RECODE, cluster Randomized clinical trial on Effectiveness of integrated COPD management in primary carE

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RECODE aims to assess the (cost) effectiveness of an ICT-supported, integrated, multidisciplinary two-year treatment of COPD in primary care as compared to usual care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34790

Source
ToetsingOnline

Brief title
RECODE

Condition

- Respiratory disorders NEC

Synonym
chronic bronchitis, COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW Doelmatigheid,Stichting Achmea Gezondheidszorg

Intervention

Keyword: Chronic Obstructive Pulmonary Disease, COPD, Cost-Effectiveness-Analysis, Integrated Care, Primary Care, Quality of Life

Outcome measures

Primary outcome

The primary outcome of this study is the difference in severity of respiratory symptoms as measured by Clinical COPD Questionnaire (CCQ) at baseline and after 12 months between patients in the intervention practices and patients in the usual care practices. The CCQ is well-validated, easily applied in primary care and sufficiently sensitive to change. The power calculation has been based on a validated clinically relevant difference of 0.4pts on the CCQ.

Secondary outcome

Secondary outcomes are differences in:

Secondary outcome measures (at 6, 9, 12, 18, 24 months) are differences in:

-disease-specific quality of life (SGRQ-C)

-dyspnoea (MRC dyspnoea scale)

-patients* experiences (CQ-index)

-utility (EQ-5D and SF-36)

-self management skills (SMAS)

-daily activities (IPAQ)

-health care use

-absence from paid work

-exercise tolerance (6MWD)

-medication use (inhaled corticosteroids and bronchodilators)

-exacerbations (oral prednisolone and/or antibiotic courses)

-hospital admissions

-lung function measurements (FEV1 absolute and predicted, FEV1/FVC)

-smoking behavior (pack years, guided cessation attempts)

-body mass index (BMI)

-experiences of health care workers (ACIC)

Study description

Background summary

COPD is a worldwide growing healthcare problem, which according to the World Health Organization will be the third leading cause of death by 2020. Given the rise in prevalence and complex treatment, COPD also constitutes an important financial burden that confronts health care providers with increasing treatment capacity shortages. The most effective treatment of COPD is, besides smoking cessation,
pulmonary rehabilitation, of which elements can be implemented successfully in primary care setting. Pulmonary rehabilitation consists of an integrated, multidisciplinary treatment of COPD. Beneficial effects are well established in severe to very severe patients and significant improvements in exercise capacity, dyspnoea and health-related quality of life have been reported.Pulmonary rehabilitation relieves dyspnea and fatigue, improves emotional function and enhances patients' control over their condition. However, it is a costly intervention, is mainly applied in secondary and tertiary care, and progressively leads to healthcare capacity shortages. In addition, patients are not intrinsically motivated to continue a more active and healthy lifestyle after treatment, as is it is organized in secondary and tertiary care, mostly during only limited periods of time. In past few years, elements of pulmonary rehabilitation like physiotherapeutic reactivation, patient education, exacerbation management, assisted smoking cessation and selfmanagement have been applied in primary care COPD management programmes, which are also accessible for mild to moderate patients. Encouraging results have been reported for patients with less advanced COPD: one-year clinically relevant improvements of exercise tolerance, dyspnea and disease-specific quality of life.
In conclusion, especially the highly prevalent early stages of GOLD I and II, together representing approximately 80% of the Dutch COPD-population, are eligible for such primary care interventions. The largest expected changes in

care will be achieved in shifting the current over prescription of inhaled steroids (according to the Dutch NHG COPD Guideline only indicated in <20% of the primary care COPD-population in the Netherlands) towards structural application of important non-medical interventions. These interventions include smoking cessation, reactivation and selfmanagement, supported by symptom-driven bronchodilator therapy. COPD-care constitutes an increasingly important topic in Dutch primary healthcare, driven by a large-scale shift of secondary and tertiary care towards treatment in primary care. In the majority of cases effective interventions are possible, but a proper evidence-base of cost-effectiveness is currently lacking.
In conclusion, favorable long-term effects on exercise tolerance and quality of life have been demonstrated, but wide introduction in the Dutch primary care setting still needs further justification in the form of a proper cost-effectiveness analysis.

Study objective

RECODE aims to assess the (cost) effectiveness of an ICT-supported, integrated, multidisciplinary two-year treatment of COPD in primary care as compared to usual care.

Study design

This study will be structured according to a two-group cluster-randomized design. Participating general practices will be divided in strata according to the characteristics both of the practice and of the GPs (age, gender, practice population size, practice situation, percentage ethnic minorities). Within these strata, practices will be randomized (by computer), either to the intervention group or to the control group. Randomization will be done after base line measurements have taken place. The effects of the 2-day course and the consecutive feedback and support, using the full application and the refresher course after one year will be measured versus usual care. The primary endpoint has been chosen at 12 months, while the total study duration provides two years of follow-up.

Intervention

The intervention consists of the aforementioned multidisciplinary course, clinical and logistical feedback and support of implementation of an ICT-based web application. During this course, Dutch primary teams will be trained during a multidisciplinary (general practitioners, practice assistants, specialized physiotherapists) 2-day course. This course will emphasize on efficient task delegation within the team, active involvement of the patient in treatment planning and designing time-contingent practice plans to improve COPD management. The accrediting course was developed according to the recent national NHG Guidelines, and is provided by experienced teachers who have taken

part in the development of NHG Guidelines. This course was fine-tuned successfully in the South and West of the Netherlands during the past four years. The intervention will be provided with a flexible web-based disease management application. This application has been tested extensively by end-users in the past year and is named Zorgdraad (www.zorgdraad.nl). Zorgdraad is essentially an optimally secured electronic patient file, accessible for patients and authorized healthcare providers. It is available free of cost for course participants and their patients. The application stimulates selfmanagement by patients, generates automated feedback on correct use of guidelines, and provides clinically relevant indicators to promote structural application of a chronic care optimalisation model. The application will continuously generate automated feedback and regular tailored benchmark reports. An additional refresher course will be offered after one year. Control primary care teams will not receive the 2-day course, nor the consecutive feedback from the Zorgdraad application.

Study burden and risks

Patients: At 0, 6, 9, 12, 18, and 24 months research nurses will deploy a 45-minute questionnaire package in all patients including the abovementioned questionnaires.
At 0, 6 and 12 months these will be scheduled individually with patients, while at 9, 18 and 24 months these measurements will be postal. Besides paper versions of the questionnaire, we will provide electronic versions of the questionnaires, which can be deployed depending on the preference of a patient. In the intervention group, patients will receive access to a flexible web-based application which will provide them education and space for personal notes, which can be used according to ones personal preferences. In addition, the research nurses will extract data regarding lung-function measurements, exacerbations, pulmonary medication use, hospital admissions, current smoking behavior and 6MWD results from practice patient files at 0, 6, and 12 months, taking approximately one-hour per patient each time.

For health care providers, the multidisciplinary course will take 2 days and 0,5 day refresher course after one year. Implementation of ICT in their primary practice will take one day.

There are no risks of participation. Treatment options all fall within current guidelines.

Implementation of the integrated care program leads to improved exacerbation management in practice and more efficient task delegation within the treatment team. Enthusiasm among health care providers will rise, as outcomes at patient level improve measurably. We expect healthcare workers participating in this educational program to improve communication between different workers, better adherence to guidelines, and by those means improve the quality of care.

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

COPD (FEV1/FVC<0.7) according to GOLD and NHG-classification

Exclusion criteria

terminally ill patients and (hard drugs) substance abusers

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2010
Enrollment:	1080
Type:	Actual

Ethics review

Approved WMO

Date:	03-06-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
ClinicalTrials.gov	NCTnummer2268
CCMO	NL31833.058.10