The influence of variations in implementation of a COPD disease management program across primary care teams on costs and effects

Master thesis

Student:	Simone Huygens (332771)
Supervisor:	Prof. Maureen Rutten-Van Mölken
Co-evaluators:	Melinde Boland and Apostolos Tsiachristas
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Erasmus University Rotterdam
Institute of Health Policy and Management (iBMG)
Master Health Economics, Policy and Law
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Abstract

Background: The implementation of disease management (DM) is expected to differ between practices. Variations in the implementation can be caused by differences in translation from the intervention to the specific practice caused by different starting levels of DM and different barriers and facilitators influencing the implementation. The implementation variations will probably have an impact on costs and effects of DM. Failing to recognize these differences in implementation may lead to inappropriate conclusions about the cost-effectiveness of DM. Therefore this study focused on the relationship between implementation of the intervention and costs and effects.

Methods: This study combined qualitative and quantitative research methods to enable a comprehensive evaluation of the implementation of the RECODE intervention. In the qualitative part the implementation variations between practices were explored by conducting interviews with practice nurses (or GPs). This part also paid attention to barriers and facilitators of implementing DM. The outcomes of the qualitative research were used to estimate scores on 18 indicators that represent the implementation of aspects of the RECODE intervention. In addition to the separate indicators, subtotal scores for the implementation of CCM elements and total implementation scores were calculated. The quantitative part of this study used these implementation variables to investigate the influence of implementation variations on costs and effects of DM.

Results: The results of this study confirm the expectation that the RECODE intervention gets tailored to the specific practice and therefore the implementation varies between practices. The variations emerged because of different starting levels of DM and barriers and facilitators encountered during the implementation. The implementation variations (represented by the implementation variables) could not explain most of the differences between practices in changes in costs and effects between baseline and 18 months after the start of the RECODE study. The few significant influences that were found had an unexpected direction; implementing (more aspects of) DM resulted in poorer disease-specific quality of life (higher CCQ scores). Some findings were consistent with the expectations. First, the use of funding for physiotherapy improved dyspnea (lower MRC scores) of patients. Second, the implementation of individual treatment plans increased the generic quality of life (higher EQ-5D scores) in the subgroup of patients with more COPD symptoms (MRC>2).

Conclusion: The implementation variations this study identified did not explain most of the differences between the practices in cost and effects. Therefore it is desirable to elaborate on the findings in this study and further explore the heterogeneity between practices and its influence on costs and effects of DM. This information could support future cost-effectiveness studies to give more accurate conclusions about the cost-effectiveness of DM.

1. Introduction

Chronic obstructive pulmonary disease (COPD) is a serious health problem in many countries throughout the world and is projected to be the leading cause of deaths and disability in 2030.[1-3] The majority of the COPD patients (over 80%) has mild to moderate COPD and can therefore be treated in primary care.[4,5] Disease management (DM) is considered as an effective way to treat COPD patients in primary care.[6-9] It is expected that DM programs will reduce healthcare costs. However, there is little evidence of the cost-effectiveness of DM programs for COPD patients in primary care.[6-8]

Considering the rising number of patients with chronic diseases and the limited resources for healthcare, research on the implementation, costs and cost-effectiveness of DM programs is increasingly relevant.[8] To answer the demand for more information about the long-term clinical and cost effectiveness of DM for COPD patients in primary care, the RECODE study is founded. RECODE is a cluster-randomized trial with two years follow-up. Forty clusters of primary care teams (with a total of 1086 COPD patients) are randomized to DM or usual care.[10] In a two-day multidisciplinary course the teams are trained in the essential elements of effective COPD rehabilitation in primary care according to the RECODE program. After the course the teams design their individual practice plan. The teams are supported with the implementation of their plan by ICT feedback, feedback reports and refresher courses at six and twelve months after the start of the RECODE study. It is expected that the implementation of DM will differ across primary care teams. After all, in each setting the involved actors will adapt the RECODE program to their own context in their own way.[11] In addition, the primary care teams will face different barriers and facilitators that respectively hinder or facilitate the implementation of the intervention. These differences will probably have an impact on costs and effects of the DM program. Failing to recognize these differences in implementation may lead to inappropriate conclusions about the cost-effectiveness of the DM program. Therefore this thesis focuses on the relationship between implementation of the intervention and costs and effects, asking the question:

'How do variations in implementation of an integrated, multidisciplinary DM program for COPD patients between primary care practices explain differences in costs and effects of this program?'

This question can be divided into four sub-questions:

a. How does the implementation of a DM program for COPD patients vary across practices?
b. What important facilitators or barriers were encountered during the implementation?
c. Do implementation variations explain differences between practices in the effects of the DM program for COPD patients?

d. Do implementation variations explain differences between practices in the costs of the DM program for COPD patients?

In the next chapter the research question is embedded in a theoretical framework. Subsequently, the research methods are explained in chapter three. In chapter four the results are described. The discussion of the results and conclusion are provided in chapter five.

2. Theoretical framework

In this chapter the research questions will be embedded in a theoretical framework. The following will discuss the concept of DM and the costs and effects of DM for COPD patients in primary care (§2.1), the DM intervention of the RECODE study (§2.2) and theories that can explain variations in implementation of the RECODE intervention (§2.3).

2.1 Disease management

Healthcare systems are often not designed to provide optimal care to patients with chronic diseases such as COPD, because they have evolved around the concept of acute, infectious disease, and they perform best when addressing patients' acute and urgent symptoms.[12] Without change, healthcare systems will grow increasingly inefficient and ineffective.[12] Recognition of this shortcoming has led to new strategies for care delivery, including the concept of DM.[13] DM can be defined as *"an organized, proactive, multi-component, patient-centred approach to healthcare delivery that involves all members of a defined population who have a specific disease entity (or a subpopulation with specific risk factors). Care is focused on and integrated across the entire spectrum of the disease and its complications, the prevention of comorbid conditions, and relevant aspects of the delivery system."*[14]

2.1.1 The Chronic Care Model (CCM)

DM programs are often based on the CCM.[15] The CCM is not a discrete, immediately replicable intervention; it is a framework that allows care delivery organizations to translate general ideas for change into specific often locally distinctive applications. As a result, the specific practice changes associated with a particular CCM element vary from organization to organization and from country to country.[16]

The core of this model is the productive interaction between informed, activated patients and prepared, proactive teams of healthcare providers. These interactions result in improved functional and clinical outcomes for patients' disease management.[17-19] This goal can be accomplished through the combination of six evidence-based elements.[16,20] The first element, self-management support, aims to activate and inform patients and families to better cope with the challenges of living with and treating the chronic illness.[17] Decision

support is the second element and enables healthcare providers to have productive patient interactions by assuring that they have the expertise to provide appropriate clinical and behavioural management.[17] Thirdly, the delivery system design implies changing the organization of systems and work to meet the needs of patients with chronic illness and complies with protocols or guidelines. The fourth element, clinical information systems, facilitates the collection of a richer array of information about patients, the useful organisation of and easy access to the information.[20] The healthcare system is the fifth element, this can influence the change process by changing the organizational culture and priorities.[20] Finally, the CCM displays the health system as a part of the larger community.[17] The CCM was designed to build on the relationships between these six elements that lead to improved clinical quality; therefore changes are necessary across most or all of the six elements.[16]

2.1.2 Costs and effects

It is widely believed that DM programs reduce healthcare expenditures, but the evidence for this claim is still inconclusive.[21] A recently performed literature review and meta-analysis provided an overview of the current evidence.[22] DM programs for COPD patients initiate more intense treatment in primary care practices which leads to increased healthcare utilization costs. However, the intense treatment leads to prevention of hospital admissions or reduction of the length of hospital stay and therefore DM programs lead to savings in hospital costs.[22] Overall disease management programs result in average healthcare utilization savings of €898 per patient, but there is a lot of variation within the studies.[22] Furthermore, it should be noted that the costs of developing, implementing and operating a DM program were excluded from this estimate. Therefore it is possible that DM programs could result in lower cost savings or even costs increases when all relevant costs are included.[22] The review also showed that savings in healthcare costs were greater when patients received 2 or even 3 or more interventions within different CCM elements in DM.[22]

The effectiveness of DM programs is shown in several studies using different outcome measures. DM programs are associated with improvements in the quality of patient care.[23-25] The greatest improvements were for patient satisfactions, patient adherence to treatment recommendations, disease control, and provider adherence to guidelines.[23] The study of Kruis et al. showed that DM improved and sustained health status and exercise capacity in primary care COPD patients during two years of follow-up. The improvements in health status are the strongest in patients with baseline MRC dyspnea score above two.[7] The review of Boland et al. also demonstrated positive results of DM programs on biomedical, physiological health outcomes and the quality of life in COPD patients.[22]

Even though there are studies that provide information about the costs and effects of DM programs for COPD patients in primary care, the need for more confirming evidence is still

present. The RECODE study can fulfil this need by performing research targeted at the cost-effectiveness of DM in primary care.

2.2 Intervention of the RECODE study

The intervention of the RECODE study (acronym for Randomized Clinical Trial on Effectiveness of integrated COPD management in primary care) contains elements of every CCM elements except community. The classification of the aspects of the intervention in CCM elements can be found in appendix A.

The primary care teams participating in the RECODE study (except for the teams in the control group) were given a two-day multidisciplinary course to educate them about the RECODE program. This course was developed according to recent national and international guidelines and was provided by teachers with hands on experience with the program.[10] The multidisciplinary teams consisted of at least three members: the general practitioner (GP), the practice nurse and a cooperating physiotherapist specialized in COPD. Optionally, the team could have been supplemented with a dietician and a pulmonologist. During the course essential elements of effective pulmonary rehabilitation in primary care were explained, trained, rehearsed and supervised (appendix B).[10] The participants of the RECODE study received access to a flexible web-based DM application, named 'Zorgdraad'. During the course an experienced instructor provided the teams with information about 'Zorgdraad'. 'Zorgdraad' supports providers by giving them access to a protocol for COPD follow-up guidance, quality of life scores, physiotherapy follow-up and examination, smoking cessation and medication records.[10] At the end of the course, the multidisciplinary team designs an individual practice plan. This plan describes the steps to be taken in order to integrate the DM intervention for COPD patients into daily practice. The teams are supported in developing and implementing their plan by ICT feedback, feedback reports and refresher courses at six and twelve months after the start of RECODE.[10]

2.3 Implementation variations

Although DM programs are based on similar ideologies of patient-centred coordinated care, the realization of these programs varies widely among healthcare settings.[11,26,27] The multidisciplinary teams participating in the RECODE study are free in the fulfilment of their plans. Therefore it is expected that there will be variations in the implementation of the RECODE intervention between primary care teams. This paragraph will discuss three theories that can explain these variations; diffusion of innovations,[28] tailoring of interventions to the local context and the four domains of barriers and facilitators of change.[29]

2.3.1 Diffusion of innovations

Rogers developed a theory about the process to get a new idea adopted: the diffusion of innovations.[28] This theory makes a distinction between diffusion and dissemination. Dissemination can be referred to as planned, systematic efforts designed to make a program or innovation more widely available to the members of a social system.[30] Diffusion can be defined as the process in which an innovation is communicated through certain channels over time among the members of a social system.[28] Diffusion is the outcome of the dissemination efforts.[30] The RECODE study can be seen as a dissemination effort to stimulate the adoption of DM by primary care teams (members of a social system). The primary care teams do not adopt the innovation at the same time. Moreover, there can be differences in time of adoption between members of primary care teams. The primary care teams or members can be classified in adopter categories on basis of innovativeness. Innovativeness is the degree to which a primary care team (member) is earlier in adopting new ideas than other members of a system. It is a relative dimension, in that a primary care team has more or less of this variable than others in a system.[28] Rogers defined five adopter categories – innovators, early adopters, early majority, late majority and laggards – where innovators are the first and laggards the last members of the social system who adopt the innovation.[28] This theory can explain why primary care teams adopt the DM program at different times; some primary care teams may have already adopted some aspects of the DM program before the RECODE study started, while others have not even started implementing DM.

2.3.2 Tailoring of the intervention to the local context

The theory of tailoring can be used to explain how the RECODE intervention can change in the process of traveling from a global to a local level. A DM program – a technology – is often developed as a general program or model. When these programs are implemented in practice it needs application at the local context; translation.[11] The principle of translation entails that technologies are always in the hands of their users and are thus employed, used, abused and changed in and through the practices of use.[31] This means that during a translation process from a global to a local level, the intervention gets tailored to the unique characteristics of each practice and incorporates the heterogeneity of patients and healthcare providers.[11,32] As a result of this tailoring, the intervention may be more likely to become incorporated into the structure and function of daily operations resulting in sustainable effects.[32,33]

2.3.3 Influencing factors: barriers and facilitators

During the implementation of the intervention the primary care teams will face different barriers and facilitators that respectively can hinder or facilitate the implementation. These influencing factors can lead to implementation variations across the practices. The barriers and facilitators can be ordered by their content in four different domains: individual, social, organisational or societal factors.[29]

The individual domain consists of cognitive, motivational, behavioural factors and personal characteristics. The cognitive factors include individual knowledge, use of information and decisions by healthcare providers. Finding and understanding new insights is crucial for the implementation of innovations. Therefore healthcare providers need cognitive skills to search and interpret information (e.g. participating in courses and conferences, contacts with colleagues and medical magazines). The motivational factors influence the intention to realise a specific behaviour or behavioural change. Healthcare providers can have different motives to change their behaviour, for example dissatisfaction with own performance or the attitude with respect to innovation. The behavioural factors and personal characteristics can take many forms; for example possessing specific skills that are needed to apply new insights, but also the tendency to accept risks.[29]

In the social domain professional development, professional teams and professional networks can influence the implementation of innovations. The professional development influences the acceptation of innovations. The implementation of an innovation in a professional group is difficult when the innovation is in conflict with the professional insights and standards. Aspects of the functioning of professional teams that can influence the implementation of innovations are for example the attitude with respect to innovations, the vision of the team and sense of security to have input and actively participate. In addition to being part of professional teams, healthcare providers are part of different professional networks (e.g. network at the workplace or (inter)national network of similarly trained professionals). The networks can influence the diffusion and implementation of innovations.[29]

In the organisational domain the implementation of innovations can be influenced by the organisations' structures and work processes, organisational processes and the availability of the necessary resources. According to Grol and Wensing the distinction between a team of professionals and a small organisation, like a primary care practice, is not always clear.[34] Therefore, this study did not make a distinction between the functioning of the primary care teams and the organisations' structures and work processes. This means the barriers and facilitators related to the organisations' structures and work processes are only included in the social domain. The organisational processes include the internal and external communication processes in an organisation. Internal communication is necessary to exchange ideas; external communication is required to discover new products or services

and to determine the preferences and needs of potential clients. Finally, the availability of the necessary resources is crucial for the implementation of innovations.[29]

The societal domain influences the implementation of innovations by financial incentives and laws and regulations. Financial incentives can stimulate innovation. The laws and regulation (including contracts with healthcare insurers) define the framework within which healthcare providers can operate.[29]

3. Methods

This chapter describes the methods of this study. The study objective and design are explained in the first paragraph. The second paragraph describes the participants of this study. Subsequently the third paragraph contains a description of the data collection. Finally, the data analysis is discussed in paragraph four.

3.1 Study objective and design

The objective of this study was to investigate the influence of variations in the implementation of the RECODE intervention between primary care practices on costs and effects of the intervention. The design of this study combined qualitative and quantitative research methods to enable a comprehensive evaluation of the implementation of the RECODE intervention. The aim of the qualitative part of this research was to explore the variations in implementation of the DM program between primary care teams by conducting interviews with practice nurses (or GPs). This part also paid attention to barriers and facilitators of implementing DM. The quantitative part of the research used the outcomes of the qualitative research to investigate the influence of implementation variations between practices in costs and effects of the DM program.

3.2 Participants

This study included two types of participants; healthcare providers (GPs and practice nurses) (§3.2.1) and patients (§3.2.2) from primary care practices participating in the RECODE study.

3.2.1 Healthcare providers

The RECODE study included forty primary care practice clusters in the Netherlands that were willing to create an integrated COPD management team.[10] This study only includes the twenty clusters that were assigned to the intervention group. The GPs completed a questionnaire about the implementation of the RECODE intervention in their practice. In addition, practice nurses were approached to participate in the interviews, because it was expected that the practice nurse is the team member who was in the best position to explain how the RECODE intervention is implemented in their practice.

3.2.2 Patients

This study only included the patients that were treated in the intervention practices of the RECODE study. Apart from this criterion the inclusion criteria of patients in this study are the same as in the RECODE study: diagnosis of COPD by their treating physician. These patients were selected from electronic medical records (EMRs) of the practices. In all included patients, it is attempted to verify the diagnosis by lung function according to the GOLD criteria.[35] If spirometry data was not available, patients were invited for a formal lung function assessment, according to the ATS/ERS guidelines from spirometry.[36] Exclusion criteria were terminally ill patients, dementia or cognitive impairment, inability to fill in Dutch questionnaires and hard drug or alcohol abusers.[10]

3.3 Data collection

This study used different methods of data collection; semi-structured interviews with primary care team members, questionnaires completed by GPs and patients and several other data sources which will be described in this paragraph.

3.3.1 Implementation variations of the RECODE intervention

To identify the heterogeneity of the RECODE intervention between different primary care teams several information sources were used. First, information is derived from a self-designed questionnaire: 'Satisfaction, involvement and implementation of the DM program' (from now on referred to as provider checklist, appendix C). This checklist contained questions about the implementation of the main aspects of the RECODE intervention and was completed by the GP. Second, the information from the provider checklist is supplemented by information derived from semi-structured interviews with a practice nurse or in some cases the GP of a primary care team. The approach of the interview was to start with open, general questions to collect information without guiding the answer by directly asking detailed questions. When information about certain topics was missing in the answer, follow-up questions were asked to try to gather this information. The interview started with questions about experiences at the start of the RECODE intervention and the teams' approach to change the care for COPD patients in their practice. Subsequently questions were asked about the developments in the CCM elements since the RECODE study started. The barriers and facilitators the primary care team encountered when making these changes were also discussed. The interview questions can be found in appendix D. Third, information about the attendance of healthcare providers at the course and refresher courses and the use of funding for physiotherapy collected by the RECODE research team was used.

3.3.2 Costs

The costs in this study were considered from a healthcare perspective. Therefore only the costs of healthcare utilization by patients were considered. These costs include all COPD- and non-COPD related hospital costs (contact with lung specialist, emergency care, hospital admissions and revalidation) and healthcare provider costs (contact with GP, practice nurse, physiotherapist, dietician, podiatrist, speech therapist, ergo therapist and home care). The costs were calculated using information from the patient questionnaires about healthcare utilization (Healthcare Usage questionnaire). In this questionnaire patients were asked to sum up their health care usage of the past three months. Medication costs could not be included because at the time of this study this data was not available.

3.3.3 Effects

This study included five outcome measures that were expected to reflect the effects of the RECODE intervention; the Patient Assessment of Chronic Illness Care (PACIC)[37,38], the Medical Research Council (MRC) dyspnea score[39,40], the Clinical COPD Questionnaire (CCQ)[41], the proportion of patients with a clinically important deterioration in CCQ score and the EuroQol-5D (EQ-5D).[42] These questionnaires are included in the questionnaire the patients filled in at baseline, 6, 9, 12, 18 and 24 months. This study used the information from baseline and 18 months.

The PACIC provides information about the integration of CCM elements in care from the perspective of the patient.[37,38] The questionnaire has 20 items with a five point response scale (1 = 'almost never' to 5 = 'almost always'). The higher the score, the more frequent this aspect of structured care is present.[38] The PACIC consists of five domains: patient activation, delivery system/practice design, goal setting/tailoring, problem solving/contextual and follow-up/coordination.[38]

The MRC dyspnea scale measures the extent to which patients' breathlessness affects their mobility.[40] The MRC scores range from 0 to 5; where 0 indicates that patients do not experience any breathlessness and 5 indicates that breathlessness restraints patients to leave their house. The scores 3, 4 and 5 correspond to more COPD symptoms.[35]

The CCQ is a disease-specific quality of life measurement developed to measure clinical control in patients with COPD.[41] The questionnaire consists of 10 items divided into three domains: symptoms, functional state and mental state. All scores range from 0 to 6 (0 = 'asymptomatic/no limitation' to 6 = 'extremely symptomatic/total limitation').[43] Therefore a high CCQ score indicates poor quality of life. The minimal clinically important difference (MCID) in the CCQ total score is 0.4.[43] In addition to the change in CCQ score, the proportion of patients with a clinically important deterioration in CCQ was determined. This outcome

measures was calculated as the proportion of patients in the practice with a change in CCQ of 0.4 or higher since the start of the RECODE study.

The EQ-5D is a generic multidimensional measure of health-related quality of life.[42] The EQ-5D consists of five domains: mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each domain is divided into three levels of functioning: no problems, some problems and extreme problems. In total the EQ-5D can define 243 health states.[42] The values of the health states are derived from the Dutch general population. This resulted in a preference-based utility score that ranges from states worse than dead (<0) to full health (1), anchoring death at 0.[10]

3.3.4 Time horizon

The provider checklist is completed by the GP of each primary care team at 12 months. The interviews were held at 20-26 months depending on the time the practices started the RECODE study. Finally, this study used 18 months follow-up data of the costs and effects. It was not possible to use the two year follow-up data, because this data was not available at the time this study is performed.

3.4 Data analysis

This paragraph describes the methods of data analysis of the interviews (§3.4.1), the conversion of information from the interviews to implementation variables (§3.4.2) and two additional variables (§3.4.3) and the statistical analysis of the influence of the implementation variables on the differences between the practices in changes in costs and effects (§3.4.4).

3.4.1 Implementation variations

The interviews were transcribed and analysed to explore the implementation variations between the practices. The information obtained from the interviews is used to determine the level of COPD DM before the start of the RECODE study and the developments in CCM elements since the RECODE study started. Further, the information is used to identify the barriers and facilitators the practices encountered during the implementation of the RECODE intervention.

3.4.2 Implementation variables

In addition to the qualitative analysis of the interviews, the information from the interviews (supplemented by other information sources) is used to estimate scores on eighteen implementation indicators. These indicators represent the implementation of the different aspects of the RECODE intervention in the practices after the start of the study. The definitions of these implementation indicators can be found in appendix A. Practices that implemented an aspect after the start of the RECODE study get the score 1 and practices

that did not make changes in this aspect as a consequence of the RECODE study get the score 0. The estimation of the scores is verified by a second researcher to reduce subjectivity.

The implementation indicators represent small aspects of the total RECODE intervention. To take into account the possibility these small changes separately will not influence the costs and effects, subtotal scores for the implementation of CCM elements and total scores for the whole implementation of the RECODE intervention are computed. The total implementation score is included in the analysis as a continuous variable or as a categorical variable. The categorical variable consists of three categories; limited (0-5 changes), moderate (6-12 changes) and major (12-18 changes) improvements. In the computation of the total scores the different aspects of DM are all weighted the same because there are no criteria on which objectively can be determined how the weight should differ.

3.4.3 Additional variables

This study includes two additional variables. The first variable reflects the degree of implementation of integrated care for COPD patients before the start of the RECODE study. Based on the respondents' description during the interviews of the COPD care in their practice before the start of the RECODE study, the practices are divided into three starting levels: (1) ad hoc COPD care, (2) structural diagnosis of COPD patients, and (3) structural diagnosis and follow-up of COPD patients. The starting level of DM influences the room for improvements in COPD care; the first groups could gain more from participating in the RECODE study than the last group. The second variable reflects to what extent the implementation of integrated care for COPD patients was successful according to the GP or practice nurse; the perceived success of implementation by healthcare providers. The response scale ranged from 1 to 5, where 1 is not successful and 5 is very successful. The variable consisted of three categories: not to somewhat successful (1-2), reasonably successful (3) and successful to very successful (4-5).

3.4.4 Statistical analysis

The analyses were performed using SPSS (version 20.0) and SAS (version 9.2). In this study a p-value of 0.05 was used as the statistical level of significance. To examine the consequences of implementing the RECODE intervention the differences between baseline and 18 months after the start of the RECODE study in the outcome measures were used as independent variables.

First, descriptive analyses of practice characteristics, patient characteristics at baseline, changes in outcome measures and scores on implementation variables were performed using means, standard deviations, frequencies and percentages. Subsequently, dependent t-tests (variables with normal distribution) and related-samples Wilcoxon signed ranked tests

(variables with no normal distribution) were used to determine whether the change in outcome measures were significant. The Kolmogorov-Smirnov test was used to test whether the distribution was normal.

Second, to determine whether there are significant differences between the practices in patient characteristics at baseline and changes in outcome measures, one-way independent ANOVA (continuous variables with normal distribution), Kruskal-Wallis (continuous variables with no normal distribution) and chi-square tests (categorical variables) were performed. Again the Kolmogorov-Smirnov test was used to test whether the distribution was normal. However, this analysis involved comparing groups and therefore not the overall distribution but the distribution in each group is important.[44] When the distribution in de majority of the groups was normal parametric tests were used, otherwise non-parametric tests were applied.

Third, to determine the influence of the implementation on costs and effects random effect models were estimated using SAS 9.2. The reason to estimate random effect models was that the data was hierarchically organized; the patients (level 1) were nested in practices (level 2). The random effect models were built by including the independent variables one at a time into the 'empty' model (a fully unconditional model without any independent variables apart from the random effect of the practice cluster) and determine with likelihood ratio tests if the independent variable is associated with the outcome variable. When the results of the likelihood ratio test is significant, there is strong evidence the added independent variable improves the fit compared to the original model. The variables that improved the 'empty' model were inserted into the final model step-wise, starting with the variable with the lowest likelihood ratio. When the likelihood ratio test showed that a variable did not improve the fit of the model, it was excluded. If the likelihood ratio test was significant, the independent variable remained in the model and the next independent variable with the lowest likelihood ratio was included. This process continued until all the independent variables that improved the fit of the 'empty' model were tested for inclusion in the final model. When the final model was finished, the total modelled proportion of variance (R^2) was calculated. For a random effect model, this indicates the proportional reduction in mean squared prediction error due to predictor variables. The R_1^2 indicates the reduction in mean squared prediction on patient level and the R_2^2 on practice level.[45]

This study included six dependent variables: one for the change in healthcare costs and five for the changes in effects: changes in MRC, CCQ, EQ-5D, PACIC scores and proportion of patients with a clinically important deterioration in CCQ between baseline and 18 months after the start of the RECODE study. For each dependent variable four random effect models were estimated with different kinds of implementation variables as independent variables; (1) the individual implementation indicators scores (score 0 or 1), (2) the subtotal scores of the implementation of the five CCM elements (maximum scores: delivery system

design=8, decision support=4, self-management strategies=4, clinical information system=1 and health care system=1), (3) the total implementation score as a continuous variable (maximum score=18) and (4) as a categorical variable (limited, moderate or major improvements). In addition to the implementation variables, the effect of the variable that indicates the estimated success of the implementation as perceived by the GP or practice nurse was tested. Every model is corrected for patient characteristics and practice characteristics (including the starting level of DM) where necessary. When the analysis resulted in more than one model for a dependent variable, the model with the lowest Akaike information criterion (AIC) and highest R_1^2 and R_2^2 was chosen.

In addition to the analysis in the total population, a subgroup analysis was performed on the patients with an MRC dyspnea score higher than 2 at the beginning of the RECODE study. This analysis is performed to confirm or refute the expectation that the implementation of the RECODE intervention predominantly influenced the patients with more COPD symptoms (MRC>2).

3.5 Hypotheses and conceptual model

The hypotheses of this research are illustrated in the conceptual model below (figure 1).

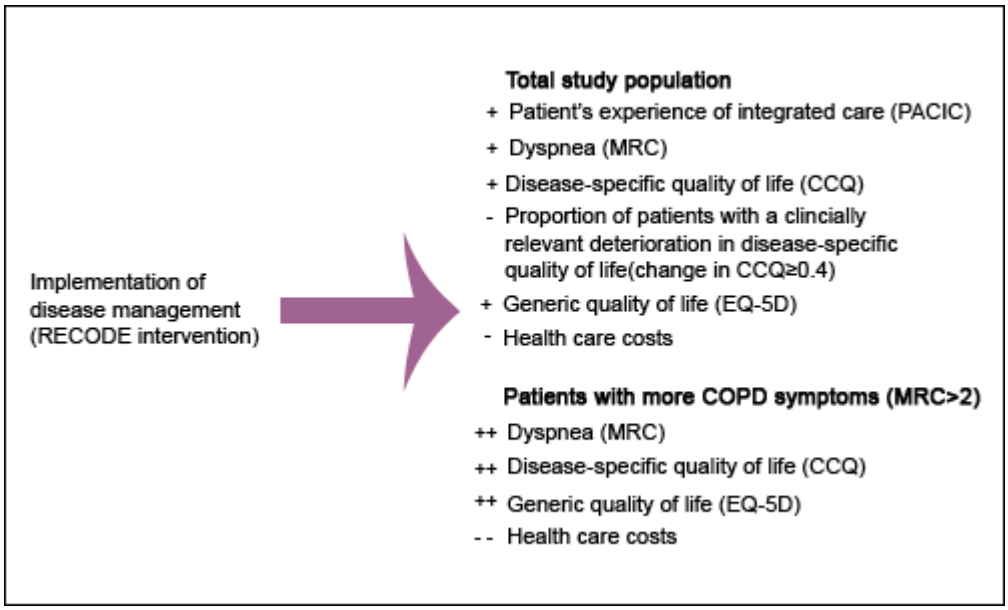

Figure 1. Conceptual model
+ improving effect, - decreasing effect, ++ strong improving effect, - - strong decreasing effect.

4. Results

In this chapter the results of this study will be described. In the first paragraph the characteristics of the participating practices will be described. The second paragraph will presents the implementation variations of the RECODE intervention using the information derived from the interviews and provider checklists. Paragraph three examines the

differences in patient characteristics between the practices. Finally, the fourth paragraph will describe the results of the random effect model analyses for the influence of the implementation variations on costs and effects.

4.1 Participating practices and patients

Twenty practices (87%) agreed to participate in this study. In fifteen practices (75%) the practice nurse was interviewed. Both the practice nurse and GP were interviewed in two practices (10%). In the other three practices (15%) the practice nurse was not available during the time of the study or employed after the RECODE study started and therefore the GP was interviewed. In eleven of the twenty practices (55%) that were interviewed the GP completed the provider checklist. If practices collaborated (for example with one practice nurse), they formed one cluster. In this study seventeen clusters participated. The characteristics of these clusters are presented in table 1.

The patient characteristics of the seventeen practice clusters that participated in this study can be found in table E1 in appendix E. The results of the chi-square and one way independent ANOVA tests (table E1) showed significant differences between the practices in the following patient characteristics: gender, age, education, relationship status, pulmonary function, MRC and CCQ scores at baseline. There were no significant differences between the practices in the employment of patients, Charlson co-morbidity index, EQ-5D, PACIC scores and healthcare costs. The results of the chi-square tests for smoking status could not be interpreted because the assumptions of the Pearson chi-square were not met.

	Mean (or n)	St dev. (or %)
Number of practices (n)	20	
Number of clusters (n)	17	
Type of practice (n,%)		
Single-handed practice	8	47.1
One or more partner practice	7	41.2
Healthcare centre	2	11.8
Practice location (urban) (n,%)	12	70.6
Patient practice population	3121.76	1137.37
COPD patients as percentage of total practice population	1.05	0.52
Percentage of patients from ethnic minorities	16.06	19.25
Percentage male GPs	64.65	42.87
Age GP	47.12	8.29
Years practicing GP	12.73	7.34

Table 1. Practices characteristics.

4.2 Implementation variations of the RECODE intervention

This paragraph will discuss the starting level of DM (§4.2.1), the variations in developments in the CCM elements the practices made since the start of the RECODE study (§4.2.2), the barriers and facilitators encountered during the implementation based on the four different

domains from Grol and Wensing (§4.2.3) and the practices' future plans for improving care delivery (§4.2.4).

4.2.1 COPD care DM before the start of the RECODE study

Before the implementation variations are discussed, it is important to discuss the variation in COPD care between the practices before the RECODE study started (i.e. starting level of DM). In this study instead of the five adopter categories of Rogers, three groups can be distinguished based on their relative innovativeness (table 2).

Four practices can be classified in the first adopter category: structural diagnosis and follow-up of the COPD patients. These practices already had a nearly complete integrated care process for COPD patients before they were approached to participate in the RECODE study. These primary care teams can be seen as the most innovative. They already had structured visits and follow-up, a clear overview of the COPD patients in their practice and proper self-management strategies and only needed to optimize the DM they already had (e.g. improve multidisciplinary co-operation).

The second adopter category is called 'structural diagnosis of COPD patients'. The five practices in this category were just starting to implement DM before the RECODE study started. They started to structure their COPD care by screening their patients and measuring lung functions to get an overview of the COPD patients in their practice.

Finally, in the last adopter group - 'ad hoc COPD care' - there were eight practices that had no or a few elements of DM before the start of the RECODE study. For these respondents the RECODE course was the reason to start structuring the COPD care. *"The extra support and the course days give you an incentive and a clear approach to get started" (R17).* These practices had to start from the ground up and focused on structuring visits and follow-up. This group is the least innovative of the practices in this study.

Starting levels DM	n	%
Structural diagnosis and follow-up of the COPD patients	4	23.5
Structural diagnosis of COPD patients	5	29.4
Ad hoc COPD care	8	47.1

Table 2. The level of implementation of integrated COPD care before the start of the RECODE study

4.2.2 Developments in the implementation of DM since the RECODE study started

This paragraph will describe the implementation of the RECODE intervention (classified by CCM element) of the different practices and will identify the reasons why some aspects of the intervention succeeded and others failed. The barriers and facilitators that do not influence a specific CCM element, but the implementation of DM in general are discussed in the next paragraph (§4.2.3).

Implementation indicators

The results of the interviews are quantified in scores (table 3) on the indicators of the implementation of the eighteen aspects of the RECODE intervention (appendix A). The results on the total implementation scores and categories and perceived success of the implementation by healthcare providers are also presented below (table 4). The subtotal scores on the implementation of the CCM elements can be found in table E3 in appendix E.

	Indicators of implementation of aspects of the RECODE intervention	**n**	**%**
	CCM: Delivery system design		
1	Improved co-operation with physiotherapist(s) or more use of physiotherapy	16	94.1
2	Improved co-operation with dietician(s) or more use of dietetics	12	70.6
3	Improved co-operation with lung specialist(s)	3	17.6
4	Multidisciplinary meetings	5	29.4
5	Task reallocation from GP to practice nurse or specialized nurse	7	41.2
6	Substitution of care from secondary to primary care	6	35.3
7	Change in follow-up and visit structure	7	41.2
8	Active tracking of high risk patients inside the practice (e.g. by using feedback reports provided by the RECODE research team)	12	70.6
	CCM: Decision support		
9	Attendance of four disciplines at the RECODE course	9	52.9
10	Attendance of two or more disciplines at the RECODE refresher courses	8	47.1
11	Changes in COPD protocol	5	29.4
12	Quality of life and symptoms questionnaires part of consultations	10	58.8
	CCM: Self-management strategies		
13	Individual treatment plan	9	52.9
14	Smoking cessation	5	29.4
15	Early recognition of exacerbation	12	70.6
16	Motivational interviewing	5	29.4
	CCM: Clinical information systems		
17	Actively tried to use Zorgdraad	5	29.4
	CCM: Healthcare system		
18	Use of funding for physiotherapy	3	17.6

Table 3. Indicators of implementation of aspects of the RECODE intervention.

Practice	Total implementation score	Total implementation categories[1]			Perceived effectiveness of implementation by healthcare providers		
	Number of changes	*Limited*	*Moderate*	*Major*	Not to somewhat	Reasonable	*(very) Successful*
AQ	9		X				X
AX	10		X			X	
BR	9		X				X
BY	5	X			X		
CT	5	X				X	
GG	10		X			X	
HD-HE	9		X			X	
HU-HV-HT	9		X		X		
IA	13			X		X	
IB	5	X				X	
IR	7		X			X	
KT	4	X					X
KW	8		X			X	
ML	12			X		X	
MQ	12			X			X
NH	4	X				X	
NQ	8		X			X	
Total (n(%))		5 (29.4)	9 (52.9)	3 (17.6)	2(11.8)	11(64.7)	4(23.5)

Table 4. Total implementation scores and categories
[1]1 = total implementation score 0-5, 2= total implementation score 6-11 and 3= total implementation score 12-18.

Delivery system design

Redesign in the practices in this study manifested itself in a more structured COPD care instead of an ad-hoc approach. This was often accompanied with improved multidisciplinary co-operation and task reallocation from the GP to practice nurse and from secondary to primary care. Each of these issues will be discussed below.

Multidisciplinary co-operation (indicator 1 - 4)

In many practices the co-operation with physiotherapists (16 practices) and dieticians (12 practices) has been improved since the start of the RECODE study. The co-operation improved by agreeing upon the indications of referral, communication regarding patients and coordination of the treatment of COPD patients. *"We made clear agreements with the physiotherapist and dietician. Those lines are very short now. […] It is now very clear who you are dealing with and what you can expect from each other, how you give feedback to each other" (R5).*

In sixteen practices the co-operation with the physiotherapist improved, while the co-operation with the dietician only improved in twelve practices. The main reason for this difference is that there were not many patients that needed nutritional advice. Furthermore respondents felt that patients were more reluctant to see a dietician compared to a physiotherapist (further discussed under self-management strategies), which makes improving the co-operation with the dietician less necessary. Although the co-operation improved in many practices, only five teams organised periodically scheduled multidisciplinary meetings regarding individual COPD patients and/or organisational issues.

The reason other practices did not organise multidisciplinary meetings differed. For example, the teams were not yet able to organise the meetings or did not feel the need because there was only a small number of patients who were treated by healthcare providers from different disciplines. In most of these practices the communication between healthcare providers was ad-hoc; when it was necessary they contacted each other to discuss a specific patient.

Task reallocation from GP to practice nurse (indicator 5)

As a consequence of the RECODE course, seven practices reallocated (more) tasks from the GP to the practice nurse. Examples of reallocated tasks are the spirometry and discussion of the spirometry results with the patient, providing information, teaching inhalation techniques and early recognition of exacerbations, smoking cessation treatments, assistance with other life style changes and discussion of quality of life and symptoms questionnaires. Most GPs saw the COPD patients once a year and the follow-up appointments in between were the responsibility of the practice nurse. In many practices the practice nurse already took over tasks that originally were performed by the GP before the RECODE study started. In some of these practices the task reallocation increased as a consequence of the RECODE course, while in other practices no more tasks were reallocated.

Task reallocation from secondary to primary care (indicator 6)

In three practices there was more attention to the referrals from primary to secondary care and from secondary to primary care after the RECODE course. When it was possible patients were treated in primary care. If patients were referred to secondary care they come back to the practice as soon as possible. In some practices the secondary healthcare providers seemed to notice the changes in primary care and referred more patients back to primary care without explicit deliberation with primary healthcare providers. In other practices the practice contacted the lung specialist to discuss the criteria for referral. *"We contacted the lung specialist and almost all patients came back to the practice, except for a few individuals" (R6).* However, not every lung specialist adheres to the agreements. *"We regularly say they can easily send the people back to us, but [once they are referred to secondary care] you do not get them back, which is a shame"* (R13). In one practice more patients were referred from primary to secondary care after the RECODE study started instead of the other way around. In this practice the quality of life and symptoms questionnaires (CCQ and MRC) showed the health status of these patients was poor and therefore they should be treated in secondary care.

More structured visits and follow-up (indicator 7 and 8)

In several practices the COPD care before the RECODE program was not structured; patients were treated when they visited the practice on their own initiative (e.g. when they had an exacerbation) and were not structurally followed up afterwards. *"Simply ad-hoc, when there was illness something happened and otherwise nothing happened. So it was reactive" (R11).* Since the RECODE study started seven practices have made progress in making their COPD care more structured by defining structural follow-up plans. In addition, twelve practices actively tracked down the COPD patients in their practice since the start of the RECODE study.

Decision support

In the RECODE intervention the two-day multidisciplinary course educated the primary care teams about the content of the RECODE program. During the RECODE course other aspects of decision support were promoted to support healthcare providers in making evidence-based decisions, namely the use of protocols, quality of life and symptoms questionnaires and feedback reports. The following will further discuss these subjects.

RECODE course (indicator 9)

The RECODE program started with a two-day multidisciplinary course for the healthcare providers of the intervention practices. The RECODE course was based upon recent national and international guidelines. This means the content of the RECODE intervention was in line with the current professional insights and standards which resulted in acceptation of the innovation by the professional groups (i.e. the primary care teams). The attendance rate of the GPs (100%), practice nurses (88%), physiotherapists (82%) and dieticians (65%) at the course was high. In nine practices representatives of the four disciplines were present. The respondents were very positive about this course. They thought it was informative, it improved their awareness about certain topics and it gave them inspiration and motivation to improve the COPD care. *"[The course] was an eye-opener […]" (R14). "The course made us more aware that COPD is more than just a lung problem" (R12).* The RECODE course increased attention for the field of COPD care and motivated some practice nurses to follow more COPD related courses. *"Yes [I did get extra motivated by RECODE] very motivated. It is almost a kind of sport. If you are not careful almost everybody has COPD [joking]. It does get your attention, absolutely" (R2).* However, not every aspect of the intervention was well explained. For some respondents the instructions about 'Zorgdraad' in the course were unclear and this hindered the use of 'Zorgdraad'.

RECODE refresher courses (indicator 10)

The attendance at the refresher courses was lower than the attendance at the course; GPs (47%), practice nurses (53%), physiotherapists (35%) and dieticians (24%). In eight practices two or more representatives from different disciplines were present. During the refresher courses, six and twelve months after the start of the RECODE study, the groups that started with the RECODE study earlier presented their experiences with implementing DM to the groups that were just started. This way the practices could motivate and inspire each other to change their COPD care. However, not every respondent was positive about the refresher courses. Some of the respondents in the groups that just started felt these presentations were not useful because some of the practices who presented their progress barely even started the implementation. In addition, some of the respondents in earlier groups felt that it was unnecessary to present their developments because they made a plan without such presentations and succeeded.

COPD protocol (indicator 11)

In most practices the RECODE program did not change the protocols and guidelines the healthcare providers used. These practices often used the protocols available in the clinical information system 'Medicom'. However, in two other practices there were significant changes in the protocols. Both these practices did not have structured COPD care and started implementing DM because of the RECODE course. In these practices the GP (sometimes with assistance of the practice nurse) developed a new COPD protocol using several sources of information, including the information obtained during the RECODE course and requirements of healthcare insures. In addition, three other practices changed the protocols since the start of the RECODE study by incorporating the information from the course in their original protocol.

More attention to quality of life by using questionnaires (indicator 12)

Another frequently mentioned (10 practices) consequence of the RECODE course is the increased attention to the quality of life of patients by using quality of life and symptoms questionnaires (such as the CCQ and MRC) in addition to the spirometry to determine the patient's health status. *"I recognize the value of the quality of life questionnaires now [after the RECODE course]. The point is that the patient is important and you should not be blinded by the spirometry. […] We, as healthcare providers, now recognize that the subjective perception of how people are doing is actually essential" (R12).*

Self-management support

As a consequence of the RECODE course many practices improved the self-management support they provide to COPD patients. However, respondents felt it was difficult to motivate

COPD patients to change their lifestyle. These developments and difficulties are described below.

Individual treatment plan (indicator 13)

Many practices already made individual treatment plans for patients before the start of the RECODE study, but there was a lot of variation in these plans. Not every individual treatment plan was made in consultation with the patient and not every healthcare provider put the plan in writing. Half of the respondents (9 practices) indicated they gave more attention to self-management and the patient's own responsibility of taking care of their health after the RECODE course. As a result many practice nurses now define personal goals in an individual treatment plan in consultation with the patient. *"I've become more aware of own personal goals […] and because I am more aware I automatically involve the patient more [in the treatment]. So really discuss what they think is important, what they want themselves. Let them describe their goals in their own words and come back to those goals later" (R16).* Some respondents feel this change is a result of the RECODE study, while other respondents state there is a general tendency to give more attention to self-management and the own responsibility of patients with chronic conditions.

Smoking cessation counselling (indicator 14)

Every practice paid attention to smoking cessation before the RECODE study started. The majority of the practices did not change their smoking cessation approach because they already focused on this before the RECODE course. *'When you come to the conclusion someone has COPD, it is the first thing you try and continue to address. It is impossible to treat someone with COPD without addressing smoking cessation' (R1).* However, five practices increased their attention to smoking cessation because of the RECODE course. Several respondents complained about the condition of the healthcare insurers to only reimburse smoking cessation counselling and medication when the healthcare providers attended a specific course.

Early recognition of exacerbations (indicator 15)

In twelve practices the healthcare providers became more aware of the importance of early recognition of exacerbations after the RECODE course. *"The most important eye-opener of RECODE was to catch exacerbations early to try to prevent hospital admissions" (R15).* In many practices this led to a policy where patients are instructed to report to the practice when they have symptoms of an exacerbation and are treated by the GP as soon as possible.

Encouraging patients to change their lifestyle (indicator 16 and 18)

Three areas of interest in the RECODE course were smoking cessation, physical reactivation and early recognition and treatment of nutritionally depleted patients. To adequately react on problems in these areas practice nurses were instructed to respectively offer smoking cessation counselling or refer the patients to physiotherapists or dieticians. However, many respondents already had difficulties getting patients in the practice. In one practice every COPD patient received a letter to get in contact with the GP at the beginning of the RECODE study but only 25% responded. Another practice experienced problems with patients who did not adhere to the appointments; the practice nurse said: *"The difficulty with COPD patients is that they do not always come back to the follow-up appointments. You lose sight of them when they cancel their appointment. […] I always call people [who cancelled their appointments] and then they say they will come, but it is difficult to keep them coming. That's my experience. It is a difficult group to follow-up" (R3).*

When patients do come to the practice it is often difficult to motivate them to change their lifestyle. The respondents reported three reasons for this lack of motivation. First, the respondents reported that (some) COPD patients were unmotivated because they did not feel ill or did not experience that many problems. Therefore they did not find it necessary to change their lifestyle. *"COPD patients are people who do not notice they are ill. They adapted their life to what they can and this almost goes unnoticed. So people who only have half of their lung function left say: "I'm not short of breath at all". They are not motivated to change [their lifestyle] because that means stop smoking and going to the physiotherapist for lung rehabilitation and people don't like that. It is hard to get those people motivated" (R7).*

Second, patients are less aware of the results of nutritional interventions compared to physical reactivation and this resulted in differences in motivation between seeing a physiotherapist or a dietician. *"If you ask people they feel a dietician is a necessary evil. If we [practice nurse or GP] think it is necessary, okay then. But for them it is hard to understand why it is important" (R12).* In contrast to nutritional interventions, patients are more aware of the results of physical reactivation; patients feel their health is improving and this keeps them motivated. *"One patient started exercising because of RECODE and therefore has fewer exacerbations. Before [RECODE] he could not be persuaded to start exercising and now he can't live without it, he never wants to skip it" (R10).*

Finally, the lack of reimbursement from healthcare insurers was often reported as a barrier for patients to visit the physiotherapist or dietician. Almost every practice noticed problems with these reimbursements. The reimbursement problems manifested themselves by a lack of motivation to see a physiotherapist or dietician when patients had to bear the costs themselves; as a result patients stop going or do not even start seeing a physiotherapist or dietician. *"As soon as I start talking about the dietician […], they say: "I have to pay that*

myself, don't I? Well, then I will pay attention to what I eat myself" (R7). The reimbursement of physiotherapy will be further discussed in the paragraph about the CCM element 'healthcare system'.

To motivate patients to start changing their lifestyle and improve their health status the motivational interviewing techniques were explained and practiced during the RECODE course. This is a technique healthcare providers can use to elicit behaviour change by helping patients to explore and resolve their reluctance or ambivalence to change.[46] In the majority of the practices motivational interviewing was already used before the start of the RECODE study. The practice nurses learned this technique during their education or other courses. For these respondents it was self-evident to use motivational interviewing when treating patients with chronic diseases. In five practices the technique was not used before the RECODE study or received more attention after the RECODE course. *'I believe everyone is responsible for their own health. So [before RECODE] I thought if people don't want to [change], then they don't want to. But [because of the RECODE course] I noticed that you can persuade people with a few very simple techniques' (R7).* Most of the respondents were positive about using this technique to motivate patients. Several respondents had difficulties using the technique; they find it hard to persuade patients to change their lifestyle, the success of the technique depends on the patients (if they are open to it and understand it) and because of the limited time of the visits they are not always able to use the technique.

When patients are less motivated to change their lifestyle, this can lead to less motivation in the primary care team to implement aspects of the RECODE intervention that aim to improve the lifestyle of the patients. For example the lack of motivation of patients to change their lifestyle results in limited use of nutritional interventions and therefore some practices did not feel it was highly needed to improve co-operation with dieticians and organise multidisciplinary meetings.

Clinical information systems

The participants of the RECODE study received access to a clinical information system named 'Zorgdraad'. Another source of information about patients was the feedback reports the RECODE team offered to the primary care teams. Both clinical information system subjects will be discussed in this paragraph.

Web-based DM application: Zorgdraad (indicator 17)

The implementation of 'Zorgdraad' did not succeed; none of the practices used 'Zorgdraad' at the time of the interviews. There are a number of reasons 'Zorgdraad' was not used. Several respondents did not have enough time or feel the need to figure out how 'Zorgdraad' worked. Other respondents found the instructions unclear and the system inconvenient and this demotivated them to (start) use 'Zorgdraad'. In practices where a new practice nurse

was hired since the start of the RECODE study, the practice nurses did not use 'Zorgdraad' because they were not instructed about the use of the system.

In five practices the healthcare providers actively tried to use 'Zorgdraad' at the beginning of the RECODE study but have now stopped using it. These respondents reported two reasons for this. First, one of the features of 'Zorgdraad' is the possibility to communicate about patients with healthcare providers from other disciplines. However, several respondents thought it was not worth the effort to use 'Zorgdraad' to communicate because of the small amount of communication they needed. "*I can imagine it would work in a big city or big town where you are dealing with a lot of physiotherapists and dieticians, than it can be a great added value. But because you only have one of each here [one physiotherapist and dietician], it does not have added value" (R5).* Other respondents said they used 'Zorgdraad' but the physiotherapist and/or dietician did not, which made it less meaningful for them to use 'Zorgdraad'. Second, there were problems with transferring the information to the clinical information system the practice used. As a result the information had to be imported in both systems. To avoid this duplication of work, many respondents stopped using 'Zorgdraad'. "*It is not the program itself but the fact that it is a separate program. Therefore everyone has to import the information double and that did not work out" (R12).*

Since none of the practices used 'Zorgdraad' at the time of the practices, it can be concluded the implementation of this clinical information system did not completely succeed. The unsuccessful implementation of 'Zorgdraad' can be seen as a barrier for the implementation of the RECODE intervention because (some of) the healthcare providers 'wasted' time and effort to use the system which they could have spent on implementing other aspects of DM.

In addition to healthcare providers, patients could also use 'Zorgdraad'. However, according to the respondents patients did not use 'Zorgdraad'. Frequently mentioned reasons were that COPD patients are relatively old and are not used to working with the computer or patients do not want to use web-based applications to manage their condition. Furthermore, it is possible the healthcare providers did not inform patients about 'Zorgdraad' and therefore they were unaware of its existence.

Feedback reports (indicator 8)

In addition to the patient information the practices collected themselves, the RECODE research team provided feedback reports. The reports contained CCQ and MRC results derived from the questionnaires and interviews with patients at six and twelve months after the RECODE study started. Several practices indicated the reports gave them a better overview of the COPD patients in their practice. "*I suddenly had nicely completed scores of the patients participating in the RECODE study, the CCQ, MRC […], whatever you can come*

up with, it was filled in. [...] Because of RECODE I now have the baseline scores of the patients who participated in the study, that show how they were performing at that time" (R15). In this way the reports helped the practices to monitor the progression of the health status of their COPD patients. Other practices indicated they did not use the reports because they could extract the information from their own clinical information system or they did not actively track high risk patients inside their practice.

Healthcare system

The RECODE program was influenced by the healthcare system in two ways. First, the reimbursement of physiotherapy and dietetics was an important condition for patients to use these disciplines. In almost every practice the lack of reimbursement discouraged many patients to visit the physiotherapist or dietician. This hindered the improvements in physical reactivation and early recognition and treatment of nutritionally depleted patients. To resolve the reimbursement problems of physiotherapy the RECODE research team arranged supplementary funding for COPD-specific exercise training programs with healthcare insurers at the beginning of the RECODE study. The healthcare providers needed to apply for the reimbursement at the university hospital performing the RECODE study to be able to offer the reimbursement to their patients. However, only three practices used these reimbursements. The reason for the limited use of the funding remains unclear. One respondent stated that the funding was not used because the attention to the RECODE program in the practice declined and many patients did not qualify for the reimbursement. Further, it is possible some healthcare providers in the practices were unaware of the funding arrangement.

Second, the healthcare system influenced the RECODE program by initiating other projects that also target COPD care alongside the RECODE program. As a result three practices abandoned the RECODE program and focused on the other project or temporarily stopped improving COPD care until the start of the upcoming project. *"When it became known we had to join the COPD integrated care program starting in July, we got detached from the plan [made during the RECODE course] because you can put a lot of energy in the plan but you don't know what the new agreements will be. So we decided to wait for a while […]" (R6).* However, the other projects can also facilitate the implementation of the RECODE intervention because they also aim to integrate the care of COPD patients. The other projects are sometimes more successful in changing COPD care because practices have more guidance in implementing DM, the focus is on COPD care in one region, they have better financial arrangements and/or secondary healthcare providers are more involved. *"Now we are in the 'integrated care train' and we have financing in return the things [implementation of DM] go better. Before it was more something you did on the side." (R18)*

The other way around, the RECODE intervention can also facilitate the implementation of the other projects by preparing the practices for the changes they need to make or already start the changes.

Community

In the RECODE program no specific interventions were aimed at improving this CCM element. During the interviews it became clear that most respondents were open to allow partners or family members to join the consultations or even recommended the patient to bring someone with them. However, besides the involvement of family, most practices did not pay much attention to involve the community in COPD care.

4.2.3 Influencing factors on implementation: barriers and facilitators

This paragraph will discuss the barriers and facilitators that do not influence a specific CCM element, but the implementation of DM in general. In addition, an overview of the barriers and facilitators of the implementation of the RECODE intervention will be presented.

First, the motivation of the healthcare providers can be a facilitator as well as a barrier. *"You have to be prepared to put something [effort] in. It is in fact a dead program. If you don't do anything with it, it is toned down to zero within three months" (R12).* The previous paragraph explained that the motivation of healthcare providers is influenced by the RECODE course and patient's motivation to change their lifestyle. Especially the motivation of the practice nurse is important, because in most practices she acted like the leader of the change (often together with the GP) and many of the aspects of the RECODE interventions predominantly influence her work (i.e. task reallocation, structured diagnosis and follow-up, quality of life and symptoms questionnaires and self-management strategies).

Second, the variability in adoption of DM among members within the team influences the implementation. The members of the team have to agree on what needs to change, how those changes will be realised and what the tasks of the different members of the team are in realising these changes. Some primary care teams failed to reach such consensus because of differences in adoption of aspects of DM. For example, some practice nurses used 'Zorgdraad' but stopped because other healthcare providers were not using the program. Another example is that despite of the efforts of the practice nurse, the GP did not pay enough attention to track down patients with COPD among the patients that visited the practice. This shows that consensus within primary care teams is important, because the efforts of one member of the team can be unprofitable if the other members do not co-operate.

Third, the availability of resources, such as time, influenced the implementation. Several respondents felt they did not have enough time beside their normal activities to invest in the implementation of DM (e.g. organising multidisciplinary meetings or getting familiar with

'Zorgdraad'). In addition, practice nurses only have a limited time for a consult and therefore there is not always time for new interventions such as motivational interviewing or quality of life and symptoms questionnaires. Furthermore, primary care teams had difficulties dividing the time and attention over several chronic conditions. In some practices the number of COPD patients was relatively low compared to patients with other chronic diseases and therefore the priority of spending time on implementing DM for COPD patients was lower.

Finally, the turnover of staff can be a barrier because it undermines the consistency of the implementation. For example when practice nurses left, the implementation was put on hold until there was a new practice nurse. Furthermore, new healthcare providers did not attend the RECODE course and therefore they had difficulties or did not put effort in implementing the intervention.

The factors that hindered or facilitated the implementation of the RECODE intervention are ordered in four different domains - individual, social, organisational or societal factors[29] - in the table below.

Barriers	Facilitators
Individual domain	
Unclear instructions regarding Zorgdraad	Improved knowledge and skills of healthcare providers
Unmotivated healthcare providers	Motivated healthcare providers
Unmotivated patients to change lifestyle	
Social domain	
Variability in adoption of (aspects of) DM between team members	No variability in adoption of (aspects of) DM between team members
	Content of the RECODE intervention in line with professional insights and standards
Organisational domain	
Limited time available for changing COPD care	
Staff turnover	
Unfinished system of Zorgdraad	
Societal domain	
Lack of reimbursement of physiotherapist and dietician	Reimbursement of physiotherapist and dietician
Abandoning implementation RECODE intervention because of other projects to improve COPD care	Better guidance and/or financial arrangements arranged by other projects to improve COPD care

Table 5. Barriers and facilitators of implementing the RECODE intervention

4.2.4 Plans for the future

There are not only variations in the implementation of the RECODE intervention so far, but the primary care teams also have different plans for the future of COPD care in their practice. Some practices did not have detailed plans. However, most of these practices stated they always search for ways to improve care and keep their knowledge up to date by following more courses.

In many primary care settings there were still issues that were not yet at the desired level. The respondents of these practices plan to put effort in those issues. Examples are tracking

down more COPD patients in their practice, encourage patients to have more active attitude and improve the co-operation with other disciplines.

Furthermore, respondents do not only have plans in the field of COPD, but also plan to improve care for patients with other chronic conditions. Some respondents state they (plan to) use the same knowledge and skills when treating COPD patients as asthma or diabetes patients. *"Look, when they are short of breath, they understand everything, but at the time they are well regulated, they do not get it. It seems as if there is suddenly nothing wrong with them. And the same holds for diabetics; if you don't feel anything, you don't have anything. […] So it [DM] is actually an approach you can use with almost all patients. […] For example the individual treatment plan. Great, think with me, think about what you [as a patient] can do yourself" (R2).*

Finally, as previously discussed, some practices participated in other projects to improve COPD care alongside RECODE and they plan to continue with those projects.

4.3 Changes in costs and effects since the start of the RECODE study

The results of the dependent t-tests and related-samples Wilcoxon signed ranked tests (table 6 and 7) showed that only the CCQ score significantly changed since the start of the RECODE study; in the total population as well as the subgroup the CCQ scores are significantly higher, indicating worse disease-specific quality of life.

Total population	n	Baseline	18 months	Difference between baseline and 18 months	Test statistic	p-value
MRC	255	1.88 (1.26)	1.96 (1.37)	0.07 (1.05)	1.082	0.279
CCQ	315	1.47 (0.94)	1.90 (1.08)	0.43 (0.76)	-9.270	0.000*
EQ-5D	324	0.76 (0.24)	0.78 (0.23)	0.01 (0.25)	15.775	0.385
PACIC	310	2.31 (0.94)	2.28 (0.96)	-0.03 (0.97)	-0.588	0.556
Healthcare costs	343	476 (977)	847 (2012)	370 (2070)	1.887	0.059

Table 6. Changes in costs and effects between baseline and 18 months in the total population
Notes: all values are means (SD) except when stated otherwise; *p<0.05

Subgroup (MRC>2)	n	Baseline	18 months	Difference between baseline and 18 months	Test statistic	p-value
MRC	255	2.01 (1.23)	1.96 (1.37)	-0.26 (1.16)	1.082	0.279
CCQ	97	2.25 (0.93)	2.65 (0.88)	0.40 (0.77)	-5.131	0.000*
EQ-5D	100	0.62 (0.27)	0.67 (0.25)	0.04 (0.29)	-0.433	0.665
Healthcare costs	113	641 (1337)	1187 (2765)	463 (2944)	-0.423	0.673

Table 7. Changes in costs and effects between baseline and 18 months in the subgroup of patients with more COPD symptoms (MRC>2)
Notes: all values are means (SD) except when stated otherwise; *p<0.05

The differences in changes in costs and effects between baseline and 18 months after the start of the RECODE study per practice in the total population are shown in table 8. The results of the Kruskal-Wallis and one way independent ANOVA tests showed significant differences between the practices in changes in costs. There were no significant differences between the practices in the changes in effects. In the subgroup of patients with more COPD

symptoms (MRC>2) none of the changes in outcome measures differed significantly between the practices (table 9).

4.4 Influence of implementation variations on costs and effects

This paragraph describes the results of the random effect models that were estimated to examine the influence of the implementation variations between the primary care teams on costs and effects. Some of the dependent variables did not have a normal distribution. Kolmogorov-Smirnov tests were performed to examine whether a log-normal or gamma distribution fitted the data of these variables better. However, this was not the case. Therefore the assumption is made that all the dependent variables follow a normal distribution in the random effect models described in this paragraph.

ΔMRC

The only implementation variable that could be included in the model was the implementation indicator 'use of funding for physiotherapy'. The other implementation indicators, subtotal implementation scores of CCM elements and total implementation scores did not improve the fit of the model. The use of funding for physiotherapy leads to a significant greater improvement or lower deterioration in MRC scores (negative sign indicates improvement in dyspnea) in the total population and the subgroup (MRC>2) (table 10). This effect is approximately twice as high in the subgroup compared to the total population. In addition to the use of funding for physiotherapy, the model of the total population also included the MRC score and EQ-5D score at baseline. The results show that only the MRC score at baseline has a significant effect on the change in MRC score; patients with a one point higher MRC score at the beginning of the RECODE study have a 0.386 points decrease or lower increase in MRC score 18 months after the RECODE study started. The proportional reduction of mean squared prediction error as a result of including the independent variables in the total population model is 6.18% and in the subgroup model 5.39% on both patient and practice level.

ΔMRC	Total population		Subgroup (MRC>2)	
	β	p-value	β	p-value
Intercept	-0.041	0.856	-0.113	0.409
MRC score at baseline	-0.386	0.022*		
EQ-5D score at baseline	0.381	0.116		
Use of funding physiotherapy	-0.326	0.000*	-0.637	0.002*
R_1^2 (%)	6.18		5.39	
R_2^2 (%)	6.18		5.39	

Table 10. Random effect models of the influence of the implementation on the ΔMRC
Notes: *p<0.05

Total population	AQ	AX	BR	BY	CT	GG	HD-HE	HT-HU-HV	IA	IB	IR	KT	KW	ML	MQ	NH	NQ	Test statistic	p-value
ΔMRC	-0.40 (0.70)	-0.29 (0.95)	0.07 (1.44)	0.57 (1.13)	0.10 (0.57)	0.62 (1.04)	0.05 (1.31)	0.18 (0.96)	-0.42 (1.16)	0.14 (1.23)	0.20 (0.94)	-0.14 (0.66)	0.22 (0.97)	0.22 (1.09)	-0.03 (1.18)	-0.07 (0.70)	0.55 (0.69)	17.491	0.355
ΔCCQ	0.61 (1.25)	0.39 (0.71)	0.86 (0.75)	0.03 (1.31)	0.09 (0.54)	0.48 (0.68)	0.37 (0.50)	0.47 (0.76)	0.49 (0.62)	-0.05 (0.79)	0.47 (0.72)	0.31 (0.73)	0.45 (0.50)	0.42 (0.91)	0.73 (0.73)	0.25 (0.66)	0.43 (0.67)	1.535	0.086
ΔEQ-5D	0.07 (0.23)	0.02 (0.24)	0.03 (0.27)	-0.14 (0.36)	0.00 (0.16)	0.05 (0.25)	0.04 (0.25)	0.01 (0.26)	0.07 (0.38)	-0.02 (0.30)	0.05 (0.16)	-0.02 (0.23)	0.04 (0.18)	-0.06 (0.21)	0.02 (0.21)	0.06 (0.21)	-0.04 (0.23)	11.492	0.778
ΔPACIC	-0.55 (1.71)	0.31 (0.76)	-0.48 (1.05)	0.13 (0.69)	0.07 (1.08)	0.16 (1.00)	0.01 (0.81)	-0.05 (1.03)	-0.29 (1.09)	-0.19 (0.94)	0.36 (0.77)	0.29 (1.07)	-0.30 (0.63)	-0.04 (0.81)	0.27 (0.81)	-0.10 (0.63)	-0.28 (1.23)	1.346	0.168
ΔHealthcare costs	-336 (952)	322 (1325)	455 (2085)	77 (515)	162 (1300)	713 (2616)	-230 (2441)	591 (2363)	303 (1104)	970 (2075)	33 (683)	74 (418)	-132 (500)	900 (1422)	263 (915)	390 (1546)	1328 (5709)	26.559	0.047*
Proportion patients with ΔCCQ≥0.4(%)	60.0	44.4	78.6	25.0	20.0	43.8	46.4	51.9	52.2	20.0	42.9	46.7	50.0	42.3	67.6	44.4	38.9	1.457	0.115

Table 8. Differences in the change in costs and effects (between baseline and 18 months) between practices in the total population
Notes: all values are means (SD) except when stated otherwise; *p<0.05

Subgroup (MRC>2)	AQ	AX	BR	BY	CT	GG	HD-HE	HT-HU-HV	IA	IB	IR	KT	KW	ML	MQ	NH	NQ	Test statistic	p-value
ΔMRC	-0.50 (0.71)	1.00 (0.00)	0.07 (0.95)	0.33 (0.58)	1.00 (0.00)	0.67 (1.15)	-0.43 (1.51)	-0.11 (1.05)	-0.80 (1.23)	-0.50 (1.29)	1.00 (1.00)	0.00 (0.00)	0.25 (0.96)	-0.50 (1.00)	-1.00 (1.22)	0.00 (1.73)	0.00 (0.00)	0.976	0.495
ΔCCQ	0.63 (0.47)	0.30 (0.00)	1.07 (0.77)	-0.53 (1.28)	0.47 (0.77)	0.12 (0.49)	0.48 (0.51)	0.36 (0.63)	0.39 (0.73)	-0.08 (0.89)	0.38 (0.86)	1.10 (0.00)	0.54 (0.53)	0.45 (0.91)	0.66 (0.78)	0.50 (1.06)	0.05 (1.17)	1.031	0.435
ΔEQ-5D	0.09 (0.05)	0.09 (0.02)	0.12 (0.31)	-0.02 (0.29)	0.23 (0.00)	0.05 (0.22)	0.10 (0.31)	0.05 (0.38)	0.14 (0.37)	-0.01 (0.20)	0.09 (0.24)	-0.04 (0.06)	0.07 (0.22)	-0.12 (0.24)	0.05 (0.29)	-0.13 (0.15)	-0.26 (0.38)	0.696	0.790
ΔHealthcare costs	-314 (532)	-252 (224)	109 (254)	-192 (559)	-215 (2452)	1688 (4525)	-804 (3941)	116 (1169)	590 (1405)	1507 (2263)	-267 (360)	-154 (223)	-40 (626)	2345 (1883)	316 (1254)	91 (166)	4497 (10628)	1.122	0.347

Table 9. Differences in the change in costs and effects (between baseline and 18 months) between practices in the subgroup of patients with more COPD symptoms
Notes: all values are means (SD) except when stated otherwise; *p<0.05

ΔCCQ

For the influence of the implementation of the RECODE intervention on the change in CCQ scores, four random effect models are estimated. The difference between the models is the kind of implementation variables. The model with the categories of the total implementation score as implementation variable (model 4) explains the variations in change in CCQ scores in the total population the best. In the subgroup, the model with the individual subtotal implementation scores of CCM elements as implementation variables best explained the variations in changes in CCQ scores. The results of these models are presented in table 11 and the other models can be found in table E5 in appendix E.

ΔCCQ	Total population		Subgroup (MRC>2)	
	β	p-value	β	p-value
Intercept	0.407	0.005	0.865	0.001
Gender			0.315	0.001*
CCQ score at baseline	-0.149	0.004*	-0.342	0.001*
Total implementation score (categorical)[2]				
Moderate improvements	0.311	0.000**		
Major improvements	0.334	0.000**		
CCM: Self-management strategies			0.089	0.032*
Perceived success of implementation[1]				
Reasonably successful	-0.069	0.099		
(Very) successful	0.150	0.034*		
R_1^2 (%)	9.00		27.77	
R_2^2 (%)	31.13		27.77	

Table 11. Random effect models of the influence of implementation on ΔCCQ
Notes: [1]reference group is not to somewhat successful, [2]reference group is limited improvements
*p<0.05, **p<0.0001

The CCQ score at the baseline has a significant effect on the change in CCQ scores in both models; a one point higher CCQ score at the start of the RECODE study results in a decrease or lower increase in the CCQ score (i.e. better quality of life). This effect is higher in the subgroup than in the total population.

In the model of the total population the effect of the implementation score indicates that implementing more parts of the RECODE intervention results in significantly greater deterioration or smaller improvement in the CCQ scores (positive sign indicates poorer disease-specific quality of life). Compared with patients in practices that made limited improvements, patients in practices that made moderate improvements had a 0.311 point higher change in CCQ score and patients in practices that made major improvements had a 0.334 point higher change in CCQ score. Further, the results showed that the patients in practices that estimated the success of the implementation of the RECODE intervention as very successful had a significantly higher increase in CCQ scores after the start of the RECODE study compared to the patients in practices that estimated their success lower.

In addition to the CCQ score at baseline, the model of the subgroup included the patient's gender; male patients have a significant higher deterioration in CCQ scores than women.

The CCM element 'self-management strategies' has a significant effect on the change in CCQ scores; the more self-management strategies the practices implemented, the higher the change in CCQ score and the poorer the disease-specific quality of life.

ΔEQ-5D

The model of the influence of the implementation of the RECODE intervention on the change in EQ-5D scores included only the EQ-5D score at baseline (table 12). This variable was also included in the model of the subgroup. The EQ-5D score at baseline has a significant effect on the change in EQ-5D scores; having a higher quality of life at the beginning of the RECODE study leads to a significant deterioration or smaller improvement of the EQ-5D score. The implementation variables did not improve the fit of the model in the total population and therefore they do not significantly influence the change in EQ-5D scores. In addition to the EQ-5D score at baseline, the model of the subgroup includes the implementation indicator 'individual treatment plan' and the patient characteristic employment. The subtotal implementation scores of CCM elements and total implementation scores did not have a significant contribution to the fit of the model of the subgroup. The implementation of individual treatment plans leads to significant improvements in EQ-5D scores. For patients in practices where treatment plans are tailored to the specific patients after the start of the RECODE study, the increase in EQ-5D score is significantly higher than in other practices. Employment has a significant effect on the change in EQ-5D scores; patients with a job have a significantly higher increase in EQ-5D score and therefore better quality of life.

ΔEQ-5D	Total population		Subgroup (MRC>2)	
	β	p-value	β	p-value
Intercept	0.441	0.000	0.332	0.003
EQ-5D score at baseline	-0.560	0.000**	-0.598	0.000**
Employment			0.132	0.027*
Individual treatment plan			0.109	0.020*
R_1^2 (%)	28.71		45.29	
R_2^2 (%)	28.71		45.29	

Table 12. Random effect model of the influence of the implementation on the ΔEQ-5D
Notes: *p<0.05, **p<0.0001

ΔPACIC

The results of the likelihood ratio tests showed that the implementation indicators 'smoking cessation' the PACIC score at baseline and the Charlson co-morbidity improved the fit of the model. None of the subtotal implementation scores of CCM elements or total implementation scores could be included in the model. The results of the final model are presented in table 13. The PACIC score at baseline has a significant effect on the change in PACIC scores; when the PACIC score at baseline is high, the change in PACIC score since the start of the RECODE study is lower. Further, the Charlson co-morbidity index has a significant effect on

the change in PACIC scores; the more comorbidity the patients has, the higher the change in PACIC score.

ΔPACIC	β	p-value
Intercept	0.955	0.000
PACIC score at baseline	-0.483	0.000**
Charlson co-morbidity index	0.076	0.010*
Smoking cessation	-0.099	0.374
R_1^2 (%)	24.69	
R_2^2 (%)	37.89	

Table 13. Random effect model of the influence of the implementation on the ΔPACIC
Notes: *p<0.05, **p<0.0001

ΔCosts

According to the likelihood ratio tests none of the implementation variables improved the fit of the model, not in the total population or the subgroup. In both models (table 14) the healthcare costs at baseline have a significant effect on the change in costs; the higher the healthcare costs at baseline, the lower the change in costs since the start of the RECODE study. Further, the model in the total population included the FER and the model in the subgroup included the EQ-5D score at baseline. However, both variables did not have a significant effect on the change in costs.

ΔCosts	Total population		Subgroup (MRC>2)	
	β	p-value	β	p-value
Intercept	2089.940	0.035	736.870	0.047
Healthcare costs at baseline	-0.645	0.000**	-0.634	0.000**
FER	-24.590	0.107		
EQ-5D score at baseline			413.64	0.390
R_1^2 (%)	10.95		11.24	
R_2^2 (%)	16.89		6.84	

Table 14. Random effect model of the influence of the implementation on the ΔCosts
Notes: *p<0.05, **p<0.0001

Proportion of patients with a clinically important deterioration in CCQ score

Four random effect models are estimated for the influence of the implementation of the RECODE intervention on the proportion of patients with a clinically important deterioration in CCQ (change in CCQ≥0.4). Just as in the four models of the change in CCQ scores, the difference between the models is the kind of implementation variables. The model with the subtotal implementation scores of CCM elements as implementation variables explained the variations in proportion of patients with a clinically important deterioration in CCQ the best. The results of this model are shown in table 15 and the other models are presented in table E6 in appendix E.

Proportion of patients with a clinically important deterioration in CCQ Model 2: CCM elements	β	p-value
Intercept	0.326	0.000
CCQ score at baseline	-0.054	0.027*
CCM: Decision support	0.053	0.000**
CCM: Self-management strategies	0.042	0.000**
Perceived success of implementation[1]		
Reasonably successful	-0.005	0.786
(Very) successful	0.188	0.000**
R_1^2 (%)	7.33	
R_2^2 (%)	27.28	

Table 15. Random effect models of the influence of implementation on the proportion of patients with a clinically important deterioration in CCQ
Notes: [1]reference group is not to somewhat successful, [2]reference group is limited improvements
*p<0.05, **p<0.0001

The results of the model of the proportion of patients with a clinically important deterioration in CCQ (change in CCQ≥0.4) are comparable with the model of the change in CCQ scores. The direction of the effect of the implementation of the RECODE intervention, in this model represented by two CCM elements (decision support and self-management strategies), is also in contrast with the expectations. The more parts of the CCM elements the practices implemented, the higher the proportion of patients with a clinically important deterioration in CCQ scores. The effects of the CCQ score at baseline are the same as in the change in CCQ scores models; practices where patients have a higher CCQ score at baseline have a lower proportion of patients with a clinically important deterioration in CCQ score in their practice. The perceived success of implementation by the healthcare providers has a significant effect on the proportion of patients with a clinically important deterioration in CCQ. Practices that estimate their implementation very successful have a higher proportion of patients with a clinically important deterioration in their CCQ score compared to the other practices.

5. Discussion

In this chapter the main findings of this study will be summarized (§5.1) and these findings will be interpreted and compared with previous published studies where possible (§5.2). Further, the strengths and limitations of this study will be identified (§5.3). Subsequently, the practical implications and recommendations for further research will be given (§5.4). Finally, this chapter will end with the conclusion of this study (§5.5).

5.1 Main findings

The objective of this study was to investigate the influence of variations in the implementation of the RECODE intervention between primary care practices on costs and effects of the intervention. The implementation variations and barriers and facilitators encountered during

the implementation of the RECODE intervention were explored by using information from provider checklists and interviewing the practice nurses or GPs from the practices. Subsequently, the influence of the implementation variations on costs and effects was examined by estimating random effect models. The results of this study confirm the expectation that the implementation of the RECODE intervention gets tailored to the local context and therefore varies between practices. Every primary care team attended the same course but the translation of the acquired knowledge to specific changes in the practices differed between the teams. For example the changes resulting from the RECODE course regarding multidisciplinary co-operation; some practices only referred more to other disciplines, other practices made agreements about the co-operation regarding treatment of COPD patients and a few practices organised periodically scheduled multidisciplinary meetings. Furthermore, the amount of change differed; on average the primary care practices implemented 8 aspects out of the 18 aspects of the RECODE intervention, ranging from 4 to 13 aspects.

The variations emerged because of the different starting levels of DM and the barriers and facilitators the primary care teams encountered during the implementation. The most important barriers and facilitators were the RECODE course, the motivation of healthcare providers, motivation of patients to change their lifestyle, the variability in adoption of DM within teams, the time available for implementing DM, staff turnover, the unfinished system of Zorgdraad, the reimbursement of physiotherapy and nutritional interventions and other (upcoming) projects targeting COPD care.

The practices particularly improved in the CCM elements delivery system design, decision support and self-management support. The implementation of the clinical information system 'Zorgdraad' did not succeed in any of the practices. The healthcare system influenced the implementation of DM by the reimbursement of physiotherapists and dieticians and other (upcoming) projects targeting COPD care. Finally, the RECODE program did not aim at improving the CCM element 'community', therefore there were no improvements in this area as a consequence of the RECODE study.

No significant differences between the practices were found in the changes in effects 18 months after the start of the RECODE study. There were significant differences between the practices in change in healthcare costs in the total population, but not in the subgroup analysis of patients with more COPD symptoms (MRC>2). The implementation variations could not explain most of the differences between the practices in changes in costs and effects between baseline and 18 months after the start of the RECODE study. The differences in changes in patients' experiences of integrated care, dyspnea, generic quality of life and the healthcare costs in the total population could not be explained by the total implementation or subtotal implementation scores of CCM elements. The total

implementation score of the RECODE intervention (total population) and the CCM elements score of 'self-management strategies' (subgroup) only explained the differences between the practices in changes in CCQ scores. However, the direction of the effects was unexpected; the more aspects of the RECODE intervention or CCM elements the practice implemented, the poorer the disease-specific quality of life of patients at the end of the RECODE study. In line with these results, the CCM elements 'self-management strategies' and 'decision support' also significantly increased the proportion of patients with a clinically important deterioration in CCQ score per practice. Two of the implementation indicators had a significant effect on some of the changes in effects. In the total population the 'use of funding for physiotherapy' leads to significantly greater improvements in MRC scores (i.e. improving dyspnea). 'Individual treatment plan' leads to significantly greater improvements in EQ-5D scores (i.e. improving generic quality of life).

5.2 Interpretation of the results (comparison with previous research)

5.2.1 Implementation variations

An important finding of this study is that the starting level of DM differed between the practices. These differences can be explained using the diffusion of innovation theory of Rogers.[28] Some of the practices that participated in the RECODE study already adopted DM. The relative early adoption of DM can be due to their innovativeness or because the primary care teams were already influenced by other dissemination efforts than the RECODE study (e.g. regional integrated care program). Practices that did not implement DM before the start of the RECODE study were not influenced by other dissemination efforts or were less innovative. For some of these practices the RECODE study was the reason to start implementing DM. Therefore the RECODE study actively disseminated DM to these practices. The innovativeness of these practices can be compared with Rogers' adopter categories the 'late majority' and 'laggards'. Participating in the RECODE study could have increased peer pressure which stimulated the practices to start implementing DM. Further, these practices might have been reluctant to innovate because their resources (e.g. time, money and/or a competent practice nurse) were limited and they wanted to be certain the new idea would not fail before they could adopt it.[28] Participating in the RECODE study could have removed their reluctance because the teams received information about DM in the course and were supported by the research team with the implementation of DM by ICT feedback, feedback reports and refresher courses.

In line with the findings in this study, previous research also found variations in implementation of the same intervention across healthcare settings.[26,27,47] Lichtman et al. concluded that despite of a standardized protocol, in-person training sessions, periodic

audits and careful monitoring by the authors of the guideline, the implementation of the guideline and subsequent change in patterns of care differed across sites.[47] This shows that the effective translation of clinical guidelines outside their original setting is a complex process.[47] The same holds for the implementation of the CCM. Pearson et al. reported wide variations in the effort organizations put into making changes according to the CCM. At the extremes, the number of changes made by the highest performer was seven times that of the lowest performer.[26]

The variations emerged because of differences in the characteristics of the local context: the starting levels of DM and the barriers and facilitators the primary care teams encountered during the implementation. As the theory of tailoring explains, the RECODE intervention is adapted to these characteristics by the primary care teams and patients.[11,32,33] For example, the multidisciplinary co-operation is adapted to the need of communication with other disciplines. This need was lower in practices where only one physiotherapist and dietician was involved compared to practices involving more physiotherapists and dieticians. The variations in amount of change can also be caused by differences in translation of the RECODE intervention to the local context. For example, some practices already implemented a lot of DM interventions and therefore the amount of change was lower or the practice nurse left the practice during the implementation and this resulted in the realisation of less changes.

5.2.2 Barriers and facilitators

Motivation of healthcare providers is a factor that influenced the implementation of DM in this study and was also found in the literature.[48-50] Sunaert et al. identified the willingness of a group of well-trained and motivated care providers to invest in implementing the CCM as the most important facilitator.[50] Several factors influenced the motivation of healthcare providers in this study. First, the RECODE course motivated the healthcare providers to improve COPD care. Second, the patients' lack of motivation to change their lifestyle as experienced by the respondents discouraged changes in behaviour of some healthcare providers. This is in line with findings of Brazil et al. where participants identified how patient factors such as patient knowledge, skills, attitude and compliance can either discourage or reinforce changes in the behaviour of providers.[49]

Another factor that might have influenced the motivation is the necessity to change. Although respondents did not clearly report this, it is expected that the necessity to change is higher in practices that implemented no or a few DM elements and that this enhanced the motivation of healthcare providers. In contrast, in practices that already had nearly complete integrated care the necessity to implement the RECODE intervention was probably lower. Lauvergeon et al. found such results in the implementation of DM in Switzerland. Some

physicians, insurers and representatives of departments of public health were sceptical about the necessity of implementing DM.[48] They saw DM only as a means to formalize what already existed, because Switzerland possessed many local healthcare structures, care was adapted to patients' need and disease severity, and the work in multidisciplinary teams already occurred in informal networks.[48] However, it needs to be noted that even though the necessity to implement the RECODE intervention might have been lower, the healthcare providers in these practices were still motivated to implement the few aspects they missed in their COPD care. Furthermore, previous research suggests that implementing the missing aspects could still increase the effectiveness of DM in these practices.[22,51-53]

Previous studies identified the complexity of the intervention as an implementation barrier.[49,50] Sunaert et al. explained that in a context where a lot needs to be changed, a DM program probably consists of too many components.[50] Each component of the intervention requires a specific implementation strategy and follow-up. In the study of Sunaert et al. this led to some confusion about the aims of the study and some components affected each other negatively. It is possible this also was a barrier for practices that had no or a few elements of DM before the start of the RECODE study, because in these practices a broad scale of change was required. However, the respondents did not mention this during the interviews.

Previous research showed the importance of a positive attitude towards DM and the compatibility of the program with the healthcare providers' beliefs for the implementation of an innovation in healthcare.[48,49,54] Recommendations that were in line with professional norms and values were better adhered to than recommendations that seemed to be in contrast with these norms and values.[54] In the study of Brazil et al. some healthcare providers expressed general disagreement with the guidelines that the DM program represented, especially in its categorization of asthma severity or the use of steroid therapy, and this hindered the implementation of the asthma DM program.[49] In contrast, the respondents in this study did not report the RECODE intervention was incompatible with their beliefs. An explanation for this difference can be that the content of the RECODE course was not controversial and more in line with professional insights and standards than the asthma DM program in the study of Brazil et al.

In addition to differences in adoption of DM between the primary care teams, there were differences within the teams. This is in line with previous research that also found variability in the adoption of aspects of DM among members within the same team.[49,50] Rogers suggested that this spread of adoption of the intervention is associated with differences in innovativeness of members in the same team.[28] For example, in this study there was a GP that did not use the tools of the practice nurse to actively track down COPD patients in his practice. In this example the practice nurse was more innovative than the GP. Brazil et al.

stated that it is important to recognize these individual differences within a team because it can be a barrier for successful implementation.[49] In this study only one member of each team was interviewed and therefore it was not possible to identify which healthcare providers were the most innovative.

In line with results of Walters et al. the ICT system of the RECODE intervention 'Zorgdraad' can be seen as a barrier because the implementation of the system was costly in both time and effort.[11] Problems with introducing computer technology in to healthcare are not uncommon. The reason for these problems is often that there is a mismatch between the model of clinical work the developers used when designing the ICT system and the actual nature of clinical work.[55] This mismatch was also present in the practices were 'Zorgdraad' was introduced. The most important flaw of 'Zorgdraad' was that the system was not tailored to the daily routines of the healthcare providers.[55] 'Zorgdraad' was a separate system besides the clinical information system the practices already used and transferring the information from 'Zorgdraad' to this clinical information system was not always possible. Comparable with findings of this study, Rousseau et al. found that when healthcare providers had to exit the system to access the patient's medical record, it was unusual for them to re-enter.[56] Further, most healthcare providers complained about the unclear instructions about 'Zorgdraad' during the RECODE course and found it difficult to navigate in Zorgdraad. However, they were reluctant to spend time to get more familiar with the system because they rather spend their limited time treating patients. Rousseau et al. argued that more training could possibly tackle these kinds of issues, but that would not tackle the more substantive challenges of providing a system that fits into the general practice context.[56] Walters et al. suggested that project leaders of implementation of DM programs sometimes need to limit the focus of the ICT system instead of wasting time and effort on implementing an unfinished system.[11] For the RECODE intervention this implies that 'Zorgdraad' should only have been implemented when the mismatches with the actual nature of the clinical work were solved.

Another barrier the respondents identified was the lack of reimbursement of self-management strategies; smoking cessation counselling, physical reactivation and nutritional interventions. This is in line with results from other studies where the problem who would pay for DM was often raised because some components (such as prevention, self-management education or coordination for teamwork) are not easily reimbursed by health insurance companies.[17,34,48,57,58] In contrast, the respondents in this study did not report barriers for the finances of cooperation with other disciplines. This is unexpected because cooperation between care providers in outpatient care is not optimally reimbursed in the Netherlands.[57] It is possible that this problem was not reported because the respondents were mainly practice nurses and they may not be fully aware of the financial issues in the practice. Furthermore,

the costs of cooperation with other disciplines are probably low because in most practices the communication with other disciplines was ad-hoc instead of in regularly scheduled multidisciplinary meetings.

Barriers regarding the availability of resources are frequently found in other studies and were also reported in this study; lack of time and staff turnover.[34,49,50] In the study of Brazil et al. providers expressed concerns about the amount of time required to adhere to a DM program.[49] More specifically, Sunaert et al. defined the extra time required during the consultation to motivate diabetes patients to participate in an education program as a barrier for the implementation of the CCM.[50] Regarding staff turnover, respondents in the study of Brazil et al. reported that it undermines the consistency in administering the DM program.[49]

The influence of other projects targeting the improvement of care of the same chronic condition as the intervention under study is seldom acknowledged in previously published studies. In this study, other projects that also targeted improvement of COPD care could hinder the implementation of the RECODE intervention when practices abandoned the RECODE intervention and focused on the other project or temporarily stopped improving COPD care until the start of the upcoming project. However, at the same time these projects often provided better guidance or financial arrangements that facilitated the improvement of COPD care. Subsequently, this facilitated the implementation of aspects of the RECODE intervention as well. For example, in some practices the reimbursement of dieticians was arranged by a healthcare group and this enhanced patients' motivation to see a dietician and thereby the treatment of nutritionally depleted patients participating in the RECODE intervention.

In the practices in this study the practice nurse (often together with the GP) was the most involved with the implementation of DM and sometimes acted like the leader of the changes. However, none of the respondents in this study mentioned the importance of leadership as a facilitator or barrier of the implementation of DM. This finding is in line with the results of Lauvergeon et al.[48] but in contrast with most other studies.[27,47,58-60] Luxford et al. identified strong leadership as a critical facilitator of implementing patient-centred care.[59] The reason that respondents in this study did not report these factors as facilitators or barriers can be that, in contrast with the other studies[27,47,58-60], this study did not pay specific attention to leadership and implementation strategies.

5.2.3 Influence of the implementation variations on costs and effects

To my knowledge there are no other studies that investigated the differences in outcomes between healthcare settings that implemented the same intervention. This study tried to determine what aspects of the RECODE intervention are most beneficial to COPD patients

by comparing practices in the intervention group that implemented a specific aspect of DM with practices that did not.

The results showed that in the practices that used the funding for physiotherapy the change in MRC scores of patients was lower, indicating improved dyspnea. This finding is in line with previous research where an exercise rehabilitation program significantly reduced the MRC score of COPD patients.[61] The influence of the use of funding was even higher in the subgroup of patients with more COPD symptoms (MRC>2). This is not surprising since the criteria for receiving the funding was that the patients' MRC score was higher than two. However, the significant influence of this indicator is somewhat surprising because the funding was only used for a few patients in three practices. Therefore the use of funding might reflect that these practices give more attention to physical reactivation by physiotherapists than the other practices and that this results in improved dyspnea in patients.

The results of the analysis of the change in EQ-5D scores shows that implementing individual treatment plans only has a significant improving effect on the generic quality of life in patients with more COPD symptoms and not on the total population. An explanation can be that individual treatment plans primarily are established with patients with more COPD symptoms and are therefore more effective in this group. This was also found in the study of Robinson et al. where some patients perceived there was little to manage and therefore the practice nurses had difficulties in facilitating goal development (i.e. developing an individual treatment plan) for these patients.[62] Furthermore, Bischoff et al. suggested there might be a tendency among healthier patients to delay their treatment.[63] This could mean that even if individual treatment plans are established for patients with less COPD symptoms, patients do not adhere to it and therefore their generic quality of life does not improve.

Only two CCM elements (decision support and self-management strategies) had a significant influence on one of the effect measures (CCQ) in the subgroup of patients with more COPD symptoms. The direction of this effect was unexpected; implementing more aspects of the CCM elements resulted in poorer disease-specific quality of life. A possible explanation for this finding will be discussed later.

Except for the two CCM elements and two implementation indicators discussed above, none of the CCM elements or indicators significantly influenced the changes in costs of effects since the start of the RECODE study. Possibly the implementation of one aspect or CCM element of the intervention alone has modest or negligible effects in practice and therefore does not result in significant changes in costs and effects. Oxman et al. described this finding as "there are no 'magic bullets' for improving the quality of healthcare".[64] Instead it is suggested that the individual components should be joined up to be more effective. Or in other words; successful integrated care is more than the sum of its parts.[65] There are several

review studies that found that patients who received 2 or even 3 or more interventions within different CCM elements in DM programs for COPD had lower rates of hospitalizations and greater savings in healthcare costs.[22,51-53] Therefore it was expected that the total implementation scores, that reflect the number of aspects of the intervention the practices have implemented, would have significant influence on the change in costs and effects. However, the results of this study show that this is not the case; the total implementation scores did not influence the change in healthcare costs, MRC, EQ-5D or PACIC scores. Possible explanations for these findings will be discussed later.

The total implementation scores only had significant effect on the change in CCQ score. However, just like the effect of the CCM elements, the direction of this effect was in contrast to what was expected; implementing more aspects of the RECODE intervention resulted in increased CCQ scores and therefore poorer disease-specific quality of life. An explanation for this finding could be that patients' awareness of the impact of COPD on their quality of life increased and as a result patients assess their disease-specific quality of life poorer than before the implementation of DM. The increased awareness of their poor quality of life is caused by increased attention of healthcare providers to prevent that patients developed into a more severe COPD stage. To achieve this, the patients' health status needs to be monitored and this means that patients have to visit the healthcare providers more often. Furthermore, to encourage patients to change their lifestyle, healthcare providers had to make them more aware of possible health improvements because COPD patients often do not feel ill or adapt their lifestyle to their abilities without noticing it. At the same time this makes patients more aware of the impact of COPD on their current quality of life.

In addition to the implementation variables, the expectation was that the estimate of success of the implementation as perceived by the GP or practice nurse could predict the change in costs and effects – the higher the estimate of success, the lower the costs and the better the health outcomes – but the opposite was true. Patients in practices where healthcare providers estimated the success of the implementation of DM as successful to very successful had a significantly higher increase in CCQ scores and proportion of patients with a clinically important deterioration in CCQ. This finding might be caused by an inadequate self-assessment of the healthcare providers. A systematic review found that there are weak or no associations between the physicians' self-rated assessment and external measures of competence.[66] In line with these findings, from the four practices that estimated their success as successful to very successful three practices estimated their success higher than the improvements they made according to the total implementation scores (table E4 in appendix E).

Although some patient and practice characteristics differed between practices, most of them did not explain differences in costs or effect changes between the practices. However,

several patient characteristics influenced the changes in costs and effects. First, the baseline scores of the outcome measures had a significant lowering effect on every change in outcome score. This may reflect that when patients have a good baseline score (i.e. high EQ-5D and PACIC score, low healthcare costs, MRC and CCQ score), they have reduced possibilities of detecting improvement and therefore the score decreases or has a smaller increase. The other way around, the possibility of detecting improvement is higher for patients with poor baseline scores (i.e. low EQ-5D an PACIC scores, high healthcare costs, MRC and CCQ score) because their health state cannot get much worse.

Second, the subgroup analysis showed that the change in CCQ score is higher for male patients compared to female patients with more COPD symptoms. This can be explained by the fact that male COPD patients often report a better health status than female patients and therefore they might have a higher possibility of detecting health deterioration. Third, patients with more COPD symptoms that have a job have a significantly higher improvement in generic quality of life compared to patients without a job. The fact that these patients experience more COPD symptoms but still are able to work might reflect that their lung function is relatively good and there are more possibilities to relieve the symptoms. Possibly this explains why the increase in generic quality of life is higher in this group of patients. Fourth, the Charlson co-morbidity index had a positive effect on the change in PACIC scores. This may be explained by the fact that patients with more comorbidity have a complex disease and need integrated care from different healthcare providers that is tailored to their individual needs. The results of the PACIC scores seem to reflect that the healthcare providers fulfilled this need and provided more integrated care for these patients.

The above discussion of the results shows that the implementation variations did not explain most of the differences in costs and effects. This is also reflected in the low proportional reductions in mean squared prediction error because of the inclusion of the independent variables in the random effect models (R_1^2 and R_2^2). There are several explanations possible for these findings.

First, the low R_1^2 and R_2^2 indicate that the variables included in this study only explained a small part of the differences between the practices in changes in costs and effects. This indicates that there are other factors that influenced these differences that were not identified in this study.

Second, it is possible that the follow-up time of this study was too short to observe the whole mechanism through which changes in the process of care delivery can lead to changes in other outcome categories. Tsiachristas et al. developed a framework in which this and other mechanisms are explained.[67] The results of the interviews showed that the healthcare providers made changes in the process of care delivery. However, these improvements are not reflected in higher PACIC scores. This might indicate that the

healthcare providers need more time to intensify the DM interventions they implemented before patients will notice them and reflect this in higher PACIC scores. Together with changes in patient lifestyle and self-management behaviour, changes in process of care delivery can lead to changes in biomedical, physiological, clinical health outcomes and health related quality of life.[67] In this study the 'use of funding for physiotherapy' improved dyspnea. However, the implementation of DM did not result in improved health related quality of life. This suggests that it may take longer before the improvements in symptoms (i.e. dyspnea) will be reflected in improvements in disease-specific and generic quality of life. Finally, there is probably more time needed to prevent exacerbations and thereby save hospital costs.

Third, the implementation of DM may have had no (or limited) effect because it is possible some patients did not adhere to the treatment and advices of healthcare providers. In terms of the framework of Tsiachristas et al. the changes in process of care delivery might not have resulted in changes in patients' lifestyle and self-management behaviour.[67] The core of the CCM model is the productive interaction between informed, activated patients and prepared, proactive teams of healthcare providers.[17-19] If one of the two actors is not motivated this will hinder the effectiveness of the DM interventions. For instance, several studies have shown that teaching early recognition and appropriate reaction on exacerbations by patients is only effective when patients comply with the instructions.[63,68] However, in these studies only forty percent adhered to the instructions and therefore the intervention was not effective in the total study population.[68] It is possible these results could also be found for the effectiveness of other aspects of DM, for example; the efforts of healthcare providers to improve the collaboration with other disciplines probably will not be effective when patients are not motivated to change their lifestyle and use the care of these healthcare providers.

Fourth, the number of patients where the treatment was intensified due to the implementation of DM may have been too small to show significant influences on costs and effects. For instance, since the change in PACIC score was higher for patients with more comorbidity, it is possible the healthcare providers used DM interventions (such as individual treatment plan) predominantly for more complex patients.

Fifth, it is possible the differences in changes in costs and effects cannot be explained by the implementation variations, because these variations where to small. They can be too small in two ways. Some aspects of the RECODE intervention are implemented by almost every practice, while other aspects are only implemented by a few practices. Therefore the number of patients in the comparator groups is sometimes small, which makes it more difficult to find significant differences between practices that implemented the specific aspect with the practices that did not. Further, the difference between implementing an aspect of DM or not was sometimes small; for example giving more attention to smoking cessation or attempted to use 'Zorgdraad'. This resulted in the comparison of two groups were the

difference in provided care is so small that it is not surprising it does not explain the differences between the groups in costs and effects.

Sixth, the differences in changes in effects were not significant and therefore might have been too small to explain. Possibly this is caused by power of this study; the number of patients per practice was too small to find significant differences.

Seventh, the investigation of the influence of the implementation variations on differences between practices in changes in costs and effects was complicated by the fact that the starting level of DM in the practices was not comparable. To correct for the different starting levels the starting level variable was included in the analysis, but this variable did not improve the fit of the models and was therefore not included. This may reflect that there were too many starting level groups. It is also possible the classification of the practices in the groups was not accurate.

Eighth, some of the random effect models might have had low explanatory power because the variables follow a normal distribution in the random effect models, while in fact they are not normally distributed. However, we chose the normal distribution, because none of the other distributions fitted the data better based on Kolmogorov-Smirnov tests.

Finally, it is possible that features of this study influenced the results. These study limitations will be discussed in the next paragraph.

5.3 Study strengths and limitations

This study has several strengths. First, an important strength of this study is that we provided a comprehensive overview of the implementation of a DM intervention by combining qualitative and quantitative research methods. This approach was unique because qualitative studies undertaken alongside randomised controlled trials of interventions to change organisation and practice are uncommon.[69] Second, by including almost every practice in the intervention group and not only the teams where the implementation was successful, this study gave a realistic view of the implementation of the RECODE intervention. However, three practices did not want to participate in this study. The non-participating practices seem to be comparable with practices that were included in the study. In two non-participating practices, the practice nurse left after the RECODE study and this hindered the implementation of DM. This was also the case in four practices that were included in this study. The other non-participating practice seems to be comparable to the practices that already had nearly completed integrated care before the start of the RECODE study and made some improvements as a consequence of the RECODE course. However, since we do not have detailed insight in the implementation of DM in the non-participating practices, we cannot totally exclude the possibility there was selective non-participation. Third, the interviewer was not involved with the RECODE intervention and therefore not known by the

respondents. This anonymity reduced the pressure to give socially desirable answers. The respondents felt free to discuss negative experiences with the RECODE study and to report aspects of the intervention they did not implement. Fourth, we used different information sources to determine the scores on the implementation indicators. The information from the provider checklist was complemented by information from the interviews, data of the attendance of the healthcare providers at the course and data about the use of funding. Fifth, the determination of the scores on the implementation indicators was checked by a second researcher to enhance the objectivity of the results. Sixth, this study included several effect measures; patients' assessment of integrated care, dyspnea, disease-specific and generic quality of life. Finally, in addition to the analysis of the influence of implementation variations on differences between practices in changes in costs and effects in the total population, these relationships were also investigated in a subgroup of patients with more COPD symptoms (MRC>2).

There are also several limitations of this study. First, the reliability of the information derived from the interviews can be questioned and therefore the implementation indicators might not reflect the real implementation of the RECODE intervention in the practices. There are several reasons for this limitation: (1) The interviews were held with one representative of the primary care teams (mostly the practice nurse) and therefore only gained insight in one point of view. The practice nurse might not be aware of some subjects, such as the finances of the practice or the cooperation with secondary care. However, we chose to interview the practice nurses because of all members of the primary care team, they probably have the best overview of COPD care in the practice. Furthermore, the GPs completed the provider checklist and some of the GPs were interviewed when the practice nurse was not available. Therefore in most practices the information is derived from two healthcare providers. (2) The formulation of some questions might have been misleading. For example, some respondents might have misunderstood what the interviewer meant with the feedback reports because in the beginning of the study the interviewer was under the assumption these reports were provided via 'Zorgdraad'. (3) As earlier discussed the self-assessment of healthcare providers' success of implementation should be doubted. (4) The interviews were held at the end of the RECODE study and therefore it is possible the respondents inaccurately remembered the changes they made since the start of the RECODE study. However, we also derived information from the provider checklists completed by the GPs at 12 months and these were consistent with the information derived from the interviews. These limitations of the interviews might have led to an over- or underestimation of the extent of implementation of the RECODE intervention. It would have been more reliable to support the results of the interviews with objective measures; such as percentages of patients within practices who actually received a specific intervention. However, this information was not available for this

study and therefore this approach was the highest attainable. Nevertheless, it is fully acknowledged that the results have to be interpreted with caution. Second, it was not always possible to determine whether improvements in COPD care were caused by the RECODE intervention or other factors; such as parallel projects targeting integrating COPD care or the general trends towards patient centeredness, increased self-management and substitution from secondary to primary care. This is caused by the fact that this study only included practices from the intervention group of the RECODE study. Comparison with practices in the control group can determine if the changes are a consequence of the RECODE intervention or are caused by other factors. Third, this study could not determine the presence of some barriers and facilitators, because of the absence of questions about these topics. For example, there were no specific questions about the perceived necessity to implement DM or the complexity of the intervention. Fourth, the intensity of the implementation of aspects of DM is considered equally in every practice that made changes in the specific aspect while in reality there can be differences between the practices. However, it was considered determining the intensity in addition to the quantity of the implementation activities but it was chosen not to because it could not be objectively determined. Fifth, this study only examined the influence of the implementation of the RECODE intervention on the proportion of patients with a clinically important deterioration in CCQ score. This outcome measure is not weighted against the proportion of patients that had a clinically important improvement in CCQ score. Therefore, this outcome measures does not give all the information about the effectiveness of the intervention. These improvements could have been taken into account by calculating the net proportion of patients with a clinical important deterioration (subtract the proportion of patients with a clinically important improvement from the patients with a clinically important deterioration in CCQ score). Sixth, the estimate of success of the implementation as perceived by the GP or practice nurse could be seen as an alternative implementation measure, but was included in the model together with the four kinds of implementation variables. Since both variables measure the implementation of the RECODE intervention, the perceived success of the implementation by the healthcare providers could have mitigated the influence of the other implementation variables. However, the results of additional analysis (appendix F) showed that in this study the results of the implementation variables were not heavily affected by the inclusion of this variable. Finally, this study was cross-sectional because only data of costs and effects of 18 months after the start of the RECODE study was included. Possibly, the peak of costs savings and health improvements was before or after this time point.

5.4 Practical implications and recommendations for further research

This study illustrates that there can be wide variations in the implementation of an intervention across healthcare settings. Studies on the (cost-) effectiveness of interventions should take this heterogeneity into account; otherwise this might lead to inappropriate conclusions about the (cost-) effectiveness of the intervention. Further, the findings of the barriers and facilitators of implementing DM can be used to enhance the success of future DM implementation.

Since this was one of the firsts studies that investigated the influence of implementation variations on differences in costs and effects of an intervention, further research is necessary to confirm the results. The lessons learned by performing this study resulted in the following recommendations for further research. Firstly, it is recommended interviewing more different stakeholders (e.g. physiotherapists, dieticians, secondary healthcare providers, healthcare insurers and patients). This will probably result in a more reliable view on the implementation of the intervention and can provide insight in barriers and facilitators from other points of view. In addition, this makes it possible to investigate differences in innovativeness within primary care teams. Secondly, more objective measures to determine the scores of the implementation indicators should support the information derived from the interviews. Thirdly, instead of the proportion of patients with a clinical important deterioration in CCQ scores, the net proportion of patients with a clinically important deterioration should be used as an outcome measure. This way the patients with a clinical important improvement in CCQ score are also taken into account. Fourthly, further research should include the estimate of success of the implementation as perceived by healthcare providers as an alternative implementation measures besides the other implementation variables (implementation indicators, subtotal implementation scores of CCM elements, total implementation scores) to exclude the possibility this variable mitigates the effect of the other implementation variables. Finally, to exclude the possibility the peak of the effect of the intervention is missed, it is advised to perform a longitudinal study (i.e. also incorporate 6, 9 and 12 months results) with a longer follow-up time.

5.5 Conclusion

This study identified variations in implementation of a DM program between practices. These variations emerged because the primary care teams tailored the DM program to the characteristics of their local context. These characteristics were the starting level of DM – which is determined by the innovativeness of the primary care teams – and the barriers and facilitators the teams encountered during the implementation. The implementation variations did not explain most of the differences between the practices in changes in cost and effects. This study suggested several explanations for these findings. Further research is necessary

to determine whether these suggestions are true. Furthermore, it is desirable to elaborate on the findings in this study by further exploring the heterogeneity between practices and its influence on costs and effects of DM. This information could support future cost-effectiveness studies to give more accurate conclusions about the cost-effectiveness of DM.

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Appendix A – Indicators degree of implementation of aspects of the RECODE intervention

	Indicators	Scale	Explanation of aspect	Information source
	CCM: Delivery system design			
1.	Improved co-operation with physiotherapist(s) or more use of physiotherapy	0 = no 1 = yes	The practice nurse, GP and physiotherapist(s) have agreed on the indications of referral, communication regarding patients, coordination of the treatment of COPD patients or patients are more often referred to a physiotherapist for physical reactivation than before the start of the RECODE study.	Interview Checklist intervention: 1, 3
2.	Improved co-operation with dietician(s) or more use of dietetics	0 = no 1 = yes	The practice nurse, GP and dietician(s) have agreed on the indications of referral, communication regarding patients and coordination of the treatment of COPD patients or patients are more often referred to a dietician for nutritional advice than before the start of the RECODE study.	Interview Checklist intervention: 1, 3
3.	Improved co-operation with lung specialist(s)	0 = no 1 = yes	The practice nurse, GP and lung specialist(s) have agreed on the indications of referral, communication regarding patients and coordination of the treatment of COPD patients after the start of the RECODE study.	Interview Checklist intervention: 1, 3
4.	Multidisciplinary meetings	0 = no 1 = yes	After the start of the RECODE study periodically scheduled meetings regarding individual COPD patients, exchanging medical knowledge, and/or organisational and administrative care are organised (with at least the GP, practice nurse and physiotherapist).	Interview Checklist intervention: 4, 5
5.	Task reallocation from GP to practice nurse or specialized nurse	0 = no 1 = yes	The practice nurse has taken over tasks that were tasks of the GP before the start of the RECODE study.	Interview
6.	Substitution of care from secondary to primary care	0 = no 1 = yes	Primary healthcare providers have taken over tasks that were tasks of secondary healthcare providers before the start of the RECODE study.	Interview
7.	Change in follow-up and visit structure	0 = no 1 = yes	Patients visit the practice nurse or GP according to a structural follow-up plan after the start of the RECODE study.	Interview Checklist intervention: 3
8.	Active tracking of high risk patients inside the primary care setting	0 = no 1 = yes	Active tracking of high risk patients inside the practice (possibly on basis of the feedback reports of ZORGDRAAD) after the start of the RECODE study.	Interview Checklist intervention: 7
	CCM: Decision support			
9.	Attendance at the RECODE courses	0 = no 1 = yes	The GP(s), practice nurse(s), physiotherapist(s) and dietician(s) all attended the RECODE course.	Attendance data

10.	Attendance at the refresher courses	0 = no 1 = yes	Two or more healthcare providers from different disciplines attended the refresher courses.	Attendance data
11.	Changes in COPD protocol	0 = no 1 = yes	After the start of the RECODE study the original COPD protocol is adapted or a new COPD protocol is developed and implemented.	Interview
12.	Quality of life and symptoms questionnaires part of consultations	0 = no 1 = yes	The practice nurse started to use quality of life and symptoms questionnaires (such as CCQ and MRC) in consultations with patients after the start of the RECODE study.	Interview
	CCM: Self-management strategies			
13.	Individual treatment plan	0 = no 1 = yes	After the start of the RECODE study patients and practice nurses or GPs begun to jointly formulate personal goals and these goals are recorded in the patient's file. This way the patients follow an individual treatment plan.	Interview
14.	Smoking cessation	0 = no 1 = yes	The practice nurse or GP pays attention to smoking cessation in a different way than before the start of the RECODE study.	Interview Checklist intervention: 3
15.	Early recognition of exacerbation	0 = no 1 = yes	The practice nurse or GP pay more attention to teaching patients the early recognition of and the way to respond to exacerbations (e.g. call the primary care setting) than before the start of the RECODE study.	Interview Checklist intervention: 3
16.	Motivational interviewing	0 = no 1 = yes	The practice nurse or GP started to use the motivational interviewing technique (more often) to understand and make use of patients' personal goals in physical reactivation and lifestyle changes after the start of the RECODE study.	Interview
	CCM: Clinical information system			
17.	Actively tried to use Zorgdraad	0 = no 1 = yes	The practice nurse (and other healthcare providers) actively tried to use Zorgdraad.	Interview
	CCM: Healthcare system			
18.	Usage of funding for physiotherapy	0 = no 1 = yes	Patients in the practice used the supplementary funding from health care insurers arranged by RECODE for a COPD-specific exercise training program in patients with MRC scores >2.	Funding data

Appendix B – Elements RECODE course

Elements	Examples
Proper diagnosis	Performing and interpreting a spirometry test and assessment of disease burden using MRC Dyspnea scale and Clinical COPD Questionnaire (CCQ).
Optimal medical adherence	Tailoring of advices from international guidelines, e.g. frequent exacerbations necessitate inhaled corticosteroids; daily respiratory complaints necessitate long-acting bronchodilators
Applying self-management plans	Teaching self-management techniques like early recognition and treatment of exacerbations.
Smoking cessation counselling	Review of the recent literature, discussion of bottlenecks, applying behavioural techniques and drug therapy for smoking cessation
Motivational interviewing	A technique to understand and make use of patients' personal goals in physical reactivation and lifestyle changes. The personal goals of the patient can be defined in an individual treatment plan.
Physiotherapeutic reactivation	Encouragement of regular exercise. Using a patients' personal goal, referral for physiotherapeutic reactivation in patients with MRC score >2.
Nutritional interventions	Early recognition and treatment of nutritionally depleted patients
Relationship with secondary care	Cooperation and collaboration with secondary care

Appendix C – 'Satisfaction, involvement and implementation of DM program' questionnaire (provider checklist)

Inleiding
De volgende vragen gaan in op een aantal hoofdcomponenten van de RECODE interventie. Het doel van de vragen is het bepalen van de mate waarin de interventie in uw praktijk is geïmplementeerd.

Vraag 1

Welke disciplines zijn er in uw praktijk bij het RECODE programma betrokken? (alle relevante opties aanvinken + aantal aangeven)

- ☐ Aantal _____ Huisarts(en)
- ☐ Aantal _____ Longarts(en)
- ☐ Aantal _____ Longverpleegkundige(n)
- ☐ Aantal _____ Praktijkondersteuner(s)
- ☐ Aantal _____ Fysiotherapeut(en)
- ☐ Aantal _____ Diëtist(en)
- ☐ Aantal _____ Apotheker(s)
- ☐ Aantal _____ Anders, namelijk

……

Vraag 2

Kunt u hieronder aangeven welke hulpverlener(s) er op de cursus en terugkomdagen aanwezig zijn (geweest) van uw huisartsengroep?

Hulpverlener	**Nascholing dag 1 ochtend**	**Nascholing dag 1 middag**	**Nascholing dag 2 ochtend**	**Nascholing dag 2 middag**	**Terugkomdag**
Huisarts 1					
Huisarts 2					
POH 1					
POH 2					
Longverpleegkundige 1					
Longverpleegkundige					
Fysiotherapeut 1					
Fysiotherapeut 2					
Diëtiste 1					
Diëtiste 2					
Anders nl:					
Anders nl:					

Vraag 3

Kunt u hieronder aangeven met hoeveel patiënten u met de interventie aan de slag bent gegaan sinds de nascholing en hoe lang uw team daar gemiddeld per patiënt mee bezig is geweest?

Element	**Aantal patiënten**	**Gemiddelde tijd per patiënt (uur)**
Oproepen voor longfunctie		
Gestructureerd vervolgen bij POH		
Gestructureerd vervolgen bij POH met individueel behandelplan (incl evt persoonlijk streefdoel)		
Vroegtijdige herkenning exacerbaties		
Stop-met-roken aanpak		
Doorverwijzing longarts		
Doorverwijzing Fysiotherapeut		
Doorverwijzing Diëtiek		

Vraag 4

Wordt er gewerkt in multidisciplinaire teams, waarbij er periodiek contact is tussen de zorgverleners (tenminste huisarts, longverpleegkundige/ POH, Fysiotherapeut)?

- ☐ Ja
- ☐ Nee
- ☐ Evt opmerkingen: ……..

……..

……

Vraag 5a

Hoe vaak vindt er multidisciplinair overleg plaats m.b.t. de zorg voor <u>individuele</u> COPD patiënten?

- ☐ Vaker dan één keer per maand
- ☐ Eén keer per maand
- ☐ Eén keer per kwartaal
- ☐ Minder dan één keer per kwartaal
- ☐ Niet

Vraag 5b

Hoe vaak vindt er multidisciplinair overleg plaats m.b.t. <u>organisatorische en administratieve</u> zorg voor COPD?

- ☐ Vaker dan één keer per maand
- ☐ Eén keer per maand
- ☐ Eén keer per kwartaal
- ☐ Minder dan één keer per kwartaal
- ☐ Niet

Vraag 6

Zijn er na de nascholing afspraken gemaakt met de <u>2e lijn</u> m.b.t. COPD zorg? Wat voor afspraken en met wie?

……..

……

……

Vraag 7

Heeft u naar de volgende rapportages gekeken? Hoeveel tijd heeft u hieraan besteed? En heeft u aan de hand hiervan actie ondernomen?

Feedback rapportages	**Tijdbesteding (uur)**	**Actie ondernomen aan de hand van feedbackrapport**
0 maanden uitdraai van al uw patiënten die luchtwegmedicatie (R03 medicatie) gebruiken (gegeven op de cursus op CD-Rom)		☐ Ja ☐ Nee
6 maanden feedbackrapport (alle patiënten met hun MRC en CCQ uitslagen, gemarkeerd welke patiënten extra aandacht behoeven)		☐ Ja ☐ Nee
Teruggeschreven MRC in uw HIS (onder diagnostisch dossier of lab resultaten)		☐ Ja ☐ Nee
Teruggeschreven CCQ (onder diagnostisch dossier of lab resultaten)		☐ Ja ☐ Nee
12 maanden feedbackrapport		☐ Ja ☐ Nee

Vraag 8

In hoeverre vindt u dat de implementatie van geïntegreerde zorg voor COPD patiënten in uw praktijk geslaagd is?

☐ Zeer geslaagd ☐ Goed geslaagd ☐ Redelijk geslaagd ☐ Matig geslaagd ☐ Niet geslaagd

Vraag 9

Kunt u hieronder aangeven welke problemen u wel/niet tegenaan loopt bij de implementatie van geïntegreerde zorg voor COPD patiënten in uw praktijk?

	Geen problemen	**Matige problemen**	**Veel problemen**
Weinig tijd beschikbaar			
Communicatie tussen disciplines in de eerste lijn			
Communicatie tussen de eerste en tweede lijn			
Toegang tot zorgdraad			
Feedback rapportages niet overzichtelijk			
Personeelstekort			
Vertrek/verandering van personeel sinds cursus			
Vergoeding stop-met-roken aanpak			
Vergoeding fysiotherapie			
Vergoeding diëtiek			

Overig

Heeft u nog op- en aanmerkingen over het RECODE programma?

……
……
……
……
……
……
……
……
……

Wij danken u hartelijk voor het invullen van de vragenlijst

Appendix D – Interview questions (Dutch)

Introductie

Om te beginnen zal ik even kort wat meer over mezelf vertellen. Ik ben bezig met een master Gezondheidswetenschappen op de Erasmus Universiteit. Voor mijn afstudeerscriptie doe ik een deelonderzoek binnen het RECODE project. Mijn doel is om erachter te komen hoe disease management programma's zoals RECODE in de praktijk worden geïmplementeerd. Daarnaast ben ik benieuwd welke factoren de implementatie van DM bevorderen of belemmeren.

Ik zal straks wat vragen stellen om erachter te komen hoe de zorg voor COPD patiënten is veranderd sinds de start van RECODE. Er zijn geen goede of foute antwoorden, wij zijn gewoon benieuwd naar uw ervaringen. Dus vertel ook gerust dat bepaalde onderdelen niet goed gelukt zijn. Dat is juist waardevolle informatie, omdat dit in volgende DM projecten meegenomen kan worden.

Ik verwacht dat het interview ongeveer een half uur duurt.
Hebt u er bezwaar tegen als ik dit interview op neem?
Hebt u nog vragen voor we beginnen?

Openingsvragen

- Hoe zag de zorg er voorafgaand aan het volgen van de RECODE cursus uit voor een COPD patiënt?
- Welke verwachtingen had u toen u naar de RECODE cursus ging?
- Welk praktijkplan hadden jullie als team op de RECODE cursus opgesteld?
  Welke afspraken zijn er tijdens de cursus met elkaar gemaakt?
- Wat is er na de cursus gebeurd met dit plan?
- Zijn er verder nog initiatieven genomen voor COPD patiënten?
- Heeft iemand de leiding genomen in het uitvoeren van het praktijkplan?
  Zo ja, wie? (op de cursus, en wie daarna?)
- Werd er regelmatig gemeten of er veranderingen hebben plaatsgevonden naar aanleiding van het praktijkplan? Zo ja, hoe?

Delivery system design

- Hoe is de zorg voor COPD patiënten veranderd door het volgen van de RECODE cursus?

Indien nodig, door vragen naar:

- ✓ Aantal betrokken disciplines
- ✓ Multidisciplinaire teams: overleggen, communicatie en samenwerking
- ✓ Doorverwijzen naar longarts, fysiotherapeut en diëtist
- ✓ Taakverschuiving van huisarts naar praktijkondersteuner
- ✓ Kennisuitwisseling (medisch) tussen professionals
- ✓ Taakverschuiving van tweedelijnszorg naar eerstelijnszorg: communicatie en samenwerking
- ✓ Gestructureerd volgen (follow-up) patiënten door POH (met of zonder individueel behandelplan, persoonlijk streefdoel)
  Patiënten die extra aandacht nodig hebben
- ✓ Gebruik feedback rapportages

Self-management support

- Heeft het volgen van de cursus iets veranderd aan de manier waarop het zelfmanagement voor COPD patiënten wordt aangepakt?

Indien nodig, door vragen naar:

- ✓ Individueel behandelplan
- ✓ Diagnose en behandeling psychologische problemen
- ✓ Leefstijlinterventies (bv. stop-met-roken aanpak)
- ✓ Zelfmanagement interventies (bv. vroegtijdig herkennen van exacerbaties)
- ✓ Motivational interviewing (motiverende gespreksvoering)

Community

- In hoeverre hebben jullie de omgeving (partner, familie) van COPD patiënten betrokken bij de zorgverlening (sinds de invoering van RECODE) (bv. bij stoppen met roken)?

Decision support

- Hoe worden protocollen en richtlijnen gebruikt bij de behandeling van COPD patiënten sinds de invoering van RECODE?
  Indien nodig, door vragen naar:
  - ✓ COPD protocol
  - ✓ Kwaliteit van leven vragenlijst als onderdeel van een consult
  - ✓ Acties op basis van de feedbackrapportages

Clincial information systems

- Wat zijn jullie ervaringen met ZORGDRAAD?
- Waarom wel of niet mee gewerkt?

Healthcare organization

- Hoe financieren jullie de onderdelen van COPD zorg?
- Hebben jullie op een bepaald onderdeel problemen ondervonden? Hoe hebben jullie die problemen geprobeerd op te lossen?

Succes- en faalfactoren

- Hoe zou je het RECODE programma omschrijven?
- Wat zijn de belangrijkste gevolgen geweest van het RECODE programma voor de COPD zorg?
- Wat heeft bijgedragen aan dit succes?
- Welke onderdelen van het praktijkplan zijn niet gelukt?
- Wat zijn de redenen dat dit niet gelukt is?
- Zijn er nog andere barrières geweest bij het implementeren van jullie praktijkplan die we nog niet hebben besproken?
- Wat zijn jullie plannen voor de toekomst van de COPD zorg? Zijn er plannen om het praktijkplan uit te breiden en/of te verspreiden naar andere huisartsenpraktijken, andere COPD patiënten (die buiten RECODE vallen) of andere ziekten?
- Zou je RECODE aanraden aan andere huisartsenpraktijken?

- In hoeverre vindt u dat de implementatie van geïntegreerde zorg voor COPD patiënten in uw praktijk geslaagd is? *(vraag gesteld indien checklist niet door huisarts was ingevuld)*
  Zeer – Goed – Redelijk – Matig – Niet

Appendix E – Results

	Overall (n=470)	AQ	AX	BR	BY	CT	GG	HD-HE	HT-HU-HV	IA	IB	IR	KT	KW	ML	MQ	NH	NQ	Test statistic	p-value
Number of COPD patients	28	19	13	22	22	22	26	46	43	35	26	32	23	19	34	45	20	23		
Gender (% men)	50.9	47.4	38.5	59.1	27.3	45.5	34.6	39.1	51.2	37.1	46.2	65.6	56.5	57.9	64.7	55.6	75.0	65.2	27.815	0.033*
Age	68.3 (11.3)	74.8 (10.1)	70.5 (11.4)	70.5 (10.5)	62.7 (10.8)	73.5 (11.0)	62.5 (11.4)	66.6 (11.2)	65.0 (10.0)	67.3 (12.7)	64.9 (12.5)	68.1 (13.6)	66.4 (14.1)	74.4 (6.6)	72.8 (10.3)	69.3 (9.0)	67.4 (8.4)	70.0 (9.5)	2.944	0.000*
Employment (%)	23.2	5.3	15.4	18.2	18.2	9.1	26.9	17.4	20.9	28.6	26.9	34.4	30.4	15.8	14.7	33.3	30.0	34.8	20.781	0.187
Low education (%)	36.2	36.8	38.5	40.9	50.0	18.2	26.9	21.7	48.8	42.9	46.2	37.5	30.4	26.3	35.3	26.7	35.0	60.9	32.825	0.008*
Single (% no partner)	36.8	68.4	46.2	22.7	68.2	54.5	34.6	41.3	27.9	31.4	46.2	21.9	30.4	31.6	29.4	35.6	40.0	21.7	35.958	0.003*
Smoking status (%)	10.2	15.8	15.4	4.5	9.1	9.1	7.7	10.9	32.6	11.4	11.5	9.4	21.7	10.5	17.6	6.7	0	21.7		
Non-smoker	50.9	47.4	23.1	68.2	36.4	45.5	53.8	50.0	41.9	45.7	53.8	59.4	26.1	63.2	58.8	60.0	85.0	52.2	-	-
Ex-smoker	30.9	36.8	46.2	27.3	36.4	40.0	30.8	32.6	74.4	31.4	34.6	21.9	26.1	26.3	20.6	31.1	15.0	26.1		
Smoker																				
Charlson co-morbidity index	2.4 (1.3)	2.6 (1.4)	2.9 (1.9)	2.3 (1.4)	3.0 (1.8)	2.4 (1.0)	2.3 (1.2)	2.4 (1.3)	1.9 (1.0)	2.2 (1.1)	2.4 (1.1)	2.4 (1.4)	2.0 (1.1)	2.1 (1.0)	2.8 (1.5)	2.1 (1.1)	2.3 (1.2)	2.1 (1.2)	17.027	0.384
Pulmonary function																				
FEV1[1]	67.5 (20.5)	64.4 (15.5)	72.7 (27.0)	51.6 (14.4)	63.3 (22.1)	64.6 (18.4)	66.0 (20.1)	73.7 (18.7)	60.1 (20.8)	66.3 (22.7)	74.9 (19.2)	66.9 (18.2)	75.1 (17.3)	67.6 (17.7)	68.0 (23.6)	72.0 (18.3)	73.3 (23.6)	63.1 (21.6)	2.367	0.002*
FER[2]	57.1 (13.1)	56.0 (11.8)	57.1 (14.7)	54.9 (16.9)	54.0 (12.1)	53.0 (12.3)	58.0 (16.6)	62.1 (10.2)	53.1 (13.9)	52.5 (12.4)	58.6 (14.8)	59.3 (8.0)	64.0 (12.7)	58.1 (11.2)	57.1 (14.8)	58.4 (11.0)	58.7 (9.2)	53.8 (15.4)	1.774	0.032*
MRC	2.1 (1.3)	2.4 (1.0)	1.9 (0.7)	2.0 (1.3)	2.5 (1.5)	1.6 (1.3)	2.0 (1.1)	2.2 (1.3)	2.0 (1.4)	2.7 (1.5)	2.2 (1.5)	2.1 (1.2)	1.4 (1.0)	2.6 (1.4)	2.0 (1.2)	1.9 (1.0)	2.0 (1.2)	2.0 (1.4)	26.778	0.044*
CCQ	1.6 (1.0)	1.9 (1.1)	1.4 (1.0)	1.4 (0.8)	2.6 (1.3)	1.6 (1.0)	1.9 (0.9)	1.6 (1.0)	1.7 (0.9)	1.9 (1.1)	1.7 (0.9)	1.5 (0.7)	1.0 (0.8)	1.5 (1.1)	1.5 (0.8)	1.1 (0.8)	1.3 (0.9)	1.5 (1.0)	3.696	0.000*
EQ-5D	0.7 (0.2)	0.7 (0.3)	0.7 (0.3)	0.7 (0.3)	0.6 (0.3)	0.8 (0.2)	0.7 (0.2)	0.8 (0.2)	0.7 (0.3)	0.7 (0.3)	0.7 (0.3)	0.7 (0.2)	0.9 (0.1)	0.7 (0.3)	0.8 (0.2)	0.8 (0.2)	0.8 (0.2)	0.8 (0.2)	26.092	0.053
PACIC	2.3 (0.9)	2.4 (1.0)	2.3 (0.8)	2.8 (1.1)	1.8 (0.6)	2.1 (0.9)	2.3 (0.9)	2.1 (0.9)	2.3 (1.1)	2.4 (1.0)	2.0 (0.9)	2.5 (0.8)	2.0 (0.8)	2.2 (0.8)	2.3 (1.0)	2.1 (0.9)	2.6 (0.8)	2.6 (1.1)	1.627	0.059
Healthcare costs[3]	452 (896)	785 (1476)	269 (313)	392 (692)	411 (333)	472 (713)	426 (420)	733 (2253)	299 (337)	387 (363)	424 (415)	394 (399)	211 (222)	493 (361)	469 (881)	361 (376)	472 (477)	671 (680)	24.666	0.076

Table E1. Patient characteristics per practice.

Notes: all values are means (SD) except when stated otherwise; *p<0.05. [1]forced expiratory volume in one second, post-bronchodilator, predicted according to age and height, [2]forced expiratory ratio (FEV1/FVC x 100%, where FVC is forced vital capacity), [3]The health care costs during the three months before the start of the RECODE study

Implementation indicators	AQ	AX	BR	BY	CT	GG	HD-HE	HU-HV-HT	IA	IB	IR	KT	KW	ML	MQ	NH	NQ	n	%
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	16	94
2	1	1	0	1	0	1	1	0	0	1	1	0	1	1	1	1	1	12	71
3	0	0	0	1	0	1	0	0	0	0	0	0	0	1	0	0	0	3	18
4	0	0	0	0	0	1	0	0	1	0	1	1	0	1	0	0	0	5	29
5	1	0	0	0	1	0	1	1	1	0	0	0	0	1	1	0	0	7	41
6	1	0	1	0	1	0	0	0	0	0	0	0	0	1	1	0	1	6	35
7	1	0	0	0	0	1	1	0	1	1	0	0	1	0	1	0	0	7	41
8	0	0	1	1	1	1	1	1	1	0	0	1	1	1	1	1	0	12	71
9	0	0	0	0	0	1	1	1	1	0	1	1	1	1	0	0	1	9	53
10	0	1	0	1	0	1	0	1	1	0	0	0	0	1	1	1	0	8	47
11	0	0	1	0	0	1	0	0	1	0	0	0	1	0	1	0	0	5	29
12	1	1	1	0	0	0	0	1	1	1	1	0	0	1	1	1	0	10	59
13	1	1	1	0	0	1	1	1	1	0	0	0	1	0	1	0	0	9	53
14	1	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	1	5	29
15	0	1	1	0	1	0	1	1	1	1	1	0	1	1	1	0	1	12	71
16	1	1	1	0	0	0	1	0	0	0	0	0	0	0	0	0	1	5	29
17	0	1	0	0	0	0	0	0	1	0	1	0	0	1	0	0	1	5	29
18	0	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	3	18
Total	9	10	9	5	5	10	9	9	13	5	7	4	8	12	12	4	8	(mean=8.18)	

Table E2. Implementation indicator scores

Starting levels DM, CCM element and total implementation scores	AQ	AX	BR	BY	CT	GG	HD-HE	HU-HV-HT	IA	IB	IR	KT	KW	ML	MQ	NH	NQ	mean
Starting level DM[1]	1	2	2	3	2	1	1	1	2	1	3	3	1	1	1	3	2	-
CCM: Delivery system design	5	2	3	4	4	6	5	3	5	3	3	3	4	7	6	2	1	3.88
CCM: Decision support	1	2	2	1	0	3	1	3	4	1	2	1	2	3	3	0	3	1.88
CCM: Self-management strategies	3	4	4	0	1	1	3	3	2	1	1	0	2	1	2	0	1	1.71
CCM: Clinical information systems	0	1	0	0	0	0	0	0	1	0	1	0	0	1	0	0	0	0.24
CCM: Healthcare system	0	1	0	0	0	0	0	0	1	0	0	0	0	0	1	4	8	0.88
Total implementation score	9	10	9	5	5	10	9	9	13	5	7	4	8	12	12	4	8	8.18
Total implementation category[2]	2	2	2	1	1	2	2	2	3	1	2	1	2	3	3	1	2	-
Perceived success of implementation by healthcare providers[3]	3	2	3	1	2	2	2	1	2	2	2	3	2	2	3	2	2	

Table E3. Starting levels DM, subtotal implementation scores of CCM elements, total implementation scores and perceived success of implementation by healthcare providers.
[1]1= ad-hoc COPD care, 2= structural diagnosis of COPD patients and 3= structural diagnosis and follow-up of COPD patients.
[2]1= total implementation score 0-5, 2= total implementation score 6-11 and 3= total implementation score 12-18.
[3]1= not to somewhat successful, 2= reasonably successful and 3=(very)successful.

		Perceived success of implementation by healthcare providers		
		Not to somewhat successful	Reasonably successful	(very) Successful
Total implementation categories	Limited improvements	1	3	1
	Moderate improvements	1	6	2
	Major improvements	0	2	1

Table E4. Comparison of perceived success of implementation by healthcare providers and our assessment of implementation according to the total implementation categories.

ΔCCQ Model 1: Implementation indicators	Total population		Subgroup (MRC>2)	
	β	p-value	β	p-value
Intercept	0.477	0.000	10.886	0.000**
CCQ score at baseline	-0.153	0.004*	-0.348	0.001*
Gender			0.295	0.010*
Individual treatment plan	0.234	0.001*		
Collaboration with the lung specialist			-0.159	0.241
Perceived success of implementation[1]				
Reasonably successful	0.011	0.765		
(Very) successful	0.158	0.015*		
R_1^2 (%)	8.04		26.62	
R_2^2 (%)	30.40		26.62	
AIC	701.66		202.47	
ΔCCQ Model 2: CCM elements	**Total population**		**Subgroup (MRC>2)**	
	β	**p-value**	**β**	**p-value**
Intercept	0.356	0.071	0.865	0.001
CCQ score at baseline	-0.140	0.002*	-0.342	0.001*
Gender			0.315	0.001*
CCM: Decision support	0.108	0.007*		
CCM: Self-management strategies			0.089	0.032*
Perceived success of implementation[1]				
Reasonably successful	-0.002	0.986		
(Very) successful	0.219	0.143		
R_1^2 (%)	8.07		27.77	
R_2^2 (%)	30.43		27.77	
AIC	701.48		200.94	

ΔCCQ Model 3: Total implementation score (continuous)	β	p-value
Intercept	0.319	0.018
CCQ score at baseline	-0.149	0.004*
Total implementation score (continuous)	0.041	0.000*
Perceived success of implementation[1]		
Reasonably successful	-0.086	0.069
(Very) successful	0.112	0.112
R_1^2 (%)	8.19	
R_2^2 (%)	30.52	
AIC	701.11	

ΔCCQ Model 4: Total implementation score (categorical)	β	p-value
Intercept	0.407	0.005
CCQ score at baseline	-0.149	0.004*
Total implementation score (categorical)[2]		
Moderate improvements	0.311	0.000**
Major improvements	0.334	0.000**
Perceived success of implementation[1]		
Reasonably successful	-0.069	0.099
(Very) successful	0.150	0.034*
R_1^2 (%)	9.00	
R_2^2 (%)	31.13	
AIC	700.30	

Table E5. Random effect models of the influence of implementation on ΔCCQ
[1]reference group is not to somewhat successful, [2]reference group is limited improvements
*p<0.05, **p<0.0001

Proportion of patients with a clinically important deterioration in CCQ Model 1: Implementation indicators	β	p-value
Intercept	0.574	0.000**
CCQ score at baseline	-0.062	0.015*
Protocol	0.117	0.000*
Perceived success of implementation[1]		
Reasonably successful	-0.095	0.059
(Very) successful	0.072	0.156
R_1^2 (%)	6.16	
R_2^2 (%)	26.37	
AIC	448.60	

Proportion of patients with a clinically important deterioration in CCQ Model 2: CCM elements	β	p-value
Intercept	0.326	0.000
CCQ score at baseline	-0.054	0.027*
CCM: Decision support	0.053	0.000**
CCM: Self-management strategies	0.042	0.000**
Perceived success of implementation[1]		
Reasonably successful	-0.005	0.786
(Very) successful	0.188	0.000**
R_1^2 (%)	7.33	
R_2^2 (%)	27.28	
AIC	446.57	

Proportion of patients with a clinically important deterioration in CCQ Model 3: Total implementation score (continuous)	β	p-value
Intercept	0.399	0.000**
CCQ score at baseline	-0.059	0.020*
Total implementation score (continuous)	0.021	0.001*
Perceived success of implementation[1]		
Reasonably successful	-0.074	0.023*
(Very) successful	0.124	0.003*
R_1^2 (%)	6.52	
R_2^2 (%)	26.65	
AIC	447.38	

Proportion of patients with a clinically important deterioration in CCQ Model 4: Total implementation score (categorical)	β	p-value
Intercept	0.440	0.000**
CCQ score at baseline	-0.058	0.021*
Total implementation score (categorical)[2]		
Moderate improvements	0.163	0.000*
Major improvements	0.166	0.001*
Perceived success of implementation[1]		
Reasonably successful	-0.063	0.002*
(Very) successful	0.148	0.000**
R_1^2 (%)	7.05	
R_2^2 (%)	27.06	
AIC	447.63	

Table E6. Random effect models of the influence of implementation on proportion of patients with a clinically important deterioration in CCQ
[1]reference group is not to somewhat successful, [2]reference group is limited improvements
*p<0.05, **p<0.0001

Appendix F – Additional analysis

ΔCCQ	Total population		Total population	
	β	p-value	β	p-value
Intercept	0.407	0.005	0.420	0.000
CCQ score at baseline	-0.149	0.004*	-0.164	0.000*
Total implementation score (categorical)[2]				
Moderate improvements	0.311	0.000**	0.300	0.000*
Major improvements	0.334	0.000**	0.366	0.000**
Perceived success of implementation[1]				
Reasonably successful	-0.069	0.099		
(Very) successful	0.150	0.034*		
R_1^2 (%)	9.00		7.61	
R_2^2 (%)	31.13		30.08	
AIC	700.3		701.1	

Table F1. Comparison of random effect models of the influence of implementation on ΔCCQ with and without perceived success of implementation.
[1]reference group is not to somewhat successful, [2]reference group is limited improvements
*p<0.05, **p<0.0001

Proportion of patients with a clinically important deterioration in CCQ Model 2: CCM elements	Total population		Total population	
	β	p-value	β	p-value
Intercept	0.326	0.000	0.382	0.000
CCQ score at baseline	-0.054	0.027*	-0.073	0.001*
CCM: Decision support	0.053	0.000**	0.053	0.007*
CCM: Self-management strategies	0.042	0.000**	0.050	0.012*
Perceived success of implementation[1]				
Reasonably successful	-0.005	0.786		
(Very) successful	0.188	0.000**		
R_1^2 (%)	7.33		4.76	
R_2^2 (%)	27.28		25.27	
AIC	446.6		451.28	

Table F2. Comparison of random effect models of the influence of implementation on ΔCCQ with and without perceived success of implementation.
[1]reference group is not to somewhat successful, [2]reference group is limited improvements
*p<0.05, **p<0.0001