Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Mahin Nomali
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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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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+98 21 8490 1000
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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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Tehran
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+98 21 8163 3698
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msahrai@tuma.ac.ir
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
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Person responsible for scientific inquiries

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Dr. Zeinab Naderpour

Position

Assistant professor

Latest degree

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Other areas of specialty/work

Internal Medicine

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Latest degree

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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