

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1373 2422

##### Email address

heidari.ma@ajums.ac.ir

##### 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

**Street address**

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

**Full name of responsible person**

Maryam Heidari

**Position**

Master Science In Nursing

**Other areas of specialty/work****Street address**

Nursing Dept, Ahvaz Jondishapur University of Medical  
Sciences, Golestan Road, Ahvaz.

**City**

Ahvaz

**Postal code****Phone**

+98 61 1373 2422

**Fax****Email**

heidari.ma@ajums.ac.ir;

heidari.maryam84@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz Jondishapur University Medical of Sciences

**Full name of responsible person**

Sedigheh Fayazi

**Position**

Master Science In Nursing

**Other areas of specialty/work****Street address**

Nursing Dept, Ahvaz Jondishapur University of Medical  
Sciences, Golestan Road, Ahvaz.

**City**

Ahvaz

**Postal code****Phone**

+98 61 1373 2422

**Fax****Email**

Sadighe\_fa@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz Jondishapur University Medical of Sciences

**Full name of responsible person**

Maryam Heidari

**Position**

Master Science In Nursing

**Other areas of specialty/work****Street address**

Nursing Dept, Ahvaz Jondishapur University of Medical  
Sciences, Golestan Road, Ahvaz.

**City**

Ahvaz

**Postal code****Phone**

+98 61 1373 2422

**Fax****Email**

heidari.ma@ajums.ac.ir;

heidari.maryam84@yahoo.com

**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*