The effects of self-treatment on duration of exacerbations, health status and costs of health care in patients with Chronic Obstructive Pulmonary Disease (COPD) and common co-morbidities.

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To investigate whether complex COPD patients are trained in the use of an individualised action plan for self-treatment have fewer COPD exacerbation days over 12 months compared to a control group. Secondary objectives are defined to investigate the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON39810

Source
ToetsingOnline

Brief title
COPE-III

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease; Chronic Obstructive Airway Disease;

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Nederlands Longfonds en Australian Lung Foundation

Intervention

Keyword: action plan, comorbidities, COPD, self-management

Outcome measures

Primary outcome

The primary outcome measure is the number of COPD exacerbation days (daily symptom diary).

Secondary outcome

Secondary outcome measures are health status (spirometry (FEV1, FVC); Health-Related Quality of Life (SF-12, Chronic Respiratory Questionnaire); subjective fatigue (Fatigue Score); anxiety and depression symptoms (HADS)), confidence and competence (COPD Self-Efficacy Scale); adherence of patients with self-treatment protocol (daily symptom diary); satisfaction and confidence of health care providers (semi-structured interviews) and patients (focusgroups); and cost data (cost-effectiveness analysis).

Study description

Background summary

COPD is a very common progressive lung condition with distressing exacerbations that regularly require medical intervention and hospitalisation. Whereas COPD action plans have now successfully become part of usual care, the plans are potentially less suitable and possible unsafe to use in the presence of comborbidities. Therefore, action plans should consider comorbidities. We hypothesise that this innovative self-treatment strategy will reduce

exacerbation severity and health care costs and improve patient*s health status by accelerating the initiation of proper treatment actions.

Study objective

To investigate whether complex COPD patients are trained in the use of an individualised action plan for self-treatment have fewer COPD exacerbation days over 12 months compared to a control group. Secondary objectives are defined to investigate the effect of a set of action plans for complex patients on hospitalisation days for COPD and relevant comorbidities, effects on overall health care use, (COPD-specific) health status, self-efficacy, the effects on chronic heart failure exacerbations, level of adherence of intervention patients, fatigue and anxiety and depression symptoms, satisfaction and confidence, effects on health care use, and cost-effectiveness of self-treatment intervention.

Study design

The COPE-III study is an international multicenter randomised controlled trial in COPD patients with comorbidities, with a 12-month follow-up. Patients will be randomly assigned to an intervention and a control group. Patients in the control group will receive usual care. All patients will be educated in completing their daily symptom diaries during 12 months. Only patients in the intervention group will participate in four self-management sessions to learn to work with an individualised action plan that is linked to a daily symptom diary. During the baseline measurements a 6 Minutes Walking Test and a spirometry test will be performed in the hospital and questionnaires have to be completed. The 6-month measurements will be collected via mailed or electronic questionnaires. In the end, the 12-month measurements will take place in the hospital where a spirometry test is performed and questionnaires have to be completed. The risks for patients are negligible and the burden is minimal.

Intervention

Intervention: self-management of COPD patients with comorbidities.

Patients will be randomised to receive the intervention will attend two individual one-hour sessions and two or three 2.0-hour group sessions guided by the study nurses. One, four, and eight months after completion of the self-management discussion sessions, the study nurse will contact the patient by phone, to reinforce self-management skills.
During the self-management course, patients will learn to treat their COPD exacerbations and/or flare-ups of comorbidities with the help of an action plan linked to the diary. The individual action plan shows the actions a patient has to take with a certain combination of symptoms. It will be repeatedly discussed with the patients during the sessions.

Besides training in self-treatment, the content and emphasis of the self-management program will be directed towards mastery of skills necessary for successful self-management, such as correct medication intake, and the early recognition of symptoms of an exacerbation of COPD and/or a flare-up of potential comorbidities.

Study burden and risks

The risks for patients are negligible and the burden is minimal. Patients will spend time related to the intervention and measurements. The 6 minute walking test is a regular test in pulmonary medicine, and will lead to increased brethlessness during the test. This is only transient. Medical treatment of the patients in this study is no other than in regular care. There is a chance that the patients who self-treat their symptoms will use more medication then necessary. However, investigators of a similar study, directed towards self-treatment in patients with solely COPD, concluded that over-treatment was not an issue in their study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) a clinical diagnosis of COPD according to the GOLD criteria (FEV1 < 80% of the predicted value and FEV1/FVC<0.70);
2) >= 1 diagnostic comorbidity: ischaemic heart disease (history of myocardial infarction, angina pectoris (stable or unstable); heart failure (defined according to the ESC guidelines); diabetes (steroid-induced or stable diabetes type 1 or 2); or active symptoms of depression and/or anxiety (AD) (using a cut-off score of >= 11 from the Hospital Anxiety and Depression Scale) (HADS) and/or having AD symptoms that are currently being treated;
3) >= 3 exacerbations, defined as respiratory problems that required a course of oral corticosteroids / antibiotics in the two years preceding study entry; and/or >= 1 hospitalisation for respiratory problems in the two years preceding study entry; and/or Modified MRC (mMRC) score of 3 or 4;
4) >= 40 years of age;
5) stable at the time of inclusion (at least 4 weeks post-exacerbation, 6 weeks post-hospitalisation or post-rehabilitation);
6) able to understand and read the Dutch language;
7) written informed consent from the subject prior to participation.

Exclusion criteria

1) terminal cancer or other serious disease with low survival rate;
2) end stage COPD or Chronic Heart Failure (expected survival < 12 months);
3) other serious lung disease (e.g. a1-antitrypsin deficiency; interstitial lung diseases);
4) patients who are currently enrolled in other randomised clinical trials.
5) Mini Mental State Examination score < 24

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2012
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-10-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-01-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	23-05-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	31-07-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-09-2013
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	16-09-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	ACTR number: ACTRN12612000514808
CCMO	NL39516.044.12