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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22200

Bron
NTR

Verkorte titel
RECODE-study

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development
Stichting Achmea Gezondheidszorg Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Baseline;

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

Primary endpoint at 12 months follow up.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2010

Aantal proefpersonen:	1080
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2144
NTR-old	NTR2268
Ander register	LUMC projectnr / ZonMW projectnr : 20513 / 171002203 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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.

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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.