

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Orem self-care model application on activities of daily living status of chronic obstructive pulmonary disease patients hospitalized in education and treating centers of Urmia University of Medical Sciences in 2016

Protocol summary

Summary

The aim of this study is to evaluate the effect of Orem self-care nursing model on activities of daily living of chronic obstructive pulmonary diseases patients. This randomized clinical trial performed on two groups of patients that matched with inclusion criteria, like lack of mental illnesses, no drugs or psychotropic abuse and age range between 40 to 65 years. Exclusion criteria includes some conditions like non-participation in more than half of classes; not having access to a phone call with patient and family during the study; death due to illness or other events. Each group consisted of 30 patients, and after sampling, patients were randomly placed in one of the two groups of case and control. Need assessments according to Orem model, Demographic questionnaire and self-made activities of daily living for chronic obstructive pulmonary disease patients questionnaire were filled by the two groups, before the intervention. 6 to 8 training meetings according to Orem self-care nursing model were held for the intervention group and after that they were followed up for 45 days. No specific interventions were taken on the control group. after the intervention, activities of daily living for chronic obstructive pulmonary disease patients questionnaires were completed again by two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081729411N1**
Registration date: **2016-09-16, 1395/06/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-16, 1395/06/26

Registrant information

Name

Belal Babakhani

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 4622 2669

Email address

babakhani.b@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Orem self-care model application on activities of daily living status of chronic obstructive pulmonary disease patients hospitalized in education and treating centers of Urmia University of Medical Sciences in 2016

Public title

The effect of self-care education on activities of daily living status of chronic obstructive pulmonary disease patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age 40 to 65 year; Capable of reading and writing; Lack of mental illnesses; Residence in Urmia; Lack of cognitive, hearing, and vision impairment; Lack of education and employment in the medical group; lack of formal education about the disease; Having the ability and desire to participate in the study; Fluent in Persian language; capable of phone call communicate; No drugs or psychotropic abuse; Specified Chronic obstructive pulmonary disease Exclusion criteria: non-participation in more than half of classes; Not having access to a phone call with patient and family during the study; Not interested to continue the participation in the study; Death due to illness or other events

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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**

Urmia University of Medical Sciences

Street address

Orjans Alley, Resalat Street

City

Urmia

Postal code**Approval date**

2016-02-04, 1394/11/15

Ethics committee reference number

IR.UMSU.REC.1395.16

Health conditions studied**1****Description of health condition studied**

Chronic obstructive pulmonary diseases

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes**1****Description**

Activities of daily living

Timepoint

1 month before the intervention and 45 days after the intervention

Method of measurement

Chronic obstructive pulmonary disease Activities of daily living questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Two 1.5-hour lecture meetings in groups of 5-6 patient to explain a full definition of COPD, symptoms, risk groups, risk factors, methods of treatment, prevention and pulmonary rehabilitation were held. data were analyzed by SPSS software.

Category

Lifestyle

2**Description**

Intervention group: 6-8 meetings were held and divided by 5 steps: 1. Determine educational needs of patients self-care (According to Orem's need assessment model). 2. Application of self-care program in physical domain. 3. Application of mental and emotional self-care program domains. 4. Application of self-care program in social domain. 5. In final step of self-care program, the strengths and weaknesses of the program, new solutions and proper ways to implement the best solution to enhance the best self-care program to patients and their families has been described. Follow up: Self-care program was conducted by patients in 45 days. the questionnaire was given to patients to fill out for the second time after the intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Iraj Mohebbi

Street address

Shahrchayi, Kashani Street

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Urmia University of Medical Sciences

Full name of responsible person

Hossein Habibzadeh

Street address

Urmia University of Medical Sciences, Orjans valley, Resalat boulevard

City

Urmia

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, Urmia 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

Urmia University of Medical Sciences

Full name of responsible person

Iraj Mohebi

Position

Vice Chancellor for Research, Urmia University of Medical Sciences

Other areas of specialty/work

Street address

Shahrchayi, Kashani Street

City

Urmia

Postal code

Phone

+98 44 3344 4591

Fax

Email

babakhani.b@umsu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Belal Babakhani

Position

MSc Student of Nursery

Other areas of specialty/work

Street address

Halaniye 9 Alley, Moallem Street

City

Javanroud

Postal code

Phone

+98 83 4622 2669

Fax

Email

babakhani.b@umsu.ac.ir,
b.babakhani1007@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Iraj Mohebi

Position

Associate Professor

Other areas of specialty/work

Street address

Shahrchayi, Kashani Street

City

Urmia

Postal code

Phone

+98 44 3344 4591

Fax

Email

bababkhani.b@umsu.ac.ir

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