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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22200

Source
NTR

Brief title
RECODE-study

Health condition

Chronic Obstructive Pulmonary Disease
COPD
Primary Care
Integrated Care
Quality of Life
Cost-Effectiveness-Analysis
Chronische obstructieve longziekten
COPD
Huisartsgeneeskunde
Geintegreerde zorg
Kwaliteit van Leven
Kosteneffectiviteits analyse

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for

Health Research and Development
Stichting Achmea Gezondheidszorg Netherlands

Intervention

Outcome measures

Primary outcome

The primary outcome of the study is the difference in health status of the participants in the intervention group versus the usual care group after 12 months, as measured with the Clinical COPD Questionnaire (CCQ).

Secondary outcome

1. Disease-specific quality of life (SGRQ);

2. Dyspnoea (MRC dyspnoea scale);

3. Quality of life (SF-36, EQ-5D);

4. Self-management (SMAS);

5. Daily activities (IPAQ);

6. Patients' experiences with health care (PACIC);

7. Smoking behaviour (packyears, guided cessation attempts);

8. Medication use (inhaled corticosteroids and bronchodilators);

9. Health care usage;

10. Exacerbations (oral prednisolone and/or antibiotic courses);

11. Hospital admissions or specialist visits;

12. Absence of work;

13. Primary care providers’ experience with health care (ACIC)

Study description

Background summary

Introduction:

COPD is a worldwide growing healthcare problem, which will be the third leading cause of death by 2020. COPD also constitutes an important financial burden that confronts health care providers with increasing treatment capacity shortages. The most effective treatment of COPD is pulmonary rehabilitation, of which elements can be implemented successfully in primary care setting. Favorable long-term effects on 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.

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:

Two-group cluster-randomized design in which a multidisciplinary course and support of implementation will be randomized per (local) cluster of primary care teams, after baseline measurements have taken place.

Study population:

Primary care COPD patients (FEV1/FVC<0.7) according to GOLD and NHG-classification.

Intervention:

A multidisciplinary (GPs, physician assistants and physiotherapists) course in which efficient task delegation, specific referral, and development of feasible treatment plans and practice plans are emphasized. Active promotion of self-management, incorporated feedback on specific parts of disease management, application of clinically relevant indicators of quality of care and structurally deploying a chronic care-optimalization model are all part of the implementation package, which is supported by a flexible web-based application.

Outcome measures:

Primary: The difference in functional status of the participants in the intervention group versus the usual care group after 12 months, as measured with the Clinical COPD Questionnaire(CCQ).
Secondary : Disease-specific quality of life (SGRQ), dyspnoea (MRC dyspnoea scale), Quality of life (SF-36, EQ-5D), self-management (SMAS), Daily activities (IPAQ), Patients experiences with health care (PACIC), smoking behaviour (packyears, guided cessation attempts), medication use (inhaled corticosteroids and bronchodilators), health care usage, exacerbations (oral prednisolone and/or antibiotic courses), hospital admissions or specialist visits, absence of work, primary care providers' experience with health care (ACIC).

Sample size:

1080 patients, 2 yrs follow up (primary endpoint 1 yr).

Economic evaluation will include the program costs, costs of implementation strategies and all other downstream costs of COPD-related care. Costs of productivity loss due to absence from paid work will be included. Incremental costs will be compared to differences in QALYs.

Study objective

An ICT-supported, integrated, multidisciplinary treatment of COPD in primary care compared to usual care in primary care practices will improve the quality of life of COPD patients at an acceptable level of cost-effectiveness.

Study design

1. Baseline;

2. 6, 9, 12, 18 and 24 months of follow up.

Primary endpoint at 12 months follow up.

Intervention

The intervention in 20 Dutch primary care practices consists of a multidisciplinary (general practitioners, physician assistants and physiotherapists) course in which efficient task delegation, specific referral, and development of feasible treatment plans and practice plans are emphasized. Active promotion of self-management, incorporated feedback on specific parts of disease management, application of clinically relevant indicators of quality of care

and structurally deploying a chronic care-optimalization model are all part of the implementation package, which is supported by a flexible web-based application. This highly integrated information can be accessed according to authorisation status, leading to the unique combination of reactivating self management and multidisciplinary COPD-care.

The control group of 20 Dutch primary care practices will continue usual care according to current guidelines, and will not be offered group training, self management support, clinical feedback or bench-mark information.

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Eligibility criteria

Inclusion criteria

Primary care patients with COPD (FEV1/FVC<0.7) according to GOLD and NHG-classification.

Exclusion criteria

Terminally ill patients and expected non-compliance according to GP.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	1080
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-03-2010
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	NL2144
NTR-old	NTR2268
Other	LUMC projectnr / ZonMW projectnr : 20513 / 171002203 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Hoogendoorn M, van Wetering CR, Schols AM et al. Is INTERdisciplinary COMmunity-based COPD management (INTERCOM) cost-effective? Eur Respir J 2010; 35(1):79-87.
Chavannes NH, Grijsen M, van den Akker M et al. Integrated disease management improves one-year quality of life in primary care COPD patients: a controlled clinical trial. Prim Care Respir J 2009; 18(3):171-176.
Kruis AL, Chavannes NH. Potential benefits of integrated COPD management in primary care. Monaldi Arch Chest Dis 2010; 73:3, 130-134.
Kruis AL, van Adrichem J, Erkelens MR, Scheepers H, in ’t Veen H, Muris JWM, Chavannes NH. Sustained effects of integrated COPD management on health status and exercise capacity in primary care patients. Int J Chron Obstruct Pulmon Dis. 2010; 5, 407-413.