

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 2026

### The effect of self- care program based on the Orem self -care model on level of fatigue and quality of life of people with chronic obstructive pulmonary disease

#### Protocol summary

##### Summary

As mentioned study population are people with chronic obstructive pulmonary disease and purpose of this study assessment effect of self- care program based on the Orem self -care model on level of fatigue and quality of life of people with chronic obstructive pulmonary disease total sample size 66 people and 33 people in each group that taken randomly assigned to intervention and control groups. in this study The Blinding in data collection is done using 2 research assistant. Intervention by the researcher will be implemented after the needs assessment is a self-care program based on Orem Self Care Model designed in 4 sessions of 30 to 45 minutes for individual and group that the intervention group will be trained at the end of the fourth session taught content in the form of a booklet will be given to the intervention group. After 2 months, data collection is done by research assistant. In this study, Self-Care is independent variable and dependent variable is fatigue and quality of life. The inclusion criteria of chronic obstructive pulmonary disease at stage 2 or 3 based on GOLD criteria and the exclusion criteria exacerbation and their inability to self-care.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017030432764N2**  
Registration date: **2017-05-19, 1396/02/29**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-19, 1396/02/29

##### Registrant information

###### Name

Shahla Abolhassani

###### Name of organization / entity

Shahrekord University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3333 5648

###### Email address

abolhasani@skums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

vice-chancellor for research and technology affairs of shahrekord university of medical sciences

##### Expected recruitment start date

2017-04-03, 1396/01/14

##### Expected recruitment end date

2018-04-21, 1397/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of self- care program based on the Orem self -care model on level of fatigue and quality of life of people with chronic obstructive pulmonary disease

##### Public title

The effect of Orem Self Care Model on patients with chronic obstructive pulmonary disease

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Specialist physician diagnosis of COPD and documented in the log file! patient hospitalized! The patient's medical condition is stable! Patients with stage 2 or 3 Gold System! Lack of debilitating disease! The patient can do her daily activities without the need for oxygen! Willingness to cooperate in the study! Lack of mental illnesses and not used psychiatric drugs ! Do not treated patients fatigue with medication! understand the Conversation with the Persian language! The patient or the patient's family have literacy Exclusion criteria: Lack of motivation to continue cooperation! Based on Orem's self-care form calculated Patient self care needs 50 Percent and more! Lack of self-care program! exacerbation patient! At the same time receive other training programs

#### Age

From **30 years** old to **80 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **66**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

in this study the samples are randomly and using computer software divided into two experimental and control groups.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

##### Street address

Shahrekord University of Medical Sciences, Kashani street, Shahrekord

##### City

Shahrekord

##### Postal code

#### Approval date

2017-02-26, 1395/12/08

#### Ethics committee reference number

IR.SKUMS.REC.1395.315

## Health conditions studied

### 1

#### Description of health condition studied

Chronic obstructive pulmonary disease

#### ICD-10 code

J44.9

#### ICD-10 code description

Chronic obstructive: airway disease NOS lung disease NOS

## Primary outcomes

### 1

#### Description

fatigue

#### Timepoint

Before and after the intervention.

#### Method of measurement

Fatigue Severity Scale (FSS)

### 2

#### Description

Quality of Life

#### Timepoint

Before and after the intervention

#### Method of measurement

Quality of life questionnaire (SF-12)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: self-Care program Based on the needs of patients and based on the Orem self-care framework Will be designed. This self-care program is performed for 4 weekly individual and group sessions for 30 to 45 minutes and during a month in the intervention group. At the end of a four-session will be given training manual that includes a comprehensive collection of all the tips during four sessions and They will be asked to self-care program will run for two months. During the two months through a call or Show up and Self-assessment form review the implementation of the program and the samples are tips for better performance.

#### Category

Behavior

### 2

#### Description

Control group: The control group receive treatment and routine care through visiting by his doctor's at office.

#### Category

N/A

Type of organization providing the funding  
*empty*

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Hajar hospital

**Full name of responsible person**

Iman reiszadeh

**Street address**

Hajar hospital, parastar street, shahrekord

**City**

Shahrekord

2

### Recruitment center

**Name of recruitment center**

Kashani hospital

**Full name of responsible person**

Iman reiszadeh

**Street address**

Kashani hospital, parastar street, shahrekord

**City**

Shahrekord

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

vice-chancellor for research and technology affairs of  
Shahrekord University of Medical Sciences

**Full name of responsible person**

Kamal solati

**Street address**

Shahrekord University of Medical Sciences, Kashani  
street, Shahrekord

**City**

Shahrekord

**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 and technology affairs of  
Shahrekord 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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Iman reiszadeh

**Position**

medical surgical Nursing Graduate Student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Phd

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## Person responsible for updating data

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**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*