# COPD Palliative and Supportive care Implementation

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26565

**Source**
NTR

**Brief title**
COMPASSION study

**Health condition**

Chronic Obstructive Pulmonary Disease

### Sponsors and support

**Primary sponsor:** Lung Alliance Netherlands, Leiden University Medical Center, Radboud University Medical Center
**Source(s) of monetary or material Support:** ZonMw, The Netherlands Organization for Health Research and Development

### Intervention

### Outcome measures

**Primary outcome**

Difference in mean quality of life of patients in the intervention group versus the control group at 6 months, as measured with the Functional Assessment of Chronic Illness Therapy-Palliative care (FACIT-Pal) scale.

### Secondary outcome

Patient level: Spiritual wellbeing (FACIT-Sp-12), Anxiety and depression (HADS), satisfaction with care (NRS), number of ED visits (without admission), hospital admission (number and number of days), IC admission (number and number of days), in the 12 months pre-enrollment up to 12 months after enrollment, if applicable place of care in last week of life, time and place of death, patient-reported and documented received palliative care and advance care planning activities.
Informal caregiver level: Caregiver burden (CRA), satisfaction with care (NRS).
Healthcare professional level: Self-efficacy (End-of-life professional caregiver survey (EPCS)).
Process level: context, reach, dose delivered, dose received, fidelity, implementation level and recruitment, maintenance and acceptability, barriers and facilitators to implementation.

## Study description

### Background summary

Rationale: Despite the high burden of disease and low quality of life, most patients with advanced COPD do not receive palliative care. In the current project, we aim to integrate existing scientific and practical knowledge and implement integrated palliative care for patients with COPD.

Objective: The aim of this study is to compare the effect of implementation of integrated palliative care for patients with COPD on implementation level and on patient, informal caregiver and professional outcomes, versus usual care. Moreover, this study aims to give in-depth insight into the implementation process of the integrated palliative care intervention in order to inform future dissemination and upscaling.

Study design: cluster randomized controlled trial with evaluation of the implementation process using mixed methods (effectiveness-implementation hybrid design type 2) in eight regions in the Netherlands.

Study population: Patients with COPD admitted to the hospital for an acute exacerbation COPD and a high risk of death within one year according to the Propal-COPD tool.
Informal caregivers of participating patients.
Health care professionals from primary and secondary care of intervention teams of participating regions.

Intervention: Implementation of integrated palliative care for patients with COPD and their informal caregivers.

Outcome measures:
Primary: difference in mean quality of life of patients in the intervention group versus the control group at 6 months, as measured with the Functional Assessment of Chronic Illness

Therapy-Palliative care (FACIT-Pal) scale.
Secondary: spiritual wellbeing, anxiety and depression, unplanned healthcare use, satisfaction with care, place of death (if applicable), caregiver burden, professional's self-efficacy.
Implementation outcomes: context, reach, dose delivered, dose received, fidelity, implementation level and recruitment, maintenance and acceptability, barriers and facilitators to implementation.

### Study objective

The aim of this study is to investigate the effect of the implementation strategy on level of implementation of palliative care and the effects on patient, informal caregiver and professional outcomes. It is hypothesized that implementation of proactive integrated palliative care will result in higher quality of life of patients, reduced unplanned healthcare use and reduced caregiver burden. Moreover, this study aims to give in-depth insight into the implementation process of integrated palliative care in order to inform future dissemination and upscaling.

### Study design

Patients and informal caregiver questionnaires at baseline (admission) and after 3 and 6 months. Retrospective medical record assessment after 12 months. Professional questionnaires before the training and 3 and 12 months after the training.

### Intervention

An integrated palliative care intervention was developed based on existing guidelines, the Quality Framework Palliative care of the Netherlands, a literature review and input from experts. These comprise of identification of patients in need for palliative care (using the earlier developed Propal-COPD tool) during hospital admission, multidimensional palliative care assessment, advance care planning, the drafting of an anticipatory treatment plan, the provision of informal caregiver support including bereavement care, interdisciplinary collaboration between professionals and the optimization of continuity of care. To facilitate implementation of the intervention in the four intervention regions, a training for healthcare professionals and an online toolbox were developed. During the training, professionals of primary and secondary care will develop a regional action plan detailing how, when and where the core elements of the toolbox will be implemented into their daily practice. In this way, action plans all contain the same core elements, but are tailored and adapted to the needs and demands per region.
Four control regions will receive the training and online toolbox at the end of the study.

## Contacts

### Public

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# Eligibility criteria

## Inclusion criteria

Patients diagnosed with COPD and
• being admitted to the hospital for an acute exacerbation COPD.
• being able to complete questionnaires in Dutch.
• having a high risk of death within one year according to the Propal-COPD tool
Informal caregivers of participating patients.
Health care professionals from primary and secondary care of intervention teams of participating regions.

## Exclusion criteria

• Patients with severe cognitive decline (e.g. dementia)
• Patients on the waiting list for lung transplantation.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 16-04-2019 |
| Enrollment: | 347 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 07-04-2019 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL7644 |
| Other | CMO regio Arnhem-Nijmegen : file number 2018-4833 (non-WMO) |

## Study results