis of Chronic Obstructive Pulmonary Disease (COPD) according to the GOLD criteria (I to IV). Patients that are with the disease exacerbation.

Exclusion criteria:

There is contraindication for pulmonary rehabilitation. Patients do not adhere to the program. Patients who are with psychiatric disorders such as dementia. Patients who are with uncontrolled cardiovascular diseases. Patients that can not do the program due to orthopedic issues, diabetes; and uncontrolled liver disease.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **47**

Actual sample size reached: **22**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Building no.1, Northern gate of the university, Poursina St. Qods St. Enqelab St.

City

Tehran

Province

Tehran

Postal code

1417653861

Approval date

2016-09-18, 1395/06/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.637

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

Health- related quality of life

Timepoint

Before initiation of the study and one week after finishing the pulmonary rehabilitation program.

Method of measurement

St. George questionnaire and SF-12

Secondary outcomes

1

Description

Pulmonary function

Timepoint

Before initiation of the study and one week after finishing the pulmonary rehabilitation program.

Method of measurement

Spirometry

2

Description

Walking ability

Timepoint

Before initiation of the study and one week after finishing the pulmonary rehabilitation program.

Method of measurement

6- minute Walk Test

3

Description

Shortness of breath

Timepoint

Before initiation of the study and one week after finishing the pulmonary rehabilitation program.

Method of measurement

Medical Research Council Questionnaire

4

Description

Anxiety and Depression

Timepoint

Before initiation of the study and one week after finishing the pulmonary rehabilitation program.

Method of measurement

Hospital Anxiety and Depression Scale

Intervention groups

1

Description

Intervention group: Implementation of pulmonary rehabilitation program including training of breathing exercises at home and aerobic exercise program according to the American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR) including respiratory muscle training, respiratory techniques and the way to discharge lung secretions, twice a week about 30 to 60 minutes for eight weeks according to patient`s tolerance by sport medicine specialist in pulmonary rehabilitation clinic at Shariati hospital affiliated to Tehran university of medical sciences.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital affiliated to Tehran University of Medical Sciences

Full name of responsible person

Dr. Zeinab Naderpour

Street address

North Karegar St., Three Way Jalal Al-Ahmad, Shariati Hospital affiliated to Tehran University of Medical Sciences

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z-naderpour@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammadali Sahraian

Street address

Keshavarz Blvd., Qods street, Research deputy of Tehran University of Medical Sciences

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141556559

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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

Dr. Farnaz Mohammadnejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

North Kargar St., 3 Way Jalal Al-Ahmad, Shariati Hospital affiliated to Tehran University of Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zeinab Naderpour

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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

All rights related to the data is for Tehran University of Medical Sciences.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Data will be shared after making characteristics of the persons, unrecognizable.

When the data will become available and for how long

Initiation of the data availability 6 months after publication of the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Using in the systematic review and meta-analysis

From where data/document is obtainable

Tehran University of Medical Sciences

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

Providing a request and receiving the university approval letter

Comments