

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

A comparative study of the effects of individual versus group Self-management education on the health-related quality of life of patients with chronic obstructive pulmonary disease

Protocol summary

Summary

The purpose of this study is assessing the effect of individual versus group self-management education on the health-related quality of life of patients with chronic obstructive pulmonary disease. The study population is 150 patients with chronic obstructive pulmonary disease hospitalized in Hajar and Ayatollah Kashani hospitals that have inclusion criteria. Allocation of samples into three groups is based on non-randomized and controlled manner. For this purpose, first the names of three groups is written and draw by lot. Then patients on continuous order respectively put into groups that drawn by lot. So that the first 50 patients put in control group, then with one week gap to discharge the latest sample of this group, the next 50 patients put in individual group, then with one week gap to discharge the latest sample of this group, the last 50 patients put in group education. All subjects will receive standard care. Individual education group will receive face-to-face education while group education depending on the number of people with Chronic obstructive pulmonary disease in research environments at the same time will receive education through group discussion in groups up to 8 to 10 people. Educational content is same in all three groups, including self-management education for chronic obstructive pulmonary disease. Number of education sessions, including four sessions for 1 hour will be on consecutive days. Before and three months after the intervention, health-related quality of life for all groups with St. George's questionnaire will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070828781N2**
Registration date: **2016-10-08, 1395/07/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-08, 1395/07/17

Registrant information

Name

Farshad Heidari Beni

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 38 3372 3354

Email address

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Recruitment status

Recruitment complete

Funding source

Research funding of Iran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effects of individual versus group Self-management education on the health-related quality of life of patients with chronic obstructive

pulmonary disease

Public title

The impact of education on quality of life of people with chronic obstructive pulmonary disease

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria were: age 40 to 75 years, confirmed by a physician in the case of patient , in phase two or three disease (diagnosed by a doctor) , have the ability to understand and speak the Persian language , have the physical ability for interview and questionnaire , not Participate in earlier chronic obstructive pulmonary disease self-management programs , absence of mental illness , absence of pulmonary tuberculosis , active cancer and severe neurological problems , lack of hearing problems and problems associated problems. Exclusion criteria: disease progression to end-stage (four) or death of the patient , any signs , symptoms or diagnosis of wheezing (asthma) , bronchiectasis, pulmonary tuberculosis , pneumoconiosis and acute congestive heart failure during the study , absent in one education session , unwillingness to continue cooperation

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Not 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

Ethic Committee of Iran University Of Medical Science

Street address

Iran University of Medical Sciences ,Hemat Highway

City

Tehran

Postal code

Approval date

2016-03-05, 1394/12/15

Ethics committee reference number

IR.IUMS.REC.1394.9211196203

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 and 3 Month after intervention

Method of measurement

St. George's questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Individual education group depending on individual learning level and stage of disease will receive face-to-face education. Educational content includes self-management education for chronic obstructive pulmonary disease , which is composed of two components: stable chronic obstructive pulmonary disease self-management involves identifying and reducing risk factors , medication, non-pharmacological , monitoring and follow up and self-management in exacerbations . Number of education sessions is four sessions on successive days in 1 hour.

Category

Lifestyle

2

Description

Group education depending on the number of people with Chronic obstructive pulmonary disease in research environments at the same time will receive education through group discussion in groups up to 8 to 10 people . Educational content includes self-management education for chronic obstructive pulmonary disease , which is composed of two components: stable chronic obstructive pulmonary disease self-management involves identifying and reducing risk factors , medication, non-

pharmacological, monitoring and follow up and self-management in exacerbations . Number of education sessions is four sessions on successive days in 1 hour.

Category

Lifestyle

3

Description

The control patients will receive standard hospital care .

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Frashad Heidari Beni

Street address

Nurse st.

City

Shahrekord

2

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Frashad Heidari Beni

Street address

Nurse St.

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Room #503, 5th floor, Central building of Iran University of Medical Sciences, between Chamran and Hemmat Expways, Hemmat Expway

City

Tehran

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, Iran 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

Iran University of Medical Sciences

Full name of responsible person

Farshad Heidari Beni

Position

Nursing Msc Student

Other areas of specialty/work

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School of Nursing and Midwifery , No 6 , Rashid Yasemi st , Vali-e-asr Ave , Tehran, Iran

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Person responsible for scientific inquiries

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Full name of responsible person

Forough Rafii

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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