A randomized controlled trial on the influence of structured advance care planning on quality of end-of-life care communication and quality of end-of-life care in patients with COPD.

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1.1 To study whether and to what extent structured advance care planning for COPD patients can improve quality of end-of-life care communication. 1.2 To study whether and to what extent structured advance care planning for COPD patients can...

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

Summary

ID

NL-OMON40110

Source
ToetsingOnline

Brief title
Advance care planning in COPD.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Astmacentrum Hornerheide
Source(s) of monetary or material Support: Nederlands Astmafonds

Intervention

Keyword: Advance care planning, COPD, End-of-life care, Palliative care

Outcome measures

Primary outcome

The main study parameters will be:

- Quality of communication about end-of-life care

- Symptoms of anxiety and depression

- Quality of end-of-life care

- Quality of dying

Secondary outcome

The secondary parameters will be:

- Patient*s preferences for end-of-life care

- Received end-of-life care

- Psychological distress in bereaved family members of deceased patients with

COPD

Study description

Background summary

Advance care planning (ACP) is the process of communication between patients, family and professional caregivers that includes, but is not limited to, the completion of 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 was 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 reported having discussed these preferences. Patients rated their clinicians' skills at discussing end-of-life topics as poor.

The hypothesis of the current study will be:
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 objective

1.1 To study whether and to what extent structured advance care planning for COPD patients can improve quality of end-of-life care communication.
1.2 To study whether and to what extent structured advance care planning for COPD patients can influence symptoms of anxiety and depression at 6 months after advance care planning.
1.3 To study whether and to what extent structured advance care planning for COPD patients can improve quality of end-of-life care and the end-of-life care received.
2.1 To investigate whether structured advance care planning can improve concordance between patient's preferences for end-of-life care and the end-of-life care received.
2.2 To investigate whether structured advance care planning can reduce psychological distress in bereaved family members of deceased patients with COPD.

Study design

The study will be a prospective randomized controlled trial in which patients, who were discharged after an acute COPD exacerbation or who started on oxygen therapy, will be assessed at baseline and 6, 12 and 24 months after enrolment. In addition, some patients who completed the study, will be selected for participation in a qualitative, structured interview about experiences with the advance care planning study. Patients will be selected based on purpose sampling until data saturation occured. A focus group interview will be held with participating respiratory nurse specialists to discuss their experiences

with regard to the advance care planning intervention.

Intervention

Respiratory nurse specialists will provide the structured advance care planning session in the patient's home environment in the presence of the patient and his or her loved ones. Respiratory nurse specialists will prepare the session with the chest physician in advance. The structured advance care planning session will pay attention to: reflection upon patient's goals, values and beliefs; understanding the current and future medical situation, possible treatments and outcomes; understanding life-sustaining treatments; determining wishes regarding current and future care; encouraging discussion of advance care planning with health care providers and loved ones; and appointment of a surrogate decision maker. The advance care planning session will be adapted to the patient's needs. The duration will be about 1.5 hours. Respiratory nurse specialists will be supervised regularly to guarantee quality of the structured advance care planning session.
After the structured advance care planning session, respiratory nurse specialists will complete, together with the patient, a feedback form showing patient's: general goals of care; preferences for life-sustaining treatments; and questions and concerns regarding end-of-life care. This feedback form will be provided to the patient, the chest physician and general practitioner.
Finally, patients will receive a brochure about palliative care for patients with COPD. This brochure is based on the Dutch guideline "palliative care for patients with COPD"and was developed for patients and their loved ones by the Netherlands Asthma Foundation.

Study burden and risks

Interviews and questionnaires will be assessed during home visits at baseline and after 6 months in patients in the intervention and usual care group (90-120 minutes per visit). At baseline and after 6 months telephone interviews with the participating family members in the intervention and usual care group will take place (20 minutes per interview). Patients and family members in the intervention group will receive a structured ACP session from about 1,5 hours. Finally, patients in the intervention and usual care group will receive a phone call 12 and 24 months after enrolment to assess survival status. If patients deceased during the study period, a bereavement interview will be conducted with participating family members.
In addition, some patients who completed the study, will be selected for participation in a qualitative, structured interview about experiences with the advance care planning study. Patients will be selected based on purpose sampling until data saturation occured. A focus group interview will be held with participating respiratory nurse specialists to discuss their experiences with regard to the advance care planning intervention.
If the hypothesis will be confirmed, the present project can be followed by

implementation of structured ACP by a trained respiratory nurse specialist in regular clinical care. In addition, the current project provides recommendations for (Dutch) guidelines on palliative care in COPD. There are no additional risks expected for the participants.

Contacts

Public
Astmacentrum Hornerheide

Hornerheide 1
Horn 6085NM
NL
Scientific
Astmacentrum Hornerheide

Hornerheide 1
Horn 6085NM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
- A diagnosis of severe to very severe COPD (GOLD grade III or IV or quadrant D) according to GOLD guidelines.
- Initiation of oxygen therapy or discharged after hospital admission for an acute COPD exacerbation.

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

Exclusion criteria

- Unable to complete the study questionnaires because of cognitive impairment.
- Unable to speak or understand Dutch.

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):	21-06-2013
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	08-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28844
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42437.060.12
OMON	NL-OMON28844