Advance care planning (ACP) in COPD.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28844

Source
NTR

Health condition

Advance care planning, end-of-life care, palliative care, Chronic Obstructive Pulmonary Disease (COPD)

Sponsors and support

Primary sponsor: Prof. E.F.M. Wouters, MD, PhD
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Source(s) of monetary or material Support: Lung Foundation Netherlands

Intervention

Outcome measures

Primary outcome

1. Quality of communication about end-of-life care;

2. Symptoms of anxiety and depression;

3. Quality of end-of-life care;

4. Quality of dying.

Secondary outcome

1. Patient's preferences for end-of-life care;

2. Received end-of-life care;

3. Psychological distress in bereaved family members of deceased patients with COPD.

Study description

Background summary

Background:

Advance care planning (ACP) is the process of communication between patients, family and professional caregivers that includes, but is not limited to, the completion off advance directives. ACP can change outcomes for patients and relatives. ACP may be particularly important for patients with Chronic Obstructive Pulmonary Disease (COPD). Data from patients, their family and physicians suggest that ACP is uncommon and poorly done. In a recent project we found that patients with advanced COPD are able to indicate their preferences for life-sustaining treatments. However, in only 6% of the patients, the patient and chest physician report having discussed these preferences. Patients rated their clinicians' skills at discussing end-of-life topics as poor.

We hypothesize that structured ACP by a trained nurse, in collaboration with the patient's physician, can improve quality of communication about end-of-life care, will not increase symptoms of anxiety and depression, and can improve quality of end-of-life care and quality of dying for patients with COPD as well as outcomes for bereaved family members of deceased patients with COPD.

Objectives:

Primary objectives of this study are to assess whether and to what extent structured ACP for patients with COPD can improve quality of communication about end-of life care; to study whether and to what extent structured ACP for patients with COPD may influence symptoms of anxiety and depression of patients and family members at six months after ACP; and to study whether and to what extent structured ACP for patients with COPD can improve quality of end-of-life care and quality of dying. Secondary objectives are to investigate whether structured ACP can improve concordance between patient's preferences for end-of-life care and the end-of-life care received; and to investigate whether structured ACP can reduce

psychological distress in bereaved family members of deceased patients with COPD.

Study design:

This study is a prospective randomized controlled trial.

Study population:

The study population will consist of 300 patients with severe to very severe COPD (Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage III or IV) discharged after hospital admission for an exacerbation of COPD and 1-3 family members per patient.

Intervention:

Patients and family members in the intervention group will receive a structured ACP session by a trained respiratory nurse specialist in their home environment within 4 weeks after discharge. Patients in the control group will receive usual care.

Primary study parameters:

The intervention and usual care group will be compared on changes in quality of communication; and symptoms of anxiety and depression. In patients who died, quality of death and dying; quality of end-of-life care; end-of-life care preferences and received end-of-life care will be compared between the intervention and the control group.

Study objective

1.1 Structured ACP for patients with COPD will improve quality of communication about end-of-life care.

1.2 Structured ACP for patients with COPD will not increase symptoms of anxiety and depression of patients and family members at six months after ACP.

1.3 Structured ACP for patients with COPD will improve quality of end-of-life care and quality of dying.

2.1 Structured ACP will improve concordance between patient's preferences for end-of-life

care and the end-of-life care received.

2.2 Structured ACP will reduce psychological distress in bereaved family members of deceased patients with COPD.

Study design

Interviews and questionnaires will be assessed during home visits at baseline and after 6 months in patients in the intervention and usual care group.

At baseline and after 6 months telephone interviews with the participating family members in the intervention and usual care group will take place.

Patients and family members in the intervention group will receive a structured advance care planning session <4 weeks after discharge.
Finally, patients in the intervention and usual care group will receive a phone call 12 months after enrolment. If patients deceased during the study period, a bereavement interview will be conducted with the participating family member.

Intervention

Intervention group:

Patients and family members in the intervention group will receive a structured advance care planning session by a trained respiratory nurse specialist in their home environment within 4 weeks after discharge.

Control group:

Patients in the control group will receive usual care.

Contacts

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Eligibility criteria

Inclusion criteria

1. A diagnosis of severe to very severe COPD (GOLD stage III or IV) according to GOLD guidelines;

2. Discharged after hospital admission for an acute COPD exacerbation;

3. At least one loved one, who will participate in the study.

Exclusion criteria

1. Unable to complete the study questionnaires because of cognitive impairment;

2. Unable to speak or understand Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-05-2013
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion
Date: 08-04-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40110
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3775
NTR-old	NTR3940
CCMO	NL42437.060.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40110

Study results

Summary results
N/A