

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of self management program on indicators of clinical status in patients with chronic obstructive pulmonary disease

Protocol summary

Summary

The purpose of this study is to determine the effect of self management program on indicators of clinical status in patients with chronic obstructive pulmonary disease. The 50 patients with COPD chosen for inclusion criteria: diagnosis COPD by physician; 45-70 years old; having literacy. Patients were randomly assigned into control and intervention group. Control group received usual care and intervention group received usual care plus intervention. Intervention contained self management program based on 5A model for 12 weeks in 5 steps: 1)Assess 2)Advise 3)Agree 4)Assist 5)Arrange. Patients who impossible Follow up were excluded. At baseline and the end of study fatigue, dyspnea, exercise tolerance and PFT were measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061713694N1**

Registration date: **2013-08-11, 1392/05/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-11, 1392/05/20

Registrant information

Name

Maryam Heidari

Name of organization / entity

Ahvaz Jondishapur University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Ahvaz Jondishapur University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-05-15, 1392/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self management program on indicators of clinical status in patients with chronic obstructive pulmonary disease

Public title

The effect of self management program on indicators of clinical status in patients with chronic obstructive pulmonary disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: COPD confirmed by physician; age between 45-70 years; having a BMI less than 30; understanding the Persian language; having literacy; absence of major psychiatric disorder; absence of other diseases such as neurological and musculoskeletal system disorders, cancer, not heart attack or angina attack in last month; having established a treatment plan. Exclusion criteria: Admission in hospital during of study; patient required to oxygen or spray during of six minute walking test; absence of patient in group

educational session; impossibility for follow up.

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Ahvaz Ethics committee of Jondishapur University of Medical Sciences

Street address

Vice Chancellor for Research, Ahvaz Jondishapur University of Medical Sciences, Golestan Road, Ahvaz.

City

Ahvaz

Postal code

61357-15794

Approval date

2013-04-13, 1392/01/24

Ethics committee reference number

U-92015

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

Dyspnea

Timepoint

before the intervention, 12 weeks after intervention

Method of measurement

Borg Scale

2

Description

Exercise Tolerance

Timepoint

before the intervention, 12 weeks after intervention

Method of measurement

Six Minutes Walking Test

3

Description

Pumonary Function

Timepoint

before the intervention, 12 weeks after intervention

Method of measurement

Spirometry Test

4

Description

Fatigue

Timepoint

before the intervention, 12 weeks after intervention

Method of measurement

Fatigue Sever Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Providing an educational pamphlet plus receive of self management program based on 5A model in the term of 12 weeks, in 5 stage: Assess, Advise, Agree, Assist, Arrange.

Category

Behavior

2

Description

Control Group: providing an educational pamphlet

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Respiratory Subspecialty Clinic

Full name of responsible person

Dr.Seyed Hamid Borsi

Street address

Apadana Specialty Clinic, East Esfand Street,
Kianpars, Ahvaz.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Ahvaz Jondishapur
University of Medical Sciences

Full name of responsible person

Dr. Mostaffa Fegghi

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Vice Chancellor for Research, Ahvaz Jondishapur
University of Medical Sciences, Golestan Road, Ahvaz.

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Ahvaz Jondishapur
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

Ahvaz Jondishapur University of Medical Science

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Maryam Heidari

Position

Master Science In Nursing

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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