Action Plan to enhance self-management and early detection of exacerbations in patients with COPD; a Randomized Controlled Trial

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Primary Objective: To evaluate the effectiveness of an individualized AP (initiating early detection of exacerbations and prompt intervention) on recovery of symptom-based Quality of life in the event of an exacerbation. Secondary Objective(s): To...

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

Summary

ID

NL-OMON32089

Source
ToetsingOnline

Brief title
ACZiE

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Bronchitis, Chronic lung disease; COPD, Emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,Een aanvullende subsidie bij ZonMw wordt aangevraagd (subsidieronde Disease Management)

Intervention

Keyword: Action Plan, COPD, Exacerbations, Self-management

Outcome measures

Primary outcome

- (Clinical COPD Questionnaire) CCQ Symptom recovery time in the event of an

exacerbation; number of 3 day CCQ units

for the CCQ symptom score to have recovered from the exacerbation onset to

the pre-exacerbation 3 unit average.

Secondary outcome

- Treatmet delay (Number of days between exacerbation onset and initiation of

treatment; course of antibiotics and/or

prednison)

- Contact delay (Number of days between exacerbation onset and contacting a

health care provider

- Health related quality of life I (St.George Respiratory Questionnaire)

- Health related quality of life II (number of unfavourable days in 6 months

that the Clinical COPD Questionnaire (CCQ)

score is >= the individual mean minus 1 standard deviation)

- Anxiety (Hospital Anxiety and Depression Scale)

- Depression (Hospital Anxiety and Depression Scale)

- Symptoms (Medical Research Counsil scale for dyspnea)

- Self-efficacy (exacerbation-related self-efficacy using a self-developped

9-item questionnaire with a 5 point-likert scale.

- Healthcare utilization:

* time to first respiratory related hospital admissions; number of days between

inclusion and first hospital admission

* number of respiratory related hospital admissions

* proportion of patients having >= 1 respiratory related hospital admission

* number of respiratory related hospital days

* number of respiratory related emergency room visits (incl. ambulance calls)

* number of respiratory related scheduled visits to GP, RN and RP.

* number of respiratory related unscheduled visits to GP, RN and RP.

* number of telephone calls to GP, RN and RP.

* number of courses of oral steroids and/or antibiotics

Study description

Background summary

Exacerbations of COPD have large impact on Health Related Quality of Life (HRQoL), mortality and lung function decline. Early detection of changing symptoms/signs and exacerbations by COPD patients initiating prompt interventions has shown to be clinically relevant. Until now, research failed to identify the effectiveness of a written individualized action plan (initiating early detection and prompt intervention) as an addition to usual care.

Study objective

Primary Objective: To evaluate the effectiveness of an individualized AP (initiating early detection of exacerbations and prompt intervention) on recovery of symptom-based Quality of life in the event of an exacerbation.

Secondary Objective(s): To evaluate the effectiveness of an individualized AP (initiating early detection of exacerbations and prompt intervention) on recovery of symptoms and treatment delay (in the event of a symptom-based exacerbation) healthcare utilisation, HRQoL, anxiety, depression, symptom severity and self-efficacy.

Study design

A multicenter, single-blind, randomized controlled parallel study with a 6 months follow up period, comparing a written and individualized AP (as an addition to care as usual) with care as usual.

Intervention

Patients in the intervention group receive and are taught how to use a written and individualized Action Plan (AP) as an addition to care as usual. This AP provides patients, a invidualized and colour- coded overview of their stable and deteriorated respiratory related symptoms/signs. In addition, the AP provides individualized treatment prescriptions (both pharmaceutical and non-pharmaceutical) related to the the colour coded symptom status. The AP is made of double printed A3 size paper, which is folded as a brochure, but can also be attached as a poster. The patient is instructed to bring the AP to every visit to the GP, RP, RN, physiotherapist and dietician. In these visits, the AP can be changed or made complete by one of these healthcare providers.

Study burden and risks

Burden and risks are minimal since care as usual is guaranteed which is checked by patients* general practitioner or respiratory physician. The AP provides a visual overview of treatment prescriptions and does not aim at changing but underlines care as usual. Patients are asked to register variations from their stable condition using symptom diary cards for the duration of 6 months. At baseline and at 6 months follow-up patients are asked to fill in a questionnaire. Every month (in total 6 times), healtcare utilization is evaluated briefly by telephone.

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

- Diagnosis of COPD based on post-bronchodilatator FEV1 according to the GOLD standards (=NHG standard).
- Diagnosis of COPD as the major functionally limiting disease.
- Current use of bronchodilator therapy.

Exclusion criteria

- Primary diagnosis of asthma (onset < 35 years, >= 12 % postbronchodilator reversibility in FEV1)
- Primary diagnosis of cardiac disease
- Primary diagnosis of other functionally limiting disease, that could significantly affect either patient mortality (e.g. malignant neoplasm) or participation in the study (e.g. confusional states, psychoses)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-12-2008
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	14-10-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-12-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL22904.041.08