Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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

he 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

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Country

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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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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Forough Rafii

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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