The effect of an active implementation of a disease management programme for chronic obstructive pulmonary disease

PhD dissertation

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PhD dissertation

The effect of an active implementation of a disease manage programme for chronic obstructive pulmonary disease.

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CONTENTS

PREFACE

Patients reap the benefits of more eyes and ears, the insights of different bodies of knowledge, and a wider range of skills. Thus team care has generally been embraced by most as a criterion for high quality care.

Dr. Edward H. Wagner

BMJ, February 2000

MOTIVATION

I have worked as a physiotherapist and a health planner both in the private and in the governmental health systems in many different areas of the World from Kirkenes in Finmarken, Norway in the north to Abu Dhabi in the UAE in the south with stints to Waterford, Eire and London, Cambridge and Newmarket in the United Kingdom. Some of the countries succeed better than others with eradicating some diseases, increasing life expectancy, lower infant mortality, reducing difference in the social differences of health and providing a cradle-to-grave care owing to cultural and structural healthcare provision.

In my experience, all countries aim to serve their population with the best possible care, but have different abilities, resources and cultures to fulfil their hopes and dreams of a just, efficient and equitable healthcare system. Not all have conceptualised it as precisely as some of the European countries, e.g. Denmark where the National Health Service shall be available to all regardless of wealth, social class, age and gender, basically be free at the point of care, universal, comprehensive and collective. It takes a high level of ambition and needs innovative, planned and targeted efforts to succeed.

When the Ringkoebing-Skjern Municipality and the Research Unit for General Practice in Aarhus initiated ideas for a study surrounding the joint work needed for providing comprehensive care to patients, I saw an opportunity to participate in a well-planned and ambitious study of effective care implemented in a real setting. I could use my knowledge and experience of different healthcare systems and my firm conviction that every implementation of introducing change needs to be anchored in the local community, but can be controlled from a central organisation.

OUTLINE OF THE THESIS

This PhD thesis is based on the project "The effect of an active implementation of a disease management programme for chronic obstructive pulmonary disease". The project was carried out during my time as a research fellow at the Research Unit for General Practice in Aarhus and the Section for General Practice, Department of Public Health, Aarhus University, Denmark.

Chapter 1 provides an introduction to the Danish healthcare system and a looks at chronic diseases' place within primary care; different theories on implementing change and disease management programmes in general practice and complex healthcare settings are also presented. The aim of the PhD thesis is presented in **Chapter 2,** whereas **Chapter 3** describes the setting, methods and materials used to reach the aims. The main results are presented in short in **Chapter 4**. In **Chapter 5,** the methods for the study are discussed and **Chapter 6** offers a general discussion of the results. The main conclusions and implications are presented in **Chapter 7,** and the chapter offers ideas for future research. **Chapter 8** describes the perspective raised by the present research. **Chapter 9** is the English and **Chapter 10** the Danish summary. The last chapter, **Chapter 11,** contains the references. Appendices I-IX follow and the four papers are inserted at the end of the thesis.

THE FOUR PAPERS OF THE THESIS

This PhD thesis is based on the following four papers referred to by Roman numerals:

I: Smidth M, Sokolowski I, Kaersvang L, Vedsted P. Developing an algorithm to identify people with Chronic Obstructive Pulmonary Disease (COPD) using administrative data. *Published in BMC Medical Informatics and Decision Making.*

II: Smidth M, Christensen M B, Olesen F, Vedsted P. Developing an active implementation model for a chronic disease management program. *Published in International Journal of Integrated Care.*

III: Smidth M, Christensen M B, Olesen F, Fenger-Grøn M, Vedsted P. The effect of an active implementation of a disease management programme for chronic obstructive pulmonary disease on healthcare utilization - A cluster-randomised controlled trial. *Accepted to BMC Health Services Research.*

IV: Smidth M, Olesen F, Fenger-Grøn M, Vedsted P. The patient experienced effect of an active implementation of a disease management programme for Chronic Obstructive Pulmonary Disease (COPD) – a randomised trial. *Accepted to BMC Family Practice.*

ABBREVIATIONS

ACIC	Assessment of Chronic Illness Care
CI	Confidence Interval
CGJ	Camilla G Jørgensen
COPD	Chronic Obstructive Pulmonary Disease
DSAM	Dansk Selskab for Almen Praksis – Danish College of General Practice
DNHIR	The Danish National Health Insurance Register
GP	General Practitioner
ICD-10	International Classification of Disease – version 10
ICPC-2	International Classification of Primary Care – version 2
MS	Margrethe Smidth
NCD	Non-communicable diseases
NPV	Negative Predictive Value
PACIC	Patient Assessment of Chronic Illness Care
PAS	Patient Administrative System
PPV	Positive Predictive Value
SD	Standard Deviation
WHO	World Health Organisation

CHAPTER 1

INTRODUCTION

This chapter gives a general introduction to the background of the study

INTRODUCTION

1.1.1 Chronic conditions

All over the world the number of people living with chronic conditions is increasing. In Danmark, close to one third of the 5.6 mill inhabitants are estimated to be living with at least one chronic condition [1]. In England, up to 16% were living with two or more chronic conditions in 2008, known as multimorbidity [2], and in Scotland it was 23%; the figures for Denmark are probably similar. This situation arises as a consequence of environmental, social and personal risk behaviour, for example inappropriate lifestyle involving for example smoking, unbalanced nutrition, physical inactivity and excessive alcohol consumption. It is also results because of the generally increased life expectancy owing to improved treatment options and growing diagnostic activity. For society, an important task is accordingly to devise an efficient strategy that meets this challenge by reaping maximum benefit from restricted healthcare resources [3-5].

1.1.2 Chronic obstructive pulmonary disease

Chronic respiratory disorders form a group of chronic conditions that has caught growing attention in recent years because of their rising prevalence. Of particular concern is chronic obstructive pulmonary disease (COPD) which is estimated to become the third leading cause of death worldwide by 2020. Most people are diagnosed so late that their disease has progressed to a stage where their daily activities are gravely reduced, wherefore they receive late and non-optimal, expensive care. Comormid diseases potentiate the morbidity of COPD which raises costs even further [6]. COPD remains much underdiagnosed in Denmark where only about 120,000 of 430,000 Danes with expected COPD are diagnosed [7]. In Denmark close to 40,000 admissions every year are due to

COPD. At least 5,000 people die each year from COPD [8], and the number of deaths is projected to increase [9] which give Denmark the highest death rate among the European countries.

Healthcare-related and social benefit costs for people with COPD are high [10;11]. In Denmark, the healthcare-related costs for COPD alone amount to 10% of all healthcare cost, close to half a billion Euros [12]. It is likely that improved and better coordinated care for this group may reduce the cost of healthcare and the aggregate costs, i.e. the direct costs of medication and the indirect costs of loss of workforce and loss of life [11;13].

1.1.3 Implementing a disease management programme in the Central Denmark Region

In 2008, the Central Denmark Region (720,000 citizens aged 35 years old or older) implemented a disease management programme as the standard care for patients with COPD. The programme is based on the Chronic Care Model (CCM) [14;15] and the clinical guideline from the Danish Society for General Practice [16]. The programme uses evidence-based clinical and organisational recommendations and is a manual on treatment, task distribution, communication and coordination between stakeholders [17]. The implementation of this programme provided an opportunity to test a model in which the programme was actively implemented and to compare the effect of this active implementation with the effect of the usual implementation strategy.

PRIMARY CARE

1.2.1 Primary care

Starfield described how health levels are associated neither with the wealth nor with the number of health professionals of a country, but with a strong primary care [18]. This position is echoed by the literature which has shown that greater effectiveness, efficiency and equity emerge as benefits of care systems that are oriented towards primary care [19]. Countries with a well-developed primary care health system have healthier populations and lower overall cost than countries without; Starfield also found that greater availability of GPs reduces the adverse effect of social inequality, [20] and Parchman et al find that effective delivery of primary care to patients with chronic disease improves their experiences of hassles in contacts with the healthcare system [21]. Strange finds that primary care is associated with better population health, lower use of health care resources and less inequality; and although the quality of care may be poor for the individual disease [22], there is overall better quality at the population level and for the functional health of the whole person [23].

When a health policy is designed to promote primary care, it must include universal financial coverage under governmental control and attempt to distribute resources equitably, and it must strive towards comprehensiveness of services with low or no co-payments for primary care services. The key components of an improved primary care comprise absence of obstacles to first contact and primary care services, more person-focused care, a wider palette of primary care services available in time, on time and where needed, and better coordination of care across sectorial interfaces [24].

1.2.2 General practice as the care coordinator in Denmark

In its recommendations for how to approach the delivery of care to the large number of people living with chronic conditions, The Danish National Health Board suggested in 2005 that general practice should act as the coordinator of the care [25]. The coordinator role would involve planning, coordinating and maintaining of care. General practice would be in an ideal position to take this coordinating role and to ensure that patients would be treated according to clinical guidelines and referred to local rehabilitation according to need.

CHRONIC CONDITIONS

1.3.1 Chronic conditions

We discussed how to define the term "chronic condition" in this present thesis and took the pragmatic approach and defined a chronic condition as a condition lasting at least six months and requiring long-term management within the healthcare system. It has been argued that classification of diseases according to their communicable or non-communicable nature may be problematic [26] as some diseases like HIV/AIDS are communicable in nature and certainly also chronic [27]. Therefore, the term "chronic conditions" is used throughout this thesis.

When patients have two or more chronic conditions it has been labelled multimorbidity and is common among almost half of all people with chronic illness who have more than just the one chronic disease [28 29 30]. The provision of adequate care for people with multimorbidity is a formidable challenge for today's healthcare systems. The system must at one and the same time coordinate the care, ensure that health professionals follow established guidelines, and ensure that patients are followed-up and taught and trained to manage their illness in order to achieve the best possible outcomes. People living with multimorbidity are more frequently being hospitalised than people with no chronic conditions, and they more often call the out-of-hours and acute services on a needs basis, which is a costly way of handling chronic conditions [31;32].

The Danish National Health Board estimates that close to 16 billion Euros, which is equivalent to 80% of the total Danish healthcare costs, are spent on care for people living with one or more chronic conditions.

DISEASE MANAGEMENT PROGRAMMES AND THE CHRONIC CARE MODEL

1.4.1 Strategies for managing chronic diseases

Seamless patient care demands implementation of an efficient strategy for comprehensive, professional and effective treatment from hospitals, general practices (GP practices) and municipalities. A disease management programme may be an efficient instrument for implementing such a strategy [15] [14] [33] . Beafflehol et al concluded that effective disease management programmes for chronic conditions, especially those directed at individuals rather than the population as a whole are highly dependent on well-functioning country health systems [4].

Disease management programmes adopt a holistic approach to the treatment of particular diseases, which involves both preventive measures, actual treatment and post-treatment measures to ensure continued optimal health. The programmes include systematic assessment and follow-up by skilled health professionals; evaluation of the prescribed medication; dietary advice; collaboration between general practice, hospitals and municipality; and education and empowerment of patients to help them manage their disease and to be involved in their own care together with their family.

1.4.2 The Chronic Care Model

One programme which has received much attention for its comprehensive approach is the Chronic Care Model (CCM). The model is a framework for delivery of health care that is safe, effective and collaborative for people with chronic illness who need long-term care and support from the health system. It was developed in the United States by Edward Wagner and the Improving Illness Care team [14] [15] (see Figure 1.1). The model envisions healthy productive

interactions between proactive practice teams and informed, activated patients. It suggests that healthcare cost for chronic conditions can be reduced by using guidelines that are evidence-based, specialty expertise when needed and information systems.

Central to the CCM is that the healthcare system needs to be proactive and collaborative to keep patients as healthy as possible rather than reactive by delivering services only in response to patients' acute needs. Such a system may be obtained where the delivery of services resorts to proven strategies and where the system is planned and managed effectively.

In the CCM, the health system's efforts are focused on keeping the population as healthy as possible [5]. To proactively do this calls for identification of the patients in order to assign them the care they need.

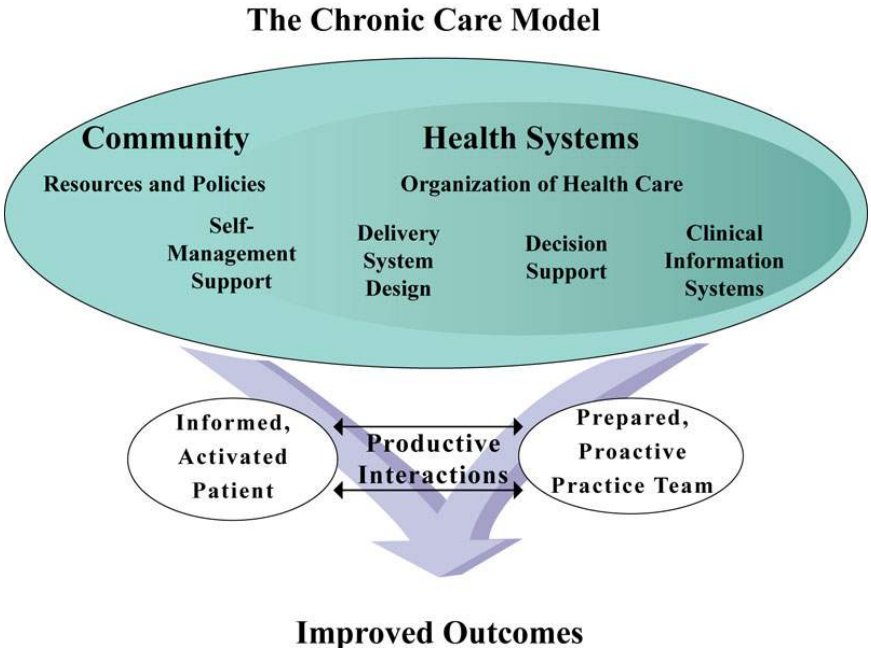


Figure 1.1

We therefore need a strategy like that provided by the CCM to support high-quality care where a continuum of services is provided within a framework that allows the primary care sector to occupy a strong position [34] [35]. In such a system, patients receive the right care at the right place at the right time to optimise the use of resources, [36] and the care is evidence-based, planned and proactive [37] [38] [39].

1.4.3 Implementation of the Chronic Care Model

One study found that implementing two or more components of the CCM lowered the rates of hospitalisation and the use of acute services of patients with COPD [40]. Another study of the implementation of a disease management programme in primary care for patients with COPD in New Zeeland found that the programme reduced admission to hospital and length of stay. However, little is known about the use of the model for implementation of change in the delivery of care to patients with chronic conditions in Denmark. We therefore need to develop an implementation model with several components and to investigate the effect of its implementation in a Danish healthcare setting

A comparison of the American insurance company Kaiser Permanente, which insures a population similar in size and otherwise fairly comparable to the Danish population, and the Danish healthcare system found that Danish GPs experience inadequate structures and few incentives to provide support for self-management to the patients, which is an integral part of the CCM [41]. We therefore need to investigate how disease management programmes where primary care assumes responsibility for coordination of care and self-management support work best in the Danish healthcare system.

1.4.4 Patient evaluation of the care

Patients want to be included in the decisions about their health, also when living with chronic conditions [42] [43] [44] [45] [46]. Society expects patients to play an active role in managing their own illness. It has been discussed and generally accepted for a long time that full healthcare quality assessment requires inclusion of the patient's perspective [47] [48] [28] [45]. However, little is known about patients' assessment of the care they receive for their chronic conditions. The perspective that patients' evaluation of their care was an outcome in healthcare evaluation was introduced by Donabedian already in the 1960s [42]. In the 2000s, Martin McKee states as obvious that health improvement should be the primary purpose of any health intervention and the primary criterion for judging its value, and that improved health involves economic as well as health benefit [28]. Thus, we need to obtain patients' assessments of newly implemented guidelines or disease management programmes for chronic conditions to properly asses the health gain obtained owing to the introduction of such programmes.

It is clearly a requirement for success of a disease management programme like the CCM that its implementation is effective.

IMPLEMENTING DISEASE MANAGEMENT PROGRAMMES

1.5.1 Acting on evidence

Evidence-based knowledge of how best to manage chronic conditions has been available for several decades. The time has now come to put current evidence at the service of clinical practice to reap public health benefit [49], as witnessed, among others, by the growing interest in change management in clinical practice.

1.5.2 Implementing change in the healthcare system

Implementing change in the healthcare system is notoriously difficult. Many stakeholders with different mindsets and professional backgrounds who all need to work together to provide the best care for the patients within the system need directions for collaboration and frameworks within which to work. In the healthcare system, implementation of change can be defined as a planned process comprising the systematic introduction of new initiatives triggering change in clinical practice and change of the structure of the system [50]. After reviewing 102 trials, Oxman et al concluded that there are no "magic bullets" for improving the quality of health care, but that a wide range of interventions exists that can lead to important improvements in professional practice and patient outcomes if used appropriately [51].

1.5.2.1 Theories

Theories of implementation give priority to different actors and elements. Cognitive theory emphasises professionals, information and the methods used in decision processes. Educational theory prioritises professionals' need for change; whereas social learning theories value learning by examples, for

instance through networking. Theories on patient influence concentrate on how patients can be involved in the planning of the implementation, and leadership theories describe the importance of engagement and commitment of leaders in change processes. Theories on organisation focus on the organisation's structure and decision processes; whereas the importance of economic and professional rewards is pivotal in economic implementation theories [50]. A multifaceted and intensive implementation, which we will call an active implementation, builds on some of these theories and has been shown to have some effect in changing professionals' conduct and to some extent change clinical values as well [52]. The design of an implementation that involves many actors therefore needs to take into consideration that within the healthcare services there are different learning styles, professions and personalities [53].

1.5.2.2 Communication

Effective communication strategies are required to ensure efficient dissemination of evidence for best care as the burden of keeping abreast of the latest developments cannot be lifted by GPs in the face of today's pace in medical knowledge generation/build-up [54]. Thus, effective communication strategies are needed; barriers to change have to be minimised and strategies that are efficient in general practice have to be used [55].

1.5.2.2 Support of leaders, local adaptation and available resources

Successful implementation also needs the active support of the leaders of the organisation, the necessary economic and professional resources and often local adaptation of programmes, education of staff and development of new ways of communicating [56] [57].

1.5.2.3 Identification of the population

One very important prerequisite for implementing a disease management programme like the CCM is that the target population can be identified [58 59]. In Denmark, patient diagnoses obtained in hospitals are coded according to the International Classification of Diseases (ICD-10). This also includes chronic conditions. However, most people with chronic diseases are seen in primary care, and in Denmark a systematic coding of diagnoses has not yet been fully established in general practice. We accordingly need models that may help identify patients with particular diagnoses in primary care.

1.5.3 The effect of the implementation

The implementation of programmes is challenging and we know too little about the effect of implementation processes and the effect of the implementation of such programmes for the patients [52 56 60-62]. A recent study of support to self-management in 13 countries concludes that the "empowerment paradigm" is insufficiently implemented and that there is a need to understand how patients and health care providers can engage in more productive interaction [63].

1.5.4 Literature search

While we realised that there is no magic bullet in the implementation process, we choose to search MEDLINE for systematic reviews and papers on implementing change in general practice for shared care for patients with chronic conditions. A snowball-search identified further literature. We did not conduct a systematic review ourselves. Two reviews of different types of continued professional education showed that studies using interactive methods were generally more effective in changing GPs' performance and in improving patient care than traditional lectures [51;64;65]. The CCM suggests using the Breakthrough Series for implementing change [59 66]. With the Breakthrough

Series, change can be adjusted during its implementation to fit experienced need. Lugtenberg et al described how implementation of change calls for active leadership [67]; whereas Greenhalgh stated that targeted change needs to be simple and adjustable to each locality [68]. Grol et al outlined how implementation in healthcare needs to involve evidence-based information, few and precise recommendations and practical advice on the change in the clinical practice [56].

Thus, our literature search gave us good guidance on which components to include in an active implementation process.

PREVIOUS STUDIES OF IMPLEMENTATION

1.6.1 Previous studies

There is a bulk of literature on implementing change in health care. Using guidelines to attain the change seems to be accepted as they are the syntheses of best available evidence, though the implementation of the guidelines is challenging [69;70]. Different theories on adherence to guidelines include how the guideline's characteristics influence the uptake [71;72] and Mitchie et al suggest a Theoretical Domains Framework using the individual's behaviour change to better the uptake of guidelines [73]. The diffusion of innovations in social networks through "contagion" is how Rogers et al envision implementation [74;75] where Finch et al suggest a Normalisation Process theory innovation becomes accepted and integrated when they fit in the culture already established. In Smith's classical economy market theory [76] it is incentives that influence the volume. Wagner et al introduced the CCM where the organisation of the healthcare influences the outcomes [14 15]; disease management programmes based on CCM uses evidence-based clinical and organisational recommendations and is a manual on treatment, task distribution, communication and coordination between stakeholders

Several randomised studies have reported that the implementation of guidelines for chronic conditions reduces healthcare costs [28 77 78 79 80], but only few studies have examined the effectiveness of various guidelines targeting patients with COPD [81 82].

In a review of 235 multifaceted intervention trials, Grimshaw et al reported that several studies find that combined interventions are more effective than single interventions [83]. Most studies take into consideration the fact that different professions and different personalities have different learning styles and will therefore respond to the approach that suits them best. If many components are

included, the likelihood will therefore rise that more people will choose an option that suits them and this will, all thing equal, enhance the chance that change is accomplished.

Most of the multifaceted studies examined by Grol et al reported an average change of 10% in main outcomes [84]. Grol and Woolf find that guidelines are the only option available for improving the quality of care in primary care; and if they are rigorously developed and evidence-based, they will minimize potential harm [85]. In another Dutch study, Steuten et al. found that self-reported medication compliance, physical activity, disease-specific knowledge, non-smoking behaviour, patient satisfaction and health-related quality of life increased in populations with chronic disease when a disease management programme was implemented that focused on patient education, protocolised assessment and treatment of COPD, and care coordination [86]. They also found improvement in health utility [87].

Conducting a literature review of 13 systematic reviews of integrated care programmes for chronically ill patients, Ouwens et al. found that all programmes seemed to have positive effects on the quality of health care by reducing fragmentation and improving continuity and coordination of care [88]. Korreisto et al found that different strategies are needed when clinical guidelines are targeted at different professional groups [89].

A review of different types of continued professional education showed that studies where interactive methods were used were generally more effective than traditional lectures in changing GP performance or improving patient care [90].

1.6.2 Conclusion of literature search

In conclusion, we know that good care for patients with chronic conditions is needed and that this need is particularly pertinent in multimorbid patients.

Disease management programmes like the CCM seem to be a framework for change management, but an active multi-component complex implementation strategy is needed to foster quality improvement as reflected in the aims of the present thesis.

INTRODUCTION AT A GLANCE

1.7.1 Identification of the target group

More and more people are living with one or more chronic conditions. To respond to their need for comprehensive care, the healthcare system must use a planned and efficient strategy to deploy available resources in the best possible way. Patients in need of care need to be identified; and as long as general practices do not consistently code the diseases, other measures must be invoked to identify the target patients.

1.7.2 General practice as the care coordinator

General practice is the obvious choice as a care coordinator because a strong primary care sector may guarantee efficient delivery of care and because GPs serve as gatekeepers in the Danish healthcare setting. GPs are able to follow the patient, to deliver efficient first-line treatment and to ensure joint decision making. We have no knowledge of the effect of what is intuitively thought to be the best practice, i.e. letting the GPs act as care coordinators, and research into this area is needed.

1.7.3 Implementing disease management programmes

The implementation of disease management programmes for coordination of care to people with chronic disease has received some positive feedback internationally. Disease management programmes have so far not been introduced in the Danish healthcare setting. Research should accordingly address how programmes may be implemented at all levels, i.e. general practice, hospitals, municipality, and how patients may effectively be involved in their own care and if changes are accomplished at all.

CHAPTER 2

AIMS

This chapter introduces the overall aim and the aims for each paper

AIM OF THE THESIS

2.1 The overall aim

The overall aim of the thesis was to develop and test a model for active implementation of a chronic disease management programme for COPD based on the CCM in a randomised controlled trial.

2.2 Aim 1

To develop an algorithm for identifying patients living with COPD from administrative data (Paper I).

2.3 Aim 2

To describe the development of a model for active implementation of a disease management programme based on the CCM using the British Medical Research Council's "Framework for design and evaluation of complex interventions to improve health" to develop the complex intervention model (Paper II).

2.4 Aim 3

To test the effect of an active implementation of a disease management programme on health utilisation patterns in a randomised trial (Paper III).

2.5 Aim 4

To test the effect of an active implementation of a disease management programme on patients' assessment of their care in a randomised trial (Paper IV).

CHAPTER 3

SETTING, MATERIALS AND METHODS

This chapter introduces a definition of the disease COPD, its diagnosing, progression and care. Furthermore, the setting of the study and the characteristics of the two municipalities in the study are described. The materials and methods used in the study are presented, and a flowchart illustrates the inclusion of the overall study population. The characteristics of the study population, the data sources and the measures used in each study are presented in tables. A detailed description of the methods used in each paper is presented in Papers I-IV.

COPD – CHRONIC OBSTRUCTIVE PULMONARY DISEASE

3.1.1 Definition and development

The Global Initiative for Chronic Obstructive Lung Disease has defined COPD as follows in the GOLD guidelines [91]:

"Chronic Obstructive Pulmonary Disease (COPD), a common preventable and treatable disease, is characterised by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients" [92].

Smoking is without doubt the leading cause of COPD and up to 40% of smokers will develop the disease [93]. The more cigarettes and the earlier in life they are smoked, the higher is the risk of getting COPD. People who never smoked rarely develop COPD [94]. However, the disease can develop if people have been exposed for long time to air pollution, chemical fumes, biomass fumes or dust and, specifically, if they were frequently exposed to tobacco smoke too [95]. A very rare but still serious inherited disposition for developing COPD is lack of alpha-1 antitrypsin. It is estimated that in the Danish population, 0.05% have alpha-1 antitrypsin deficiency, so most people with COPD have a normal alpha-1 antitrypsin level [96].

3.1.2 Diagnosing

The first symptom to develop is usually cough which progresses and becomes chronic as explained in the Danish teaching book for medical students [97]. It goes on to explain that breathlessness due to the inflammation and obstruction of the

airways occurs in the beginning of the disease when the patients exert themselves and the damaged airways produce more mucus and the sputum needs to be coughed up. The students also learn that exacerbations with infections are common in patients with COPD. Other symptoms of COPD can be tiredness and in later stages weight loss and swelling of the ankles due to secondary cordial disease [16]. The breathlessness gradually increases, which leads to a more sedentary life causing the symptoms to become even worse, where feelings of suffocation, depression, anxiety and/or social isolation can be the result [16;98].

Few people younger than 35 years are diagnosed with COPD, and the disease remains much underdiagnosed in Denmark where only about 120,000 of 430,000 expected cases of COPD are diagnosed [7]. In Denmark close to 40,000 admissions every year are due to COPD and at least 14 people die each day from COPD [8]. The number of deaths is projected to increase due to the aging population and the decrease in other major chronic diseases [9].

Because they have adapted their behaviour to the gradually worsening of the symptoms, most patients have lost almost half of their lung capacity before they realise that they have COPD [8;99]. The GOLD guidelines advise that a COPD diagnosis should be considered in a case finding strategy when a patient presents with dyspnoea and chronic cough or sputum production and has a history of exposure to the risk factors for COPD [91]. This approach may be supplemented with an additional opportunistic screening strategy targeted at high-risk groups, for instance heavy smokers, when they visit the health care provider for reasons that might be related to lung disease. The diagnosis of COPD must be confirmed by post-bronchodilator spirometry that shows a

forced expiratory volume in one second (FEV1)/forced vital capacity (FVC)<70% [91].

3.1.3 Progression

The progression of COPD is characterised by a gradual decline in health with frequent chest infections characterized by worsening exacerbations and ultimately respiratory failure [99].

Patients with COPD may have one or more of the following co-morbidities: cor pulmonale and ischaemic cardiovascular disease due to impaired pulmonary circulation, osteoporosis, depression and anxiety [98;100]. Patients with COPD also often develop lung cancer during the course of their disease [101]. The patient's disability is often rooted in multiple causes and treatment of any co-morbidity is accordingly very important [98]. Treatment of COPD will not cure the patient, but may easy the patient's symptoms and make daily life easier for both the patients and their families [16;102].

3.1.4 Treatment and care

Many guidelines around the globe advise on the treatment for COPD and they agree that the most important treatment or advice is to stop smoking [16;103]. Damaged lung tissue cannot be repaired, but the progression of the disease is delayed or may even stop; and the patient will benefit whatever the stage of the disease. Short- and long-acting bronchodilator alone or in combination with steroid inhalers may make breathing easier for the patients and help prevent exacerbations [104;105]. Physiotherapy and controlled exercise will also help alleviate symptoms [106]. Exacerbations can be treated with courses of prednisolon and infections with antibiotics [16]. Patients should receive an annual vaccination

against flue, and pneumococcal vaccination should be considered [16]. If an exacerbation persists or causes severe respiratory impairment, the patient will be admitted to hospital - often as an emergency; thus, acute admissions and out-of-hours visits are an indicator of how severe the disease stage is and/or of lack of sufficient treatment [107]. In advanced stages of COPD, the patients may benefit from oxygen that may be administered at home or in hospital in case the disease has progressed to a very severe stage [108]. Some may be offered the option of surgical procedures, and even lung transplant can be suggested as an option [16]. When a patient with COPD is likely to die within a year, palliative care should be discussed and offered [109].

Self-management is crucial to avoid severe exacerbations and should be encouraged by the GP, the other health professionals at the clinic or be taught at courses in health centres [110]; it should include advice on various issue such as use of medications and antibiotics, breathing techniques to develop suitable breathing patterns, use of positive expiratory pressure flutes (PEP- flutes) to encourage "getting up the sputum" although a recent study suggests that there is no more benefit of a PEP flute that huffing and puffing the sputum up, and finally when to contact a doctor [111-113]. Other advice for patients includes recommendations on exercises and information about how useful it is to increase the level of fitness to be able to handle more of the daily routines [110]. Dietary advice should also be given; if the patient is overweight, it is more difficult to breathe; if the patient has severe COPD, he or she might have lost much weight and therefore needs advice on how to prepare and consume nutritious food [16].

Care for patients with COPD should be multidisciplinary and the GP should act as the co-ordinator of such care and ideally as a proactive partner to ensure control of treatment and the progression of the disease [16]. GPs should therefore ensure annual follow-up visits at which the progression of the disease is

monitored, spirometry performed, medication adjusted and the patients offered support to stop smoking, lose weight or any other support needed to live as comfortable as possible with COPD [16]. If the COPD is severe, the patient might need to be followed with two, three or four planned visits a year [16].

SETTING

3.2.1 Characteristics of Denmark and the study setting

Denmark is divided into five regions with 98 municipalities in all. The total population counts approximately 5.6 million people of whom more than 99% are registered with one of the approximately 3,600 Danish GPs. The municipalities typically have 40-50,000 inhabitants with the exception of the major cities like Copenhagen with nearly 600,000 and Aarhus with more than 300,000 citizens. The municipalities are responsible for most preventive and rehabilitation services. Each of the five administrative regions has 0.6-1.6 million inhabitants. The regions run regional hospitals where diseases and procedures demanding hospital expertise are dealt with [114 115]. The GPs are independent contractors with the region and currently remunerated on a combination of fee-for-service and capitation basis (75/25) and with a special fee for extra procedures, for instance spirometries.

The setting for the study is the two municipalities in the western part of the Region, the Central Denmark Region with 1.5 million people. The study was expanded by use of regional health registry data. For details of the two municipalities, please see Table 3.2.

Table 3.2 *Characteristics of the two study municipalities as of October 2009 from Statistics Denmark*

County/Municipality	**Inhabitants Approx.**	**Inhabitants at 35+**	**GPs**	**GP practices with 3+ GPs**	**GP practices with 2-3 GPs**	**GP practices with 1 GP**
Ringkoebing-Skjern	58,000	34,500	38	6	5	4
Ikast-Brande/comparable neighbouring municipality	40,000	23,600	25	4	3	3

Below is a brief description of the methods used in the study and in each paper. For detailed descriptions of the materials and the methodology used, please see Papers I-IV.

THE STUDY DESIGN

3.3.1 The intervention study

This main study is an intervention study with the overall aim as stated in Chapter 2. The study was conducted as a block- and cluster-randomised trial in Ringkoebing-Skjern municipality and targeted patients with COPD. The aim of our first paper was therefore to develop a valid algorithm for identifying patients with COPD for the intervention. To control for the spill over effect of the intervention to the local control group in Ringkoebing-Skjern municipality, we added a "blinded" external control group from a comparable neighbouring municipality [116 117].

Within healthcare research, reviews of randomised controlled trials are considered to have the highest ranking by providing high-quality evidence. The second-best design is a study with a randomised controlled design [118-120]. The randomised design is one of the most reliable study designs for obtaining information about the clinical effect of interventions and one of the best designs for comparison of the efficacies of different interventions [121 122 123] as confounding is equally distributed and bias is reduced [124].

Randomised trials are most often conducted under experimental, optimal conditions, in which case they generally provide information about the efficacy of an intervention rather than about its effectiveness, which is, of course, appraised when the intervention is implemented in daily practice [125 126]. The interventions used in this study were implemented in normal daily clinical practice life and they could therefore be directly transferred to the daily routines of the municipality, the GP practices and the hospital. For this kind of intervention study, there may be no significant difference between efficacy and effectiveness.

In our study, two GP practices declined to be in the randomised intervention group and to participate in the active invitation. These GP practices were kept in the study and in our analysis when we performed intention-to-treat analysis and as-treated analysis, but they were not included in the per-protocol analysis.

3.3.2 Allocation

As the intervention required active involvement of the participating GP practice in continuing medical education (CME) and a reorganisation of the routines in their practices, the allocation of both GPs and patients was open and well-known to the GPs and the health professionals in both municipalities and at the hospitals and to the researchers for the intervention and the control groups. The patients belonging to the intervention group were sent a flyer together with the questionnaires, and a poster was on display in the intervention practices with information about the study. For the external control group, only the researchers knew the allocation.

3.3.3 Comparability

Comparability between the groups at baseline is secured by randomisation, and internal validity is strengthened by increasing the size [127]. An equal distribution of baseline characteristics in the different groups can only be expected if many clusters are randomised to each group. In this study, we intended to include enough clusters to obtain sufficient power to detect an effect of the intervention, but a larger trial with more practices and patients would obviously have provided further evidence of the effect of the active implementation.

3.3.4 Cluster randomisation

Cluster randomisation enjoys less statistical power than where individuals are randomised [128;129]. We found individual patient randomisation non-suitable for this study because part of the intervention was targeted at the GP (the head of the cluster). If we had chosen individual patient randomisation, one GP would potentially have patients randomised both to the intervention and to the control group. We also found that this would involve a large risk of contamination between GPs in partnership practices; it is possible to actively implement the disease management programme with the whole GP practice, but it is very difficult to have just one GP in a GP practice with more doctors participating in the intervention group without any contamination. We therefore chose a GP setting as our cluster and therefore block-randomised the GPs (all single-handed GP practices were one block; practices with two GPs were another block; and practices with three or more GPs formed the last block). Please see the section on Randomisation in this chapter.

In conclusion, the units of randomisation were the GP practices with their respective listed patients; these clusters were randomised to either intervention or control group. The outcomes were measured at the individual patient level, and cluster bias was accounted for in our analysis.

RANDOMISATION

3.4.1 The randomisation process

An independent researcher drew slips that were matched to an electronic record with all the GP practices in the Ringkoebing-Skjern municipality. The practices were block-randomised using three blocks: the first block was solo practices with two practices allocated to the intervention group and three to the control group. The second block was practices with two GPs with two practices allocated to the intervention group and three to the control group. The third block was practices with three or more GPs with three practices in both the intervention and the control group. There were two solo practices, three practices with two GPs and four with three or more GPs in the external control group. One practice with three GPs was allocated to the intervention group as one of the GPs was partly involved in the overall planning of the study. Seven of the nine invited intervention practices accepted the invitation to participate. Then, in total, 21 GPs were randomised to the intervention group and 17 to the control group; the external control group counted 25 GPs.

The allocation of both GPs and patients to the intervention and to the control group was open and known to the GPs and the researchers. Patients in the intervention group were sent a flyer; and a poster in the practice informed them that their practice was an intervention practice. The external control group was only known to the researchers.

DATA

3.5.1 The Danish Civil Registration System (CRS)

In Denmark, like in the other Nordic countries, the recording of health data in registries that can be linked through a unique personal identification number offers exceptional possibilities for register-based studies. At birth or immigration, all citizens in Denmark are allocated a personal 10-digit identification number, the CPR number. This number allows linkage between all national registries at the individual level, and the number is registered in the CRS [130]. The CPR number was introduced in Denmark in 1968, and it enables longitudinal follow-up on individuals as it is continuously updated and old information is stored. Information recorded in the registries is generally accepted as being of high quality because the information is being used by the Danish administrative system; and any errors encountered are continually corrected. Registration is required by law and validation of the information is ongoing [131]. The first six digits of the number give the person's day of birth, the next three digits are a serial number to distinguish between persons with the same birthday and the last digit is a control digit added to minimise errors and to indicate the person's gender – even numbers for women and odd numbers for men.

3.5.2 Register data

There are many health registries in Denmark and they are highly valid as they are often used for administrative and remuneration purposes as well as for research; they contain much useful information [132;133]. Any use of services from general practice and hospitals is recorded to reimburse the providers, and, likewise, any prescription medicine provided by pharmacies is recorded in the

registries. To identify the use at the personal level, data can be linked by use of the unique CPR number.

In this study, we used the CRS to identify patients and linked the individuals' data on consumption of GP services from the Danish National Health Insurance Service Registry (NHSR), hospital services from The Patient Administrative System (PAS) and prescribed medication from The Regional Prescription Registry (DNRP).

To measure adherence to the disease management programme and the success of the implementation model, we used the extra remunerated services, like spirometry, and the codes for yearly follow-up visits and joint home-visit with the district nurse after discharge from hospital which is the recommended activity.

Out-of-hours services are provided by the GPs in Denmark and such services are costly like the use of emergency room and admissions to hospital. One of the key purposes of implementing the disease management programme is to assist a change in the use of the health care services from out-of-ours and secondary healthcare services to daytime primary care. We therefore investigated which services were provided by the hospitals and the use of out-of-hours services to assess the effectiveness of the active implementation.

3.5.3 The Danish National Health Insurance Service Registry (NHSR)

The purpose of the NHSR is to document activities in primary healthcare for administrative use and for fee-for-service remuneration [134]. Information about all citizens' use of general practice can be obtained from this registry. The NHSR has been collecting information about the activities of health professionals contracted with the public healthcare system since 1990. Danish GPs report the

type of services they have provided to the registry to be reimbursed; the NHSR also contains information about the citizen and the provider, and each GP setting has a unique provider number [135] [136].

3.5.4 The Patient Administrative System (PAS)

The PAS collect information on the regional hospitals' activities as part of the hospital fee is linked to activity at the hospital; using ICP-10 codes for each patient, all regional hospitals report their contacts to the regional PAS, e.g. outpatient visits, visits to the emergency room, hospital admissions and discharges. For each patient, the GP's provider number is registered together with different additional codes. The PAS from each region provides data to the Danish National Patient Registry (NPR), which stores data on discharges from Danish somatic hospitals. All Danish hospitals are committed to send their data to the NPR by the 10th of each month [137]. To ensure that registrations in the PAS are consistent all over the country, the Danish National Board of Health has issued a national guideline for data registration [138]. Besides serving remuneration purposes, the NRP facilitates hospital physicians' access to patients' hospitalisation history, monitors the frequency of diseases and treatments, provides data for research purposes and facilitates quality assurance in Danish health care services.

3.5.5 The Regional Prescription Registry (DNRP)

Information on all dispensed prescriptions with Anatomical Therapeutic Chemical (ACT) Classification System codes sold over-the-counter or for inpatient use in the Central Denmark Region is collected in The Regional Prescription Registry (RPR) [139;140] which feeds into the DNRP. Individual-level

data on all prescription drugs sold in community pharmacies have been registered in the Register of Medicinal Products Statistics of the Danish Medicines Agency in Denmark since 1994. The DNRP holds information on the prescription user, the prescriber and the pharmacy; it is one of the few registries to hold individual-level information on prescriptions that covers an entire nation.

Table 3.5 gives a description of the used variables and names the registry sources.

Table 3.5 *Variables used in this study with a description and collection source*

Variable	Description of variable	Data sources
Planned preventive consultation	Patients who had agreed on the topic for the consultation and planned it in advance to be able to be prepared for the consultation	DNHISR
Additional preventive consultation	Preventive additional utility for yearly follow-up consultations	DNHISR
GP performed spirometry	At least one spirometry performed within the year	DNHISR
Contact to out-of-hours services	Patients who had at least one contact to out-of-hours services	DNHISR
Number of contacts to out-of-hours services	All contacts to out-of-hours services	DNHISR
Number of joint home visits	All home visits made jointly with the community nurse	DNHISR
Number of conventional consultations	All conventional consultations	DNHISR
Contact to emergency department	Patients who had at least one contact to the emergency department	PAS
Number of contacts to emergency department	All contacts to the emergency department	PAS
Hospital admission	Patients who were admitted at least once with a non-lung-related diagnosis	PAS
Number of hospital admissions	All admissions with diagnoses other than the lung-related ones	PAS
Admission with a lung-related diagnosis	Patients who were admitted at least once with a lung-related diagnosis	PAS
Number of admissions with a lung-related diagnosis	All admissions with a lung-related diagnosis	PAS
Beddays	Number of days patients stayed in the hospital	PAS
Number of readmissions	All readmissions with a diagnosis concerning COPD	PAS
Number of outpatient contacts	All contacts to the outpatients clinic	PAS
Number of lung-related outpatient contacts	Lung- related contacts to the outpatients clinic	PAS
Redeemed prescription of a medication for lung-related disease	At least two prescriptions had to be redeemed within the past year to satisfy the purpose of the algorithm	RPR

QUESTIONNAIRE DATA

Questionnaire data were obtained to be able to identify patients and to obtain patient-reported characteristics and patient-recorded outcome measures.

3.6.1 Patient questionnaires

We used separate baseline and follow-up questionnaires. The baseline questionnaire contained questions on socioeconomics issues which were not included in the follow-up questionnaire.

3.6.2 Developing the patient questionnaires

We searched the literature in depth for instruments used to measure patients' assessment of their care, their evaluation of their GP and the GP practice and their evaluation of their health-related quality of life. The CCM contains a tool that measures the components of the model called Patient Assessment of Chronic Care (PACIC) [141]. We chose to use this tool as it had been translated and validated in a Danish context [142]. This tool was supplemented with the Danish Patients Evaluate Practice (DANPEP) [143], which is a questionnaire that explores patients' experience of practice. We also included five questions from the European Quality of Life with five dimensions (EQ-5D) instrument designed to measure self-reported health status. These five questions were translated and validated to be used in a Danish healthcare setting [144] . Finally, the questionnaire included the question used in the MRC's dyspnoea scale to assess the gravity of the patient's respiratory state [145].

To assess the patient's emotional condition, we identified nine questions used in general practice to assess a patient's level of depression and anxiety, the MDI -

Major Depression Inventory [146]. To map the patient's relation to smoking, use of medication, support and socio-economy, the research group designed questions based on literature, clinical experience and interviews with patient groups and health professionals in the health centre in Ringkoebing-Skjern Municipality, Sundhedscenter Vest. Already designed questions were used whenever possible.

3.6.3 Pilot-testing the patient questionnaires

The questionnaires were tested in two focus groups with patients and one with health professionals in Sundhedscenter Vest, Tarm, Denmark. The comments received helped to organise the questionnaires and make adjustments to the questions designed by the research group. The questionnaires were then pilot-tested by seven patients, and a few minor changes resulted from their comments. No questions were added or removed in the final version of the questionnaires, which had a high content validity in relation to the research question [147].

3.6.4 Questionnaire logistics

In each questionnaire survey, i.e. both the baseline and the follow-up survey, those patients who possibly had COPD were sent the questionnaire (Appendix I and II) together with a one-page cover letter and a pre-stamped envelope; the intervention patients also received a flyer (Appendix III) with information on contacts for information about COPD, both at the local and the national level. In both surveys, the non-responders were sent a reminder after three weeks [148] [149] [150].

A database management system was created, using Microsoft Access, to manage the logistics of the questionnaires. An assistant (CGJ) or MS filled in the date and the unique serial number of each questionnaire upon its return. CGJ scanned all the returned questionnaires. The questionnaires were designed and processed in the computer programme for TELEform Enterprise version 8.0 (Cardiff Software Inc., San Marcos, CS, USA) for data capture by optical scanning. If the TELEform programme could not read the answer, the questionnaire was thoroughly examined by the assistant and MS. The accuracy of this process has been documented by Jørgensen et al [151], and the data processing procedure was well known in the Research Unit. Data were transferred to the statistical software programme and checked for logical errors. When any errors were found, the original questionnaire was inspected and the correct data entered into the database for the study.

SAMPLING OF PATIENTS WITH COPD

3.7.1 Sampling of patients

The first goal in our investigation was to identify patients in the population with known COPD as well as possible. The first study therefore focused on the development of a COPD identification algorithm.

3.7.2 Collection of patient data

Data on citizens in Ringkoebing-Skjern and Ikast-Brande and their registration with a GP practice were collected from the CRS. Data on their use of general practice were obtained from the NHSR (please see Table 4.1.1 in Chapter 4 for healthcare use data). From the PAS, data were collected on sampled inhabitants' use of prescribed medication that might be related to COPD (please see Table 4.1.1 in Chapter 4 for ATC codes used). Data on outpatient visits, emergency-room visits, hospital admissions and discharges were collected from the PAS based on ICD-10 codes related to COPD (please see Table 4.1.1 in Chapter 4 for diagnosis). From these data, an algorithm was developed to identify patients with COPD [140] (Paper I).

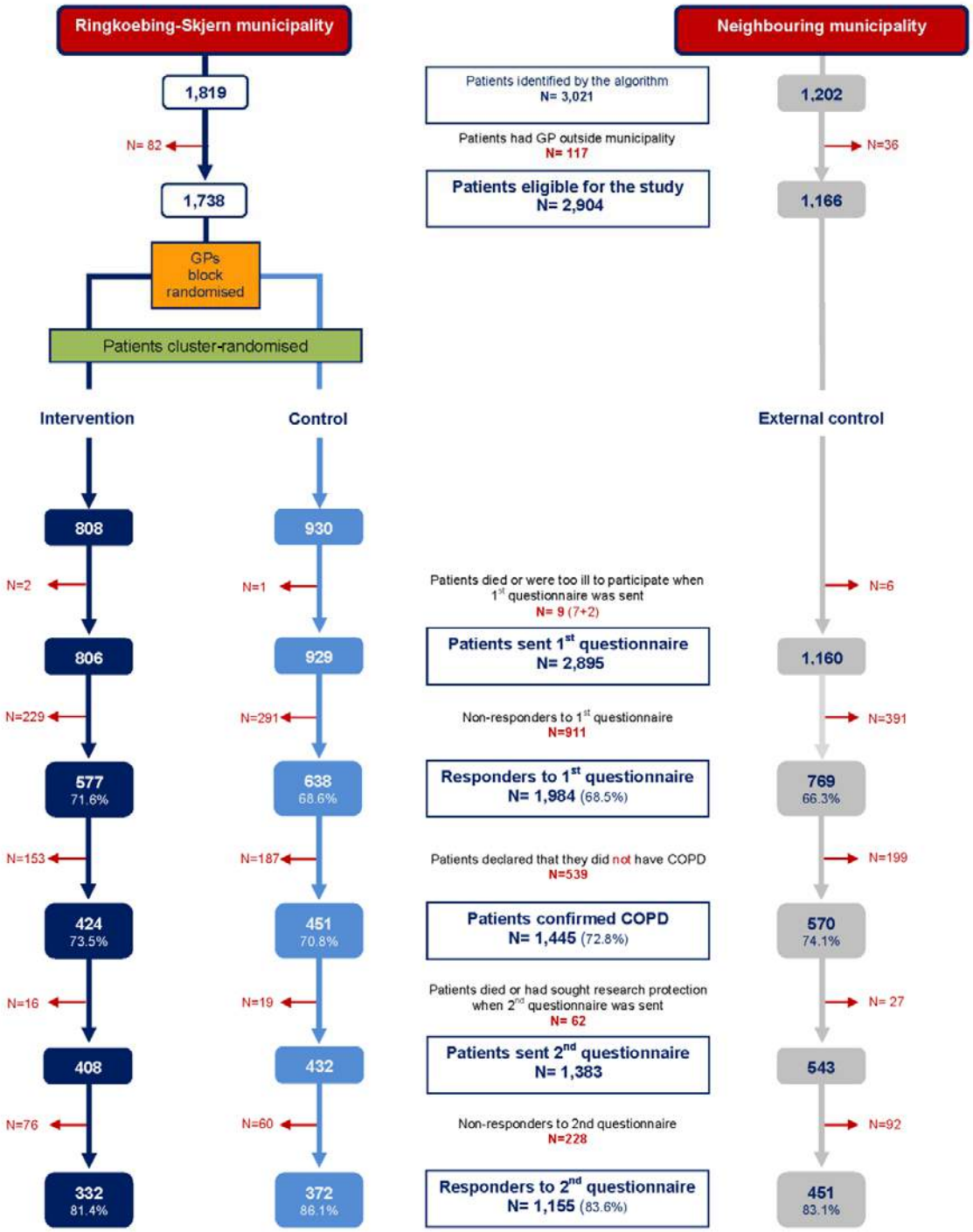
3.7.3 Eligible patients

The algorithm identified 3,021 patients as possibly having COPD; 117 of these patients were registered with a GP outside the municipality in which they were living. They were therefore excluded because only GP practices and the municipality's health centre in Ringkoebing-Skjern would participate in the randomised study, and GP practices in Ikast-Brande were the external control group for the study. That left 2,904 patients eligible for the study and they were sent a questionnaire in which they were invited to confirm or deny their

diagnosis of COPD. A total of 1,984 patients (68.5%) answered the questionnaire, and 1,445 (72.8%) of those confirmed their diagnosis of COPD. At follow-up, a total of 1,383 patients were sent a questionnaire and 1,155(83.6%) answered. For further details, please see Figure 3.8.

Figure 3.8 Flowchart of the included patients from the two municipalities. The allocation in this flowchart is for the as-treated analysis. The distribution for the intention-to-treat and the per-protocol analysis can be found in Figure 1 in Paper III. A flowchart with all three distributions is found in Chapter 4 Figure 4.3.1.

Figur 3.7


Ringkoebing-Skjern municipality
Neighbouring municipality
1,819
N= 82
1,738
GPs block randomised
Patients cluster-randomised
Patients identified by the algorithm N= 3,021
1,202
N=36
Patients had GP outside municipality N= 117
Patients eligible for the study N= 2,904
1,166
Intervention
Control
External control
808
930
N=2
N=1
Patients died or were too ill to participate when 1st questionnaire was sent N= 9 (7+2)
N=6
Patients sent 1st questionnaire N= 2,895
806
929
1,160
N=229
N=291
Non-responders to 1st questionnaire N=911
N=391
577 71.6%
638 68.6%
Responders to 1st questionnaire N= 1,984 (68.5%)
769 66.3%
N=153
N=187
Patients declared that they did not have COPD N=539
N=199
424 73.5%
451 70.8%
Patients confirmed COPD N= 1,445 (72.8%)
570 74.1%
N=16
N=19
Patients died or had sought research protection when 2nd questionnaire was sent N= 62
N= 27
Patients sent 2nd questionnaire N= 1,383
408
432
543
N=76
N=60
Non-responders to 2nd questionnaire N=228
N=92
332 81.4%
372 86.1%
Responders to 2nd questionnaire N= 1,155 (83.6%)
451 83.1%

SAMPLE SIZE

3.8.1 Sample size calculation

To detect a change from 50% to 60% in the proportion of patients having a yearly follow-up consultation for their chronic disease with 80% power at the 0.05 significance level, a total of 816 patients with 408 in each group would be required to be included in the study. With a cluster effect of 1.6, we would need 1,306 patients for the study.

INTERVENTION

The aim of the main study was to assess the effect of an active implementation of improved treatment and care for patients with COPD according to the CCM. We developed a model for actively implementing a structured disease management programme for COPD to be used in the intervention practices. The development is described in detail in Paper II.

3.9.1 The elements in the intervention

The intervention comprised components from the CCM's main areas - policies and resources, self-management support, delivery system design, organisation of health care, clinical information system and decision support [152]. A summary of the intervention is as follows:

We negotiated our implementation strategy with the municipality, which actively took part by increasing the number of already implemented courses for COPD and smoking cessation.

The region provided remuneration for planned preventive consultations and for joint homevisits together with the district nurse to newly discharged patients who had been hospitalised for COPD.

Targeted self-management support to cope with exacerbations of the disease was an integral part of our strategy, and we developed an action-card with sputum advice to patients based on the research by Robert Stockley [153] [154]. To provide family, friends and the patients with enhanced knowledge in order to allow them to better cope with the disease, we designed a website with information about COPD including contact details to the municipality, patient support groups and the involved GPs.

Routines were established in the GP clinic to proactively invite patients for yearly follow-up visits; it was organised for practice staff to do part of the follow-up and monitoring of the patients and a feasible routine for adjustment of the delivery of COPD care was implemented. A fax was sent from the hospital to the GP practices when a patient was discharged after an admission for COPD; this enabled a joint homevisit with the district nurse to newly discharged patients who had been hospitalised for COPD to plan further care.

Each GP practice was supplied with a database containing data on the expected practice attendees with COPD and the municipality's health centre provided feedback on patients' participation and progress to the GP practices when a patient had finished a course.

GPs were offered supervision by the local lung consultant and they had access to a podcast with expert advice on the treatment and care of patients with COPD as prescribed in the clinical guideline from the Danish Society of General Practice [16].

3.9.2 The processes of the intervention

The intervention practices were invited to participate in four two-and-a-half-hour sessions. As a framework for implementation of planned and targeted changes, we used the Breakthrough Series [155] [60]. We used experts and experienced facilitators at all meetings; all were clinically educated and experienced in aiding change in practice. The day after the meeting, a summary was sent by e-mail to all intervention GPs and the practices staff. A facilitator (MS) visited each practice to explore and/or address challenges they had encountered while implementing their set goals.

We used a local, accepted opinion-leader (Lars Foged, GP and advisor to the municipality and the region on GP-related issues) to introduce and support the

implementation both with GPs and in the municipality to stimulate the process [156].

Details of the intervention are described in Paper II.

ANALYSES IN THE INCLUDED PAPERS

3.10.1 Paper I

The algorithm was developed and tested in this paper.

Sensitivity, specificity as well as positive and negative predictive values were calculated for all algorithms and for the final algorithm for all age groups as well. The age-specific positive predictive value (PPV) was calculated on the basis of the prevalence [15784]. For patients aged 35-44, the prevalence for the 45-54-year-olds was used; and for patients aged 85 and above, the prevalence for patients aged 75-84 years was used.

In connection with patient validation, responders and non-responders were compared in terms of gender, age and the criteria deployed in the algorithm using two-sample t-test. The gender distribution within the two groups was tested by Pearson's chi-squared test, and Fischer's exact test was used for comparison of the criteria used to identify the patients.

3.10.2 Paper II

In this Paper, we describe the use of Medical Research Council's "Framework for design and evaluation of complex interventions to improve health" [158]. We selected both the components in an active implementation model and the components from the CCM [34 35] to design an implementation model for a disease management programme for patients with COPD.

The step-wise procedure and the systematic description of each component in the complex intervention facilitated the implementation of the programme and eased further research on the effects hereof as described in detail in a PatPlot [159].

3.10.3 Paper III

The aim of this paper was to describe the effect of the active implementation model for a disease management programme for COPD (described in Paper II) on healthcare utilization both in primary and in secondary care.

Our primary outcome was the GP's adherence to the guideline. We found no proxy measure for this and chose to measure adherence in terms of the provision of specific services in the GP practices. We chose increased use of the planned preventive consultation, the additional preventive consultation, more performed spirometries and/or more joint homevisits undertaken together with the community nurse as measures for increased adherence. The joint homevisits are not reported in the paper.

The effect of the active implementation was analysed in an intention-to-treat analysis by comparing the changes in the intervention group with the changes in both the control group and the external control group. For each of the outcomes, we calculated yearly rates and rate ratios (RRs) between the year before and the year after the intervention start. To determine the differences between the groups, the corresponding pairwise RRs between the groups were calculated. To facilitate estimation of the RRs, we used a binomial regression model with log-link when analysing each of the following outcomes: proportion of planned preventive consultations; additional preventive consultations; performed spirometries; and the proportion of patients who had contact to the out-of-hours services, were admitted with and without a lung-related diagnosis and who had contact to the emergency department. A negative binomial regression model allowing for the heterogeneity between subjects [160] was used to analyse the counts of the outcomes: conventional consultations, contacts to the out-of-hours services, joint homevisits, use of beddays, contacts to the outpatient services with and without a lung-related diagnosis, number of contacts to the emergency department, number of admissions with and without a lung-related diagnosis

and number of readmissions. In all cases, 95% confidence intervals (CIs) were assessed and robust variance estimation were performed to account for a cluster effect at the GP level and, consequently, also at the patient level; and adjustment was made for age and gender, although this had only a negligent effect on the estimates of interest.

3.10.4 Paper IV

The aim of this Paper was to describe the effect of the active implementation model for a disease management programme for COPD on patients' assessment of their care measured with the PACIC instrument.

We used as-treated analysis to measure the effectiveness of the implementation, i.e. the intervention group comprised of the practices actually participating in the interventions. To make a sensibility analysis of the as-treated analysis, we also did effectiveness analyses where the two practices that declined the invitation to participate in the intervention were analysed as intervention practices in an intention-to-treat analysis.

We compared the difference between the mean difference in change in scores for the corresponding pairwise comparisons between intervention, control and external control groups. We used a two-sample t-test to test the differences as the differences were normally distributed.

Responders and non-responders were compared in terms of gender and age at baseline. Responders with full follow-up and non-responders to the follow-up questionnaire were compared in terms of age and baseline PACIC scores for each scale and the total PACIC score using two-sample t-test. The gender distribution was tested by Pearson's chi-squared test.

3.10.5 Standards

P-values of 5% or less were considered statistically significant. Analyses were performed using STATA version 11.0. (StataCorp, College Station, Texas). The trial followed the consolidated standards of reporting trials guideline extended for cluster-randomised controlled trials [161]

ETHICS AND APPROVALS

3.11.1 Ethical considerations

Special ethical considerations apply in cluster-randomised studies of changes in daily clinical practice. Some argue that the ethical issue of informed consent of participants is not addressed properly unless all individuals have given their consent [162;163]; whereas others find that the approval of the gatekeepers of access to patient groups is sufficient [164]. We followed the UK Medical Research Council and different other authors who have argued that there are studies where cluster participants like the patients in our study will find it difficult to avoid the intervention which makes a refusal to participate meaningless [162;165].

3.11.2 The Scientific Ethics Committee, the Central Denmark Region

According to the Scientific Ethics Committee in the Central Denmark Region, the Act on Research Ethics Review of Health Research Projects did not apply to this project.

3.11.3 Trial approvals and registrations

The Multi Practice Committee of the Danish Collage of General Practitioners and the Association of Danish General Practitioners (MPU 17-2009) recommended the study and encouraged the GPs to participate. The study was approved by the Danish Data Protection Agency (J.nr. 2008-41-2855), the Danish National Board of Health (J. NR.: 7-604-04-2/71 /EHE) and the RCT was indexed at www.clinicaltrials.gov (NCT01228708).

SUMMARY OF THE FOUR PAPERS IN THIS THESIS

Table 3.12 provides an overview of the aim, study population, data sources and outcomes of the four papers in the thesis.

Table 3.12 *Characteristics of the four papers in this present thesis*

Paper	Aim	Study population	Data sources	Outcomes
I	To identify patients with known COPD using administrative data	1. Patients identified and verified by their GP as having COPD. 12 GP practices in Aarhus County. 2. Patients identified by their lung related contact to the healthcare system from two municipalities.	Data from health registries, GPs and questionnaire survey	COPD algorithm
II	To describe the development of a model for actively implementing a disease management programme using the MRC's "Framework for design and evaluation of complex interventions to improve health"		Literature on implementing change in healthcare	Active implementation model for a disease management programme
III	To test the effect of the active implementation model for a disease management programme for COPD on healthcare utilisation	Patients identified by the COPD algorithm. Patients confirmed their diagnosis by returning a questionnaire from two municipalities	Data from health registries	Healthcare utilisation
IV	To test the effect of the active implementation model for a disease management programme for COPD on patients' evaluation of their care	Patients who confirmed their diagnosis of COPD and answered at least 50% of the PACIC instrument in two questionnaire surveys a year apart. Patients recruited from two municipalities	Data from questionnaire surveys	Patients' assessment of the care they received measured with the PACIC instrument

CHAPTER 4

RESULTS

This chapter offers a brief summary of the main results presented in the thesis. A more detailed description of the results is presented in each of the papers.

DEVELOPING AN ALGORITHM TO IDENTIFY PATIENTS WITH COPD FROM ADMINISTRATIVE DATA

4.1 Paper I

The study showed how an algorithm was developed from administrative data, validated and tested and could be used as a screening tool to identify patients with chronic lung disease, primarily COPD, who had already been in contact with the health system for a lung-related complaint. Three different patient populations were used for the development of this algorithm.

4.1.1 Population A

In population A, a group of GPs in the Central Denmark Region identified 266 patients with clinically diagnosed COPD who attended their practices. Registry data were combined in different ways to determine which combination would best identify the largest proportion of the clinically diagnosed COPD cases. The criteria for hospital admissions, redeemed prescriptions and performed spirometries in general practice are outlined in Table 4.1.1. Table 4.1.2 features the nine different data combinations. The simplest algorithm with the highest PPV contained three criteria and had a PPV of 72.2%; it was chosen as the COPD algorithm to identify patients from administrative data.

4.1.2 Population B

The above COPD algorithm was used to identify population B in a different group of GP practices in the Central Denmark Region. A total of 532 patients were identified with this algorithm. The GPs clinically verified the COPD diagnosis for 244 (45.9%) of the patients. For 102 (19.1%) patients, the GPs were not sure of the diagnoses. The PPV for a possible or definite COPD was 65.0%,

the sensitivity was 44.8 [95%CI: 41.3-48.4] and the specificity was 97.7% [95% CI: 97.3-98.0]. The 10-year age-span-specific PPVs varied from 30% to 97%.

4.1.3 Population C

The COPD algorithm identified population C; 2895 patients in Ringkoebing-Skjern and Ikast-Brande municipalities; a total of 1,984 (68.5%) patients who were eligible for inclusion in the study returned the questionnaire; of these 1,445 (72.8%) had COPD. The sensitivity was 29.7% [95% CI: 28.4-31.0], the specificity was 98.9% [95% CI: 98.8-99.0] and the overall PPV was 72.8% [95%CI: 70.8%;74.8%] with a prevalence of COPD of 9% in the population in this region. The 10-year age-span-specific PPVs ranged from 41.8% to 81.8%.

The three populations are illustrated in Figure 4.1.1.

(Please see Paper I for further details)

Table 4.1.1

The table illustrates the criteria for being sampled as a possible patient with COPD.

ALGORITHM:	
Age: All citizens ages 35 and up at the time of identification in the registry.	
Vital status: Alive at the time of identification in the registry.	
Selection of COPD patients: People who meet at least one of the following criteria can be sampled as possible patients with COPD:	
1. Hospital contact. People who have been hospitalised or have had an outpatient visit at least once during the past 5 years with one or more of the following ICD-10 codes as their main diagnosis:	
Bronchitis without specification	DJ40
Bronchitis without specification	DJ409
Simple and mucopurulent chronic bronchitis	DJ41
Bronchitis chronica simplex	DJ410
Bronchitis chronica mucopurulenta	DJ411
Bronchitis chronica simplex et mucopurulenta, mixed type	DJ418
Chronic bronchitis without specification	DJ42
Chronic bronchitis without specification	DJ429
Tracheobronchitis chronica	DJ429A
Tracheitis chronica	DJ429B
Expansion of the lungs	DJ43
MacLeod's syndrome	DJ430
Emphysema pulmonum unilaterale	DJ430A
Emphysema pulmonum panlobulare	DJ431
Emphysema pulmonum panacinare	DJ431A
Emphysema pulmonum centrilobulare	DJ432
Emphysema, other kinds	DJ438
Emphysema without specification	DJ439
Emphysema pulmonum bullosum	DJ439A
Chronic obstructive lung disease, other	DJ44
Chronic obstructive lung disease, with acute lower respiratory tract infection	DJ440
Chronic obstructive lung disease, with acute exacerbation without specification	DJ441
Chronic obstructive lung disease, other specified version	DJ448
Bronchitis chronica obstructive	DJ448A
Bronchitis chronica asthmatica	DJ448B
Chronic obstructive lung disease without specification	DJ449
Expansion of bronchia	DJ47
Bronchiectasia	DJ479
Respiratory insufficiency not classified any other place	DJ96
Insufficientia respiratoria acuta	DJ960
Insufficientia respiratoria chronic	DJ961
Respiratory insufficiency without specification	DJ969
Only the diagnosis coding was examined, not the way the patients were referred or any other matters.	
2. COPD medicine. People who have redeemed at least two prescriptions on different dates within the past 12 months from the time of identification in the register, with one or more of the following ATC codes: R03AC; R03AK; R03BA; R03BB; R03CC; R03DA; R03DC; V03AN01	
3. Spirometry in general practice. People who have had at least two spirometry tests on different dates within the past 12 months from the time of identification in the register and defined as a fee-for-lab test called: 7113, expanded lung function test verified by spirometry or 7121, double lung function test for exertion provoked asthma or reversibility test done by spirometry in the same consultation.	

Table 4.1.2

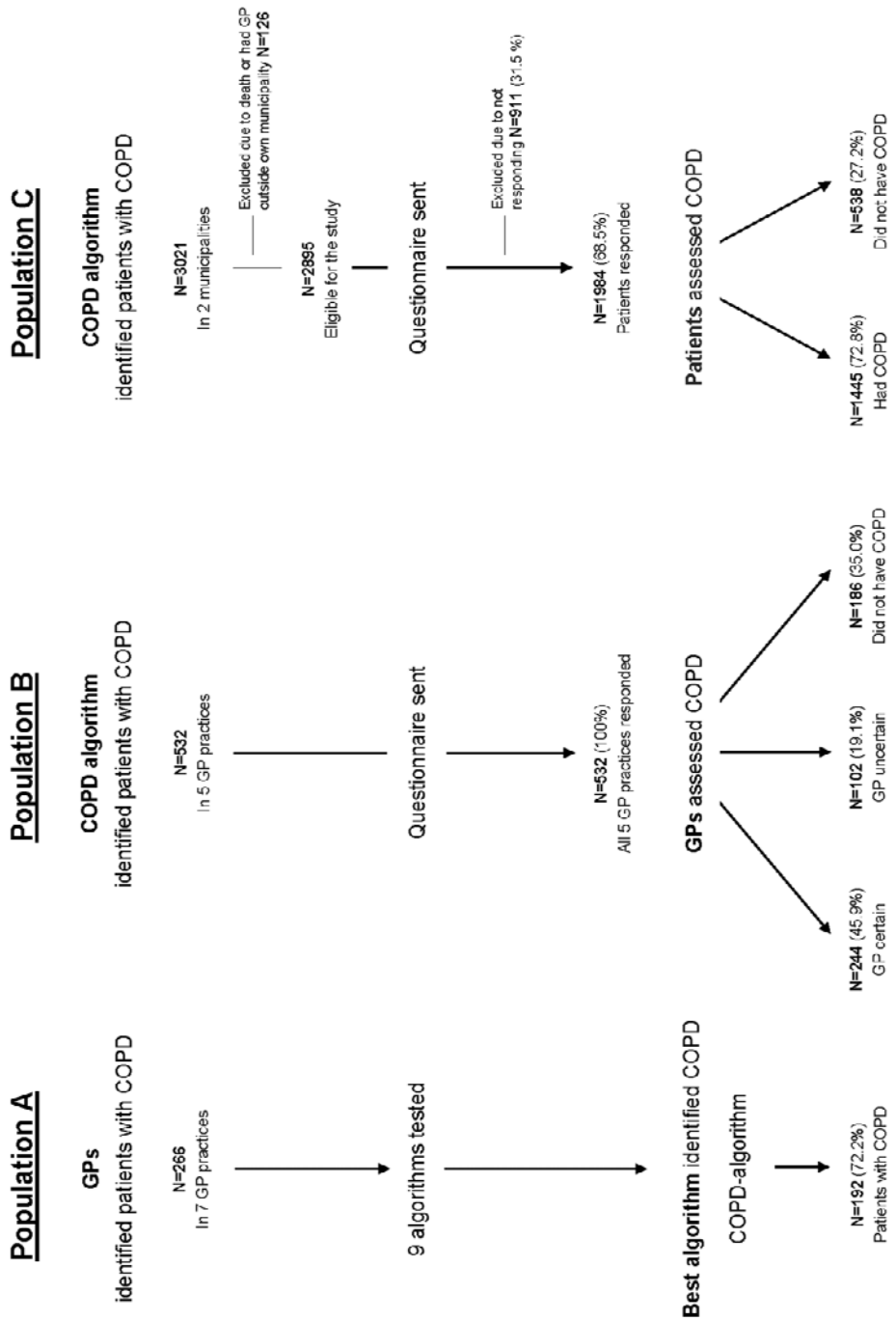
The table illustrates nine combinations of hospital admissions, redeemed prescription medication and performed spirometries, each of them forming an algorithm.

Identification of patients with COPD using different algorithms.
Nine different combinations were tested on 266 patients identified by 26 GPs.
A prerequisite for inclusion was to be 35 or above and to be alive at the time of identification in the registries.

Algorithm	Identified by All	Identified by %
1. In-patient at least once during the past 5 years Redeemed prescription medication at least twice during the past year Redeemed prescription medication once and spirometry performed once at GP during the past year	189	71.1
2. In-patient at least once during the past 5 years Redeemed prescription medication at least twice during the past year Redeemed prescription medication once and spirometry performed once at GP or specialist during the past year	189	71.1
3. In-patient at least once during the past 5 years Redeemed prescription medication at least twice during the past year Spirometry performed at least twice during the past year at the GP Redeemed prescription medication once and spirometry performed once at the GP or a specialist during the past year	193	72.6
4. In-patient at least once during the past 5 years Redeemed prescription medication at least twice during the past year Spirometry performed at least twice during the past year at the GP Redeemed prescription medication once and spirometry performed once at the GP or a specialist during the past year	189	71.1
5. In-patient at least once during the past 4 years Redeemed prescription medication at least twice during the past year Spirometry performed at least twice during the past year at the GP Redeemed prescription medication once and spirometry performed once at the GP or a specialist during the past year	192	71.4
6. In-patient at least once during the past 3 years Redeemed prescription medication at least twice during the past year Spirometry performed at least twice at the GP during the past year Redeemed prescription medication once and spirometry once at the GP or a specialist during the past year	191	71.8
7. In-patient at least once during the past 2 years Redeemed medication at least twice during the past year Spirometry performed at the GP at least twice during the past year Redeemed prescription medication once and spirometry done once at the GP or a specialist during the past year	190	71.4
8. In-patient at least once during the past 5 years Redeemed prescription medication at least twice during the past year	188	70.7
9. **In-patient at least once during the past 5 years** **Redeemed prescription medication at least twice during the past year** **Spirometry performed at least twice at different dates during the past year at the GP**	**192**	**72.2**

Figure 4.1.1

The figure depicts the three different designs involved developing the COPD algorithm in population A and testing it in two different populations B and C.



THE INTERVENTION – AN ACTIVE IMPLEMENTATION OF A DISEASE MANAGEMENT PROGRAMME

4.2 Paper II

We found the MRC's [158] model for designing a complex intervention to be a transparent model that made it easy to replicate our developed model to actively implement the disease management programme as described above. We decided to call the developed complex intervention model an active implementation. We conducted three focus group interviews with patients and one with GPs to investigate some of the barriers and needs for supplying optimised care for patients with COPD. Likewise, we had several consultations with health professionals in the health care centre to assess the experienced need for collaboration and the available resources, but also to encourage ownership to the implementation at the health centre; illustrative quotes from the focus groups and consultations are listed in Table 4.2.1. The elements in the CCM [33] [152] were found to be feasible for implementing change in healthcare. We combined the following strategies, which were identified as efficient, into a multifaceted complex intervention and captured the timeline and process in the PaTPlot [159] (please see Figure 4.2.1): use of the Breakthrough Series [155] [60], academic detailing [166] [167] [168] , provision of patient material [169], and common meetings and communication [170] between providers. In the following, each of the strategies and the process of implementation are described in more detail.

Table 4.2.1 *Quotes from three focus groups with patients and one with GP practices and several consultations with the health centre staff*

Patients	General practices	Municipality's Health Centre staff
"I would like one system for accessing my file both for the hospital, the health centre, my doctor and myself or at least a system where there is exchange between those who treat me when something has happened to or with me".	"We really need a report on what has happened when the patient has been at the health centre"	"We want patients from all social groups to feel equally comfortable while attending classes".
"My doctor should know about and inform me about the COPD classes at the health centre and the groups for people with my condition".	"Please, update us on the newest and most current medication advice".	
"I would like to know my lung function and what it means that it is reduced".		
"I would like to be able to handle more – like medication - myself".		

4.2.1 Breakthrough Series

The GP practices in the intervention group were invited to participate in an introduction session informing them about the intervention. The session was headed by the local GP in the project group who served as an opinion leader, and the session was followed by three two-and-a-half-hour sessions during seven months. At the meetings, GPs and the other health professionals in the GP practices were updated on COPD treatment. The consultant in lung diseases from the local hospital held a lecture on the most appropriate use of medication and suggested ways for collaboration when patients needed care from both secondary and primary care; he also offered access to a mobile number 24 hours a day with contact to a specialist in lung diseases offering treatment advice; a representative from the municipality's health centre provided information about the courses on smoking cessation and "How to live with your COPD" offered to the patients by the municipality; and an experienced patient told about her experience of coping with the disease. The meetings introduced the health professionals to the use of the Breakthrough Series to

implement change in the individual practices, and each GP practice worked with the goals they wanted for their practice to successfully implement the disease management programme. To guide the change and the use of the Breakthrough Series in the individual practices, we used experts and experienced facilitators, all of whom were clinically educated. One facilitator visited the GP practice between meetings to follow up on the set goals. After all meetings, a summary of the discussion was sent to the GPs.

For detailed agendas from each meeting, please see Appendix IV.

4.2.2 Academic detailing

All intervention practices were visited by MS just after the first breakthrough meeting to help each practice implement the goal they had set for themselves at the meeting. At this first meeting, the practices were provided with a list of the patients found by the algorithm to possibly have COPD. This gave the practices the opportunity to organise follow-up consultation for their patients. A week after the meeting, the practice coordinator was telephoned to discuss the progress made. After the second Breakthrough meeting, the practices were offered another visit; and six practices were visited for an exchange of ideas on the challenges they had encountered implementing the recommendations of the disease management programme.

Extra access to expert knowledge was arranged as the local consultant in lung diseases offered to do consultations in the GP practices alongside the GPs.

4.2.3 Provision of patient material

Intervention patients received written information about COPD and contact to the municipality's health centre, the GPs and several websites where more information could be obtained about COP when they received the baseline questionnaire. Self-management was supported by the development of an action card about dynamic self-management based on the research by Robert Stockley [153] [171] . We expanded the card with written advice on what to do in case of exacerbations. The card was designed to have the size of a credit card so that it could fit into a wallet and was given out with a leaflet explaining how to use it. Contact and personal information could be written down in the leaflet. The card was distributed to the GP practices and the municipality's

health centre so that they could explain the use of the care when handing it to patients. Please, see Appendix V.

A website was created to offer information to patients, family, friends and health professional about COPD and the support provided by the municipality and the GP practices. Please, see http://kol.au.dk. Posters advertising the website and the support provided by the intervention practices were produced and were placed on display in the practices and at the health centre. Please, see Appendix VI.

4.2.4 Common meetings and communication between providers

Different approaches were used to support the communication between the municipality, the GP practices and the hospitals. Referral and feed-back forms (please see Appendix VII) were designed for use when GPs wanted to refer patients to the municipality's health centre. Podcasts for consultations with smoking cessation, instruction in the use of spirometry and a follow-up consultation were made available on the website [169] to provide easy access to up-to-date knowledge. To alert the GPs when a patient from their clinic was discharged after an admission for COPD, a system was designed whereby the hospital informed the GP practices of the patient's discharge. Joint homevisits with the GPs and the community nurse to the newly discharged patients who needed further care were negotiated with the Region. A special remuneration for this service was arranged, [172] and the GPs were advised at the meetings to undertake these visits when receiving faxes that recommended follow-up.

4.2.5 Implementation process

MS introduced the project to the hospitals involved, to the municipality's health centre and to the community nurses. The roles of the staff were explained and any questions clarified.

4.2.6 PatPlot

The PatPlot graphically outlines the components in the different arms of a randomised controlled trial and the timeline of the implementation process (please see Figure 4.2.1). We used the PatPlot

159 to enhance the transparency of both the contents and the process of developing the complex intervention for the researchers.

(Please see Paper II for further details).

Figure 4.2.1. *The PaTPlot depicting the timeline and the contents. Squares illustrate fixed objects, e.g. printed materials like questionnaires. Circles illustrate that an activity was involved in the component, e.g. Continued Medical Education meetings.*

TIMELINE	INTERVENTION	CONTROL	EXTERNAL CONTROL
-3 weeks	(1)	(1)	
Week 1	Patients identified by COPD algorithm		
	GPs block-randomized		No randomization
Week 2	[a]	[a]	
Week 3	[b] [c]	[b]	[b]
Week 4	(2) (3) (4) [d]		
Week 5	(5) [e] [f]		
Week 9	(6)		
Week 11	[g]		
Week 12	(7) [h]		
Week 12-16	(8)		
Week 22	(9) [i]		
Week 24	[j]		
Week 28	(10)		
Week 38	(11) [k]		
Week 40	[l]		
Week 44	(12)		
Week 50	[m]		
Week 52	[n]	[n]	[n]
Week 54	[o]	[o]	
Week 110	(13)	(13)	

(1)	15 GP practices invited to a meeting with information about the study
[a]	Baseline questionnaires sent to GPs. http://kol.au.dk/fileadmin/www.kol.au.dk//mest_til_praksis/sp__rgeskemaunders__gelse/sp.pdf
[b]	Baseline questionnaires sent to patients identified by the COPD algorithm. http://kol.au.dk/fileadmin/www.kol.au.dk/mest_til_patienter/spunder/patientskema.pdf
[c]	Information about project and places to go for information about COPD supplied in a flyer sent with the questionnaire.
(2)	Project lead developed and implemented feedback paper from health centre to GPs when patients had finished "Stop smoking" or attended COPD courses together with the staff. The health centre increased the course capacity.
(3)	Project lead held meetings with staff and the COPD consultant at the three hospitals. GP practices received a fax from the hospital when one of their patients with COPD had been discharged.
(4)	Project lead visited all GP practices. Options and possibilities for each clinic to change treatment and procedures for patients with COPD were discussed.
[d]	Referral papers to "Stop smoking" and "Living with COPD" courses at the health centre sent to each GP practice.

5	1. Breakthrough meeting with GPs and clinic staff. Consultant specialized in COPD updated on evidence-based care. Specialist in implementing change in practice introduced the Breakthrough method and shared care in GP practice. Health centre staff introduced the "Living with COPD" course and told about its contents to the GP practices.
e	Each GP practice supplied with a list of the COPD population identified by the COPD algorithm in their clinic.
f	Action card and explanatory brochure distributed to GP practices with verbal information on how to inform patient about the use of the action card. http://kol.au.dk/menu1/dksgn/handlingskort/
6	Project lead called to the project coordinator at each GP practice to exchange experience and to encourage each practice to keep implementing small changes with the Breakthrough method.
g	http:\\kol.au.dk. Website launched with information for patients and GP practices. Advertised to GP practices and the health centre by email.
7	2. Breakthrough meeting with GPs and staff. GPs and practice staff work discussed which of the changes worked in their practices and whic needed to be adjusted. Each practice developed plan for change to be implemented before next meeting.
h	Poster for display in the waiting room of the GP practices advertising the website supplied to each practice at Breakthrough meeting.
8	Project lead visited the GP practices that wanted to exchange views on their progress and to get support.
9	3. Breakthrough meeting with GPs and practice staff. Professional patient tells her story of living with COPD and her experience of the healthcare system. Practice consultant tells how he supports patients' self-management. Some baseline data are presented from the patient's questionnaire.
i	Each person wrote a postcard to themselves reminding them what two things they wanted to see implemented in their practice during the next half a year.
j	Film clip on: "A smoker wanting to give up" consultation - "How to do a spirometry" - "A 12-month check-up for a patient with COPD". Film clips are on the website to remind GPs and practice staff of all components prescribed in the guideline. http:\\kol.au.dk.
10	Project lead visited the hospitals to encourage continued practice of sending a fax to GP practice when one of their patients with COPD was discharged.
11	Project lead visited GP practices to encourage continued focus on the guideline's recommendations for treatment and care of patients with COPD.
k	Practice staff is sent the postcard reminding them on which two things they wanted to see implemented in their practice.
l	More action cards and brochures sent to the GP practices to maintain focus on support for self-management .
12	Project lead visited GP practices to encourage continued focus on the guideline's recommendations for treatment and care of patients with COPD.
m	GPs were sent the postcard reminding them on which two things they wanted to have implemented in their practice.
n	Patients who confirmed their diagnosis of COPD in the baseline questionnaire were sent a follow-up questionnaire. http://kol.au.dk/fileadmin/www.kol.au.dk/mest_til_patienter/spunder/2010_Spoergeskema_hjemmesiden.pdf
o	The GP practices, the health centre and the hospitals were informed by email of the collection of register data for outcome measures for the study.
13	GP practices, health centre and COPD consultant were invited to a meeting with presentation of the results from the study.

THE CLUSTER RANDOMISED CONTROLLED TRIAL

4.3 Paper III and Paper IV

We conducted a block- and cluster-randomised controlled trial and tested the active implementation model developed and described in Paper II. Patients were identified using the COPD algorithm, which was developed and described in Paper I. The effect was measured in terms of both health utilisation and patients' assessment of their care.

The COPD algorithm [140] identified 3,021 patients for inclusion in the study. Among those, a total of 2,894 participated in the questionnaire study and 1,372 in the registry study (please see Table 4.3.1). In Paper IV, a total of 744 patients were included as they had answered both questionnaires with at least 50% of the questions in the PACIC (please see Table 4.3.2.).

A total of 68.5% of the identified 2895 patients with possible COPD responded to the first questionnaire; of those, 72.8% (n=1445/1,984) confirmed their COPD diagnosis. The response rate to the follow-up questionnaire sent 12 months after the start of the intervention was 83.6% (n=1155/1383) (please see Figure 4.3.1).

The control group counted statistically significantly more men than women (59.7% men (p=0.007)); but otherwise no gender differences were observed, and no statistically significant age difference between responders and non-responders was found in any of the groups in the study population in Paper IV. The mean score on the Medical Research Council's dyspnoea scale [173] at baseline was statistically significantly lower among those who answered the follow-up questionnaire 2.08 [95%CI:2.00;2.14] than among those who did not 2.52 [95%CI:2.34;2.70], (p<0.001).

In Paper III, intention-to-treat analysis was used as the main analytical strategy for the population that had confirmed their diagnosis of COPD, and a per-protocol analysis was used to determine sensitivity; furthermore, both analyses were performed in the population which was identified by the COPD algorithm; furthermore, an as-treated analysis of both populations was performed. In Paper IV, as-treated analysis was used to illustrate the patients' assessment of their care and an intention-to-treat analysis served as a sensitivity analysis, also here a per-protocol analysis was conducted.

Table 4.3.1.

Baseline data for patients as listed in the Danish Health Insurance Service Registry by 1 November 2008

Patients identified by the COPD algorithm

	Intervention	Control	External Control	Total
N (%)	877 (32.1)	767 (28.0)	1,092 (39.9)	2,736 (100)
Men (%)	399 (45.5)	354 (46.2)	492 (45.0)	1,244 (45.5)
Female (%)	478 (54.5)	413 (53.8)	600 (55.0)	1,492 (54.5)
Mean age (min-max)	63.9 (35-97)	63.3 (35-96)	63.3 (35-101)	63.5 (35-101)

Study population in Paper III

Patients identified by algorithm who confirmed that they had COPD

	Intervention	Control	External Control	Total
n (%)	458 (33.4)	376 (27.4)	538 (39.2)	1,372 (100)
Proportion of N %	52.2	49.1	49.3	50.2
Men (%)	222 (48.5)	179 (47.6)	264 (49.1)	665 (48.5)
Female (%)	236 (51.5)	197 (52.4)	274 (50.9)	707(51.5)
Mean age (min-max)	67.6 (36-91)	66.3 (35-91)	66.7 (36-94)	66.9 (35-94)

Table 4.3.2

Baseline data for patients as listed in the Danish Health Insurance Service Registry by 1 November 2008

Patients identified by the COPD algorithm

	Intervention	Control	External Control	Total
N1 (%)	765 (27.9)	879 (32.1)	1,092 (39.9)	2,736 (100)
Men (%)	354 (46.3)	398 (45.3)	492 (45.0)	1,244 (45.5)
Female (%)	411 (53.7)	481 (54.7)	600 (55.0)	1,491 (54.5)
Mean age (min-max)	64.3 (35-97)	63.1 (35-96)	63.3 (35-101)	63.5 (35-101)

Patients who confirmed that they had COPD

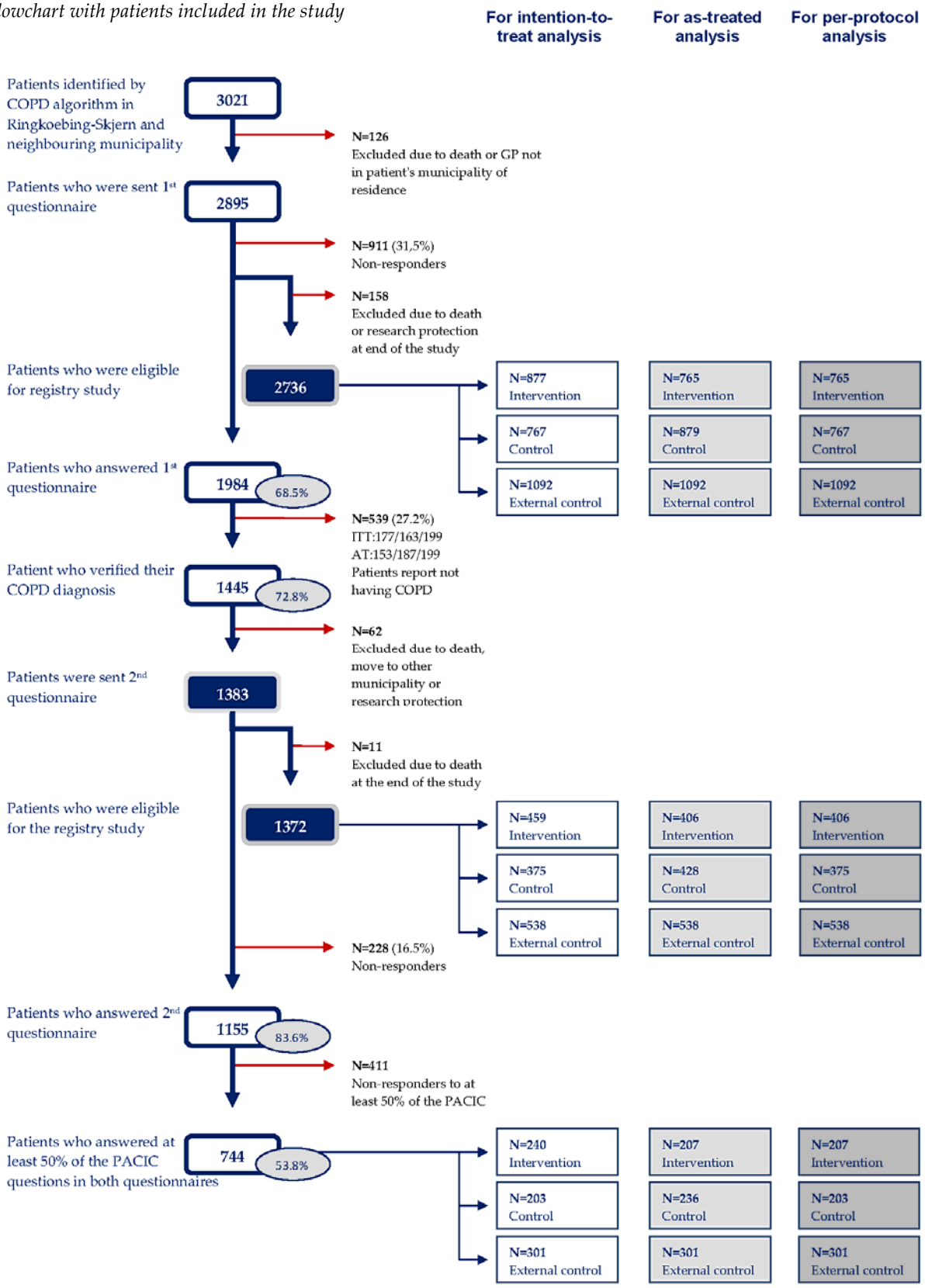
	Intervention	Control	External Control	Total
N2 (%)	424 (29.3)	451 (31.2)	570 (39.4)	1,445 (100)
Men (%)	206 (48.3)	217 (48.1)	284 (49.8)	707 (48.9)
Female (%)	218 (51.7)	234 (51.9)	286 (50.2)	738 (51.1)
Mean age (min-max)	68.3 (35-91)	66.5 (35-95)	67.2 (36-95)	67.3 (35-95)

Study population in Paper IV

Patients who answered at least 50% of PACIC questions in both questionnaires

	Intervention	Control	External Control	Total
n (%)	207 (27.8)	236 (31.7)	301(40.5)	744 (100)
Proportion of N2 %	48.8	52.3	52.8	51.5
Men (%)	106 (51.2)	126 (53.4)	143 (47.8)	375 (46.6)
Female (%)	101 (48.8)	110 (46.6)	158 (52.2)	369 (53.4)
Mean age (min-max)	68.7 (39-91)	65.8 (35-89)	67.2 (36-90)	67.1 (35-91)

Figure 4.3.1
Flowchart with patients included in the study



EFFECT ON HEALTHCARE UTILISATION

4.4 Paper III

4.4.1 Patients

The patients identified by the algorithm and those patients who also confirmed their COPD diagnosis, i.e. the CD group, are characterised in Table 4.3.1. In the CD group, the intervention group counted 458 (33.4%) patients, the control group 376 (27.4%) patients and the external control group 538 (39.2%) patients. The sub-group where patients from the two non-participating practices were omitted called the population comprised 406 (29.6 %) patients in the intervention group, 376 (27.4%) patients in the control group and 538 (39.2%) patients in the external control group (please see Figure 4.3.1).

4.4.2 Primary outcome

Table 4.4.1 and Table 4.4.2 show the changes in each group and the differences in changes between the groups for the study population. Data from the sub-group analysis are presented in Appendix VIII.

More intervention patients than patients from the control practices had a planned preventive consultation (RR=1.77, p=0.001) after the active implementation of the disease management programme. The intervention patients also doubled their additional preventive consultations (RR=2.03, p=0.004) and more had a spirometry at least once a year (RR=1.36, p=0.006).

Interestingly, the use of conventional consultations decreased among the patients in the intervention group, while an increase was seen in the control group; thus, there was a statistically significant difference in use of conventional consultations (RR=0.85, p=0.005).

4.4.3 Secondary outcome

Patients from the control group made more contacts to the out-of-hours services at the end of the study period than in the beginning (IRR=1.22, p=0.032). No difference in the change of contacts to out-of-hours services was observed between the intervention group and the control groups.

Fewer patients from the intervention group than from the control group were admitted without a lung-related diagnosis (RR=0.71, p=0.018); and fewer patients from the intervention group than from the external control group were readmitted (IRR=0.33, p=0.003). The use of hospital bed days did not change in the intervention group; whereas it rose in the control group (IRR=1.35, p=0.008).

Although patients from the external control group visited the outpatient services more at the end of the study period (IRR=1.41, p=0.002), there was no difference in the change in visits to the outpatient services between the intervention group and either the control group or the external control group.

No difference was observed in the three groups' use of emergency department services before and after the intervention.

4.4.4 Sensitivity analyses

Two new findings emerged when data from the two practices that did not participate in the intervention were removed: more patients in the intervention group than in the control group had an additional preventive consultation (RR=1.95, p=0.049), and the number of acute admissions in the intervention group fell to less than half (RR=0.43, p=0.002) (please see data in Appendix IX). The rest of the results were fairly similar to the findings reported above. The same was the case for the results for the population identified by the algorithm both for the intention-to-treat and the sensitivity analysis (please see data in Appendix VIII). For the population identified by the algorithm, the intention-to-treat analysis showed the same number of readmissions in the intervention group after the active implementation, but the number of readmissions rose in both the control group and the external control group (IRR=1.41, p<0.001; and IRR=1.66, p=0.014).

(See Paper III for further details).

Table 4.4.1

Rates and rate ratios (RRs) for specific variables for patients who confirmed their diagnosis of COPD – Intention-to-treat analysis

Rates and RRs for planned preventive consultations, additional preventive consultations and spirometries performed at GP practices as well as for patients who were admitted. The RRs are presented with 95% confidence intervals (95% CI)

N= 1,372	Intervention (N=501)	Control (N=333)	Ext. control (N=538)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
	Number of patients who had a planned preventive consultation					
2008	0.34 [0.27;0.44]	0.24 [0.17;0.33]	0.25 [0.14;0.45]	1.43 [0.96;2.13] p=0.082	1.35 [0.72;2.52] p=0.343	0.95 [0.49;1.81] p=0.867
2009	0.53 [0.42;0.68]	0.21 [0.15;0.30]	0.29 [0.17;0.48]	2.52 [1.62;3.92] p<0.001	1.84 [1.05;3.24] p=0.034	0.73 [0.39;1.36] p=0.322
RR	1.55 [1.23;1.96] p<0.001	0.88 [0.69;1.12] p=0.295	1.14 [0.91;1.42] p=0.249	1.77 [1.26;2.48] p=0. 001	1.36 [0.98;1.88] p=0.062	0.77 [0.55;1.07] p=0.121
	Number of patients who had an additional preventive consultation					
2008	0.11 [0.05;0.27]	0.06 [0.03;0.14]	0.10 [0.06;0.18]	1.86 [0.56;6.17] p=0.309	1.09 [0.39;3.07] p=0.869	0.59 [0.22;1.55] p=0.283
2009	0.23 [0.11;0.48]	0.08 [0.03;0.21]	0.12 [0.07;0.24]	3.00 [0.87;10.35] p=0.082	1.86 [0.70;4.91] p=0.213	0.62 [0.19;2.03] p=0.429
RR	2.03 [1.26;3.27] p=0. 004	1.26 [0.84;1.89] p=0.259	1.19 [0.84;1.71] p=0.330	1.61 [0.86;3.01] p=0.135	1.70 [0.94;3.09] p=0. 081	1.05 [0.62;1.81] p=0.843
	Number of patients who had a spirometry performed at the GP					
2008	0.33 [0.26;0.41]	0.23 [0.16;0.33]	0.22 [0.17;0.28]	1.43 [0.92;2.23] p=0.115	1.48 [1.05;2.08] p=0.025	1.03 [0.66;1.63] p=0.883
2009	0.45 [0.34;0.58]	0.24 [0.16;0.36]	0.22 [0.15;0.34]	1.82 [1.23;2.94] p=0.014	2.01 [1.23;3.01] p=0.006	1.10 [0.62;1.96] p=0.730
RR	1.36 [1.09;1.70] p=0. 006	1.07 [0.85;1.34] p=0.558	1.00 [0.70;1.44] p=0.996	1.27 [0.93;1.75] p=0.134	1.36 [0.89;2.08] p=0. 155	1.07 [0.70;1.64] p=0.760

Proportion who used out-of-hours services – no noteworthy change– data not reported

N= 1,372	Intervention (N=501)	Control (N=333)	Ext. control (N=538)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
	Number of patients who were admitted with a lung-related diagnosis					
2008	0.12 [0.08;0.16]	0.13 [0.09;0.19]	0.11 [0.08;0.17]	0.92 [0.56;1.52] p=0.741	1.03 [0.62;1.72] p=0.896	1.13 [0.65;1.94] p=0672
2009	0.10 [0.08;0.12]	0.11 [0.06;0.20]	0.14 [0.10;0.21]	0.89 [0.47;1.68] p=0.715	0.69 [0.45;1.07] p=0.095	0.78 [0.38;1.60] p=0.493
RR	0.84 [0.54;1.32]p=0.458	0.87 [0.67;1.14] p=0.329	1.27 [0.95;1.68] p=0.101	0.97 [0.57;1.62] p=0.896	0.67 [0.39;1.13] p=0.134	0.69 [0.46;1.02] p=0.065
	Number of patients who were admitted to hospital with another diagnosis					
2008	0.24 [0.20;0.29]	0.21 [0.17;0.26]	0.24 [0.21;0.28]	1.16 [0.86;1.55] p=0.321	1.01 [0.80;1.29] p=0.922	0.88 [0.67;1.15] p=0.340
2009	0.22 [0.18;0.26]	0.26 [0.23;0.30]	0.26 [0.21;0.31]	0.82 [0.66;1.02] p=0.073	0.83 [0.64;1.07] p=0.153	1.01 [0.81;1.26] p=0.927
RR	0.88 [0.74;1.05] p=0.154	1.24 [0.99;1.56] p=0.059	1.08 [0.92;1.26] p=0.351	0.71 [0.53;0.94] p=0.018	0.82 [0.65;1.03] p=0.093	1.15 [0.87;1.52] p=0.311

Patients who visited the emergency department - no noteworthy change - data not reported

Too few planned joint homevisits undertaken to do any analysis

Table **4.4.2**

Count and incidence rate ratios (IRRs) for specific variables for patients who confirmed their diagnosis of COPD – Intention-to-treat analysis

Counts and IRRs for conventional consultations, contacts to out-of-hours services, admissions, beddays, readmissions and contact to outpatient services. The IRRs are presented with 95% confidence intervals (95% CI)

N= 1,372	Intervention (N=501)	Control (N=333)	Ext. control (N=538)	Intervention vs. control IRR	Intervention vs. ext control IRR	Control vs. ext control IRR
	Consultations with GP (daytime)					
2008	7.75 [6.76;8.87]	7.57 [6.43;8.92]	6.75 [6.24;7.29]	1.02 [0.83;1.26] p=0.830	1.15 [0.98;1.34] p=0.084	1.12 [0.94;1.34] p=0.214
2009	7.34 [6.60;8.17]	8.50 [7.12;10.14]	7.28 [6.73;7.88]	0.86 [0.71;1.06] p=0.158	1.01 [0.88;1.15] p=0.895	1.17 [0.96;1.41] p=0.117
IRR	0.95 [0.88;1.02] p=0.145	1.12 [1.08;1.17] p<0.001	1.08 [1.02;1.44] p=0.012	0.85 [0.78;0.92] p<0.001	0.88 [0.80;0.96] p=0.007	1.04 [0.97;1.12] p=0.294
	Contacts to out-of-hours services					
2008	0.68 [0.47;0.98]	0.60 [0.42;0.86]	0.61 [0.51;0.74]	1.12 [0.66;1.90] p=0.674	1.10 [0.73;1.66] p=0.637	0.99 [0.66;1.47] p=0.942
2009	0.69 [0.47;1.01]	0.74 [0.56;0.98]	0.56 [0.46;0.68]	0.93 [0.60;1.45] p=0.761	1.23 [0.83;1.83] p=0.303	1.32 [0.94;1.85] p=0.106
IRR	1.02 [0.85;1.22] p=0.818	1.22 [1.02;1.48] p=0.032	0.92 [0.78;1.08] p=0.283	0.83 [0.64;1.08] p=0.170	1.12 [0.88;1.42] p=0.375	1.34 [1.05;1.71] p=0.019
	Admissions with lung-related diagnosis					
2008	0.12 [0.08;0.16]	0.13 [0.09;0.19]	0.12 [0.08;0.17]	0.91[0.56;1.51] p=0.741	1.03 [0.62;1.72] p=0.896	1.12 [0.65;1.94] p=0.672
2009	0.10 [0.08;0.12]	0.11 [0.06;0.21]	0.14 [0.10;0.21]	0.89 [0.45;1.68] p=0.715	0.69 [0.45;1.07] p=0.095	0.78 [0.38;1.60] p=0.493
IRR	0.84 [0.54;1.32]p=0.2458	0.87 [0.67;1.14] p=0.329	1.27 [0.95;1.68] p=0.101	0.97 [0.57;1.62] p=0.896	0.67 [0.39;1.13] p=0.134	0.69 [0.46;1.02] p=0.065
	Admissions with another diagnosis					
2008	0.35 [0.27;0.45]	0.36 [0.28;0.46]	0.33 [0.28;0.38]	0.97 [0.68;1.38] p=0.850	1.06 [0.79;1.43] p=0.699	1.10 [0.82;1.46] p=0.526
2009	0.33 [0.27;0.41]	0.47 [0.38;0.58]	0.45 [0.36;0.56]	0.70 [0.52;0.94] p=0.019	0.74 [0.55;1.01] p=0.055	1.06 [0.78;1.43] p=0.712
IRR	0.95[0.69;1.32] p=0.761	1.31[0.91;1.88] p=0.146	1.36 [1.06;1.74] p=0.015	0.73 [0.44;1.18] p=0.199	0.70 [0.47;1.05] p=0.083	0.96 [0.62;1.49] p=0.871
	Bed days					
2008	1.56 [1.09;2.22]	2.07 [1.55;2.63]	1.48 [1.11;1.98]	0.77 [0.49;1.21] p=0.256	1.05 [0.67;1.63] p=0.831	1.36 [0.90;2.06] p=0.145
2009	1.61 [1.33;1.96]	1.70 [1.26;2.29]	2.01 [1.59;2.56]	0.95 [0.66;1.36] p=0.774	0.80 [0.60;1.07] p=0.129	0.84 [0.58;1.23] p=0.377
IRR	1.04 [0.69;1.56] p=0.862	0.84 [0.64;1.11] p=0.225	1.36 [1.09;1.70] p=0.008	1.23 [0.75;2.02] p=0.415	0.76 [0.48;1.21] p=0.248	0.62 [0.43;0.89] p=0.010
	Readmissions*					
2008	0.07 [0.05;0.12]	0.13 [0.10;0.17]	0.05 [0.04;0.08]	0.56 [0.33;0.97] p=0.040	1.38 [0.78;2.47] p=0.269	2.45 [1.53;3.94] p<0.001
2009	0.07 [0.05;0.09]	0.12 [0.06;0.21]	0.14 [0.11;0.19]	0.59 [0.30;1.15] p=0.124	0.48 [0.32;0.72] p<0.001	0.82 [0.42;1.60] p=0.556
IRR	0.95 [0.55;1.63] p=0.840	0.90 [0.50;1.64] p=0.737	2.71[1.90;3.86] p<0.001	1.05 [0.46;2.38] p=0.912	0.35 [0.18;0.66] p=0.001	0.33 [0.16;0.68] p=0.003
	Contact to outpatient services with a lung-related diagnosis					
2008	0.16 [0.11;0.24]	0.28 [0.19;0.40]	0.19 [0.12;0.30]	0.59 [0.35;0.99] p=0.046	0.86 [0.48;1.57] p=0.632	1.47 [0.83;2.62] p=0.186
2009	0.22 [0.13;0.36]	0.28 [0.17;0.46]	0.26 [0.19;0.38]	0.78 [0.67;0.94] p=0.482	0.83 [0.45;1.54] p=0.551	1.07 [0.59;1.92] p=0.832
IRR	1.35 [0.76;2.40] p=0.313	1.02 [0.67;1.54] p=0.939	1.41 [1.13;1.74] p=0.002	1.33 [0.65;2.70] p=0.439	0.95 [0.51;1.81] p=0.895	0.72 [0.46;1.15] p=0.171

*A readmission was defined as an acute admission within 30 days of the last admission

EFFECT ON PATIENT EVALUATION

4.5 Outcome

Table 4.5.1 shows the baseline scores, the follow-up scores and the differences between the groups for PACIC. For all three groups, the mean scores for each of the scales and for the total PACIC score were all below 3, both at baseline and at follow-up (max. score is 5). The scores in the intervention group tended to be higher, though not statistically significantly so, than in both control groups at baseline (see Table 4.5.1).

The total PACIC score rose from 2.06 to 2.14 (difference=0.08 [95%CI: 0.00;0.16]) in the intervention group, while a decrease of 0.05 [95% CI: -0.14;0.04] was seen in the control group; thus, the effect of the active implementation of the disease management programme was 0.12 [95%CI: 0.00;0.25], (p=0.048). Comparison of the intervention group and the external control group showed an effect of the intervention of 0.14 [95%CI: 0.03;0.25], (p=0.014). No difference between the control and the external control group was observed for any of the scales. Although these results were just significant according to the 1% Bonferroni level, together they point in the same direction.

(Please see Paper IV for further details)

Table 4.5.1 As-treated analysis

The mean PACIC scores for each dimension and the total score for each group recorded at baseline and at follow-up. The change in difference of means scores when comparing the control and external control group, respectively, with the intervention group is shown together with a comparison of change in mean scores between the control and external control groups.

Table 2 - PACIC scores

N=744	Intervention N=207	Control N=236	External control N=301
PACIC dimension 1 – Patient Activation	(203)	(230)	(298)
Baseline	2.39 [2.25;2.54]	2.31 [2.15;2.46]	2.27 [2.15;2.41]
Follow-up	2.48 [2.33;2.64]	2.22 [2.07;2.37]	2.11 [1.99;2.23]
Difference	0.09 [-0.06;0.23]	-0.07 [-0.22;0.08]	-0.16 [-0.28;-0.03]
Difference compared with Control	0.16 [0.05;0.37] p=0.142	-	-
Difference compared with External control	0.25 [0.05;0.44] p=0.013	0.09 [-0.10;0.28] p=0.363	-
PACIC dimension 2 – Delivery System Design/Decision Support	(206)	(233)	(299)
Baseline	2.78 [2.65;2.92]	2.76 [2.63;2.90]	2.67 [2.55;2.78]
Follow-up	2.86 [2.73;3.00]	2.63 [2.49;2.77]	2.53 [2.42;2.64]
Difference	0.07 [-0.05;0.19]	-0.12 [-0.25;0.02]	-0.13 [-0.24;-0.02]
Difference compared with Control	0.19 [0.00;0.37] p=0.044	-	-
Difference compared with External control	0.20 [0.04;0.37] p=0.018	0.01 [-0.16;0.19] p=0.868	-
PACIC dimension 3 – Goal setting	(204)	(234)	(299)
Baseline	1.74 [1.62;1.89]	1.80 [1.69;1.92]	1.65 [1.55;1.75]
Follow-up	1.88 [1.76;2.00]	1.71 [1.60;1.81]	1.64 [1.55;1.73]
Difference	0.12 [0.01;0.23]	-0.08 [-0.19;0.02]	-0.01 [-0.09;0.08]
Difference compared with Control	0.20 [0.05;0.35] p=0.009	-	-
Difference compared with External control	0.12 [-0.01;0.26] p=0.071	-0.08 [-0.21;0.07] p=0.260	-
PACIC dimension 4 – Problem-solving/Contextual	(204)	(231)	(296)
Baseline	2.26 [2.12;2.40]	2.22 [2.08;2.37]	2.05 [1.93;2.17]
Follow-up	2.33 [2.18;2.48]	2.13 [2.00;2.27]	2.00 [1.89;2.12]
Difference	0.06 [-0.07;0.18]	-0.05 [-0.18;0.08]	-0.06 [-0.16;0.05]
Difference compared with Control	0.11 [-0.08;0.29] p=0.258	-	-
Difference compared with External control	0.11 [-0.05;0.28] p=0.172	0.01 [-0.16;0.17] p=0.929	-
PACIC dimension 5 – Follow-up/Coordination	(200)	(223)	(288)
Baseline	1.56 [1.45;1.66]	1.48 [1.40;1.56]	1.44 [1.36;1.51]
Follow-up	1.58 [1.48;1.67]	1.51 [1.42;1.60]	1.42 [1.35;1.49]
Difference	0.01[-0.08;0.11]	0.03 [-0.05;0.12]	-0.05 [0.12;0.03]
Difference compared with Control	-0.02 [-0.15;-0.11] p=0.760	-	-
Difference compared with External control	0.06 [-0.06;0.18] p=0.343	0.08 [-0.04;0.20] p=0.179	-
PACIC Total – the overall score	(207)	(236)	(301)
Baseline	2.05 [1.95;2.15]	2.02 [1.92;2.13]	1.92 [1.83;2.01]
Follow-up	2.14 [2.03;2.24]	1.97 [1.86;2.07]	1.87 [1.78;1.95]
Difference	0.08 [0.00;0.16]	-0.05 [-0.14;0.04]	-0.06 [-0.13;0.01]
Difference compared with Control	0.12 [0.00;0.25] p=0.048	-	-
Difference compared with External control	0.14 [0.03;0.25] p=0.014	0.01 [-0.10;0.13] p=0.827	-

The mean PACIC scores for each dimension and the total score for each group recorded at baseline and at follow-up. The change in difference of means scores when comparing the control and external control group, respectively, with the intervention group is shown together with a comparison of change in mean scores between the control and external control groups.
The number of patients who have scored 50% of the dimension is shown for each group in brackets ( ).

CHAPTER 5

DISCUSSION OF METHODS

This chapter discusses the methodological issues raised in the study in relation to design, sampling, data quality, outcome measures, and analysis.

STUDY DESIGNS

5.1.1 Identification of patients with COPD

In order to improve the use of clinical guidelines and the medical outcome for patients with COPD in accordance with the disease management programme for COPD [17], we developed an algorithm to identify the population with COPD. Three steps and three different GP and patient populations were used for developing the algorithm using registry data on lung-related general practice services, hospital services and prescriptions because these data have been shown to be highly valid [174-177] (see Figure 5.1) .

Figure 5.1

<table>
<tr><td>Step 1</td><td>GPs list their patients with known COPD</td><td>Population A</td><td></td></tr>
<tr><td>Step 2</td><td>Different combinations of data on hospital admissions, redeemed prescriptions and performed spirometries were tested</td><td colspan="2">The simplest algorithm identifying the most patients was chosen</td></tr>
<tr><td>Step 3</td><td>The chosen algorithm used to identify patients</td><td>Tested with GPs
Population B</td><td>Tested with patients
Population C</td></tr>
</table>

5.1.1.1 Step 1

In the first step, one group of GPs was asked to make a list of those of their patients they knew had a diagnosis of COPD. This group formed population A. The GPs were not instructed to use the GOLD guideline for COPD [91] when identifying the patients.

We wanted to obtain a patient population that had been treated for COPD by their GPs; by asking the GPs to list their patients with COPD we could be certain that the GPs had treated these patients for COPD. The GP practices may have had more patients with COPD than those who were on these lists as we know that only about a quarter of people with COPD are identified as having COPD [7]. People whose COPD disease goes unnoticed by their GP will probably not receive coordinated COPD-related care. Had we emphasised the use of the specified diagnostic criteria from the GOLD guideline, [91] we would have been certain that all patients were true positives for COPD; this was, however, not the case and the algorithm may therefore have been less sensitive than if the GOLD guidelines had been used. It is also possible that the GPs might have identified more patients if they had performed post-bronchodilator spirometry together with their clinical assessment as specified in the GOLD guideline [91]. Still, we argue that our pragmatic approach is sufficiently accurate because we expect GPs to know their patients well and to list only patients they were certain had COPD and who they were treating for COPD. We cannot rule out that we may have missed some patients with COPD and the sample may also have false positives. In our judgment, this would not impair the next step in the design of the algorithm to any significant degree although were we to develop an algorithm again, we would consider either asking the GPs to perform spirometries or have an independent group of doctors examine the patients and diagnose the patients according to the GOLD guidelines [91].

5.1.1.2 Step 2

As a second step, we designed the simplest possible algorithm based on data from registries that would find as many as possible of the patients identified by the GPs in Step 1 as having COPD. We wanted to identify patients with possible COPD from administrative data on hospital admissions, redeemed prescriptions

and performed spirometries. Such health care services are registered routinely in Denmark and the registries are considered to be highly valid [174-177] and could therefore be used to serve our purpose.

Admission to hospital for a lung-related disease was used as a proxy for a possible COPD exacerbation and a sign that the patient experienced a worsening of COPD symptoms. We could also have used a redeemed prescription for antibiotics as a proxy for a COPD exacerbation. However, antibiotics prescriptions are not always duly registered and, furthermore, they may be prescribed for conditions other than COPD exacerbations. We therefore found that admission with one or more of the lung-related diagnosis outlined in Additional file1 (Paper I) suited our purpose of identifying patients with COPD.

Redemption of prescriptions for lung-related drugs was chosen as a second possible marker of COPD on the assumption that many patients who were taking lung-related drugs could have COPD. Redemption of a single prescription during the past year would not necessarily indicate that the patient was having COPD, and redemption of several prescriptions could indicate that the patient were taking medications for asthma; we might therefore have included patients who did not have COPD even if they redeemed prescriptions that would seem to suggest that they had COPD.

Spirometries performed either in a GP or in a specialist practice were thought to be an indicator of lung-related problems that could be due to COPD as we expected that health professionals would perform spirometries only if they suspected that a patient's lung capacity was reduced. We obtained data on performed spirometries even if we do know that it is an underused diagnostic test in COPD [178 179 180 181] and that its use is linked to practice characteristics as reported in a recent Danish study [182].

We would be missing numerous patients if we only relied on patients who had had a spirometry performed as the GOLD guidelines recommends [183]. Data on these three indicators - hospital admissions, redeemed prescriptions for lung-related medication and performed spirometries - were therefore combined in different ways with two to five factors, i.e. two hospital admissions and one redeemed prescription over different time spans, two hospital admissions during the past five years and one prescription during the past year to, determine which combination identified the largest percentage of the 266 patients in Population A identified by the GPs, and was easiest to use, i.e. in which the fewest factors were involved. We found that it would entail more cumbersome work to use the algorithm with four factors involved than the one which we chose with three factors even though it performed slightly better (see Additional file 3 in Paper I).

Many other indicators or markers could have been used to construct the algorithm. Out-patient visits to the lung specialist by people with a lung-related diagnosis could have been another indicator used to identify people with possible COPD. Influenza vaccination could have been yet another indicator; the latter would have meant that many more patients would have been included because the Danish Board of Health recommends that those who are 65 years old or older and people at risk of getting severe influenza be vaccinated. The algorithm would thereby undoubtedly have produced both false positives and false negatives.

The chosen algorithm identified likely COPD-related encounters with the healthcare system; yet, it may have been more efficient in identifying patients with COPD if more indicators had been included, like the North American algorithm containing 19 indicators [184]. We chose to keep it simple and easy to use with the following three indicators – one hospital admission with a lung-related diagnosis during the past five years or/and at least two redeemed prescriptions

for lung medication during the past year or/and two performed spirometries in the GP practice on different days during the past year (see Additional file 1 in Paper I).

5.1.1.3 Step 3

In the third and last step, we validated the algorithm. The algorithm was first used to sample patients from five other GP practices than those whose patients formed population A. We contacted these five GPs and asked them if patients identified by the algorithm as having COPD were listed with COPD in their records. Patients verified as having COPD formed population B. The algorithm was then used to identify a group of patients in two other municipalities who could possibly have COPD. This group of patients, population C, was invited to verify whether they had COPD or not.

5.1.1.3.1 GP validation

Cases in which GPs were in doubt as to whether the patient had COPD or not were classified as positive cases if at least one of the criteria for COPD had been fulfilled. In addition, the GPs could not reject the diagnosis. This approach could involve information bias because some of these possible COPD cases, which we classified as positive, might, in fact, not have COPD but some other lung-related disease. We did a test on one of the intervention GP practices where the algorithm had identified 254 (5.1%) patients with possible COPD within the practice population aged 35 or above. The GP practice verified the diagnosis for 171 (67.3%) of these patients, 76 (29.9%) had another lung-related diagnosis and 7 (2.8%) had no lung-related diagnosis. The intervention GP practice added 26 patients with COPD whom the algorithm had not identified. This intervention GP practice therefore had 197 (3.9%) patients with a certain COPD diagnosis when the GPs had consulted their own lists. We did not investigate further why

the algorithm did not identify all the patients even if such analysis could have identified elements of the algorithm that could be improved. The algorithm could have been improved in other ways. First, we could have instructed the GPs to use the GOLD guidelines to ensure that a firm COPD diagnosis was established. Second, we could have examined the patients ourselves to ensure an intra-observer, bias-free diagnostic procedure. Both approaches would be very time-consuming and would have demanded many resources, wherefore we chose to rely on the GPs in the five GP practices.

5.1.3.2 Patient validation

In population C, the patients identified by the algorithm in Ringkoebing-Skjern and Ikast-Brande confirmed their COPD diagnosis by NOT ticking off a questionnaire box saying 'I do not have a COPD diagnosis'. It is likely that more valid diagnoses would have been obtained for the patients identified by the algorithm in the two municipalities if we had asked the GPs in the municipalities to perform clinical assessments and spirometries of these patients or, indeed, had done so ourselves. More valid diagnoses would also have been obtained if we had examined the patients identified by the algorithm in population B and C using the GOLD guidelines [183]. Still, we trust that our approach produced very few false positive answers for two reasons. First, a thorough explanation of disease was offered on the first page of the questionnaire (please see Appendix II). Second, we trust that because of the serious, even stigmatising, nature of COPD, patients would not confirm having COPD unless they had discussed the diagnosis with a health professional and were truly living with COPD

Our approach may have introduced an overweight of confirmatory answers among the patients with COPD at the most advanced stage of the COPD disease

continuum. Thus, some of the respondents who denied having COPD may, nevertheless, still have the disease, but only in a mild, as yet undiagnosed form. This would mean that we lost some of the sensitivity of the algorithm which is supported by the fact that we found a higher sensitivity among the older patients than among the younger patients; probably because the former had been living longer with their disease which had therefore progressed further over the years and had accordingly been diagnosed. However, we chose to let the patients confirm their diagnosis in the baseline questionnaire.

5.1.1.4 Strength and further development of the algorithm

The very high specificity of the algorithm is one of its main strengths because it implies that people who have been hospitalised with a lung-related diagnosis, been prescribed lung-related medication or had a spirometry test for other diagnoses will not unnecessarily be suspected of having COPD.

If we want to further develop the algorithm to identify only patients with COPD, we could include more variables into the algorithm, e.g. the International Classification of Primary Care (ICPC-2) codes where patients are coded for all contacts with a diagnosis (the use of which become compulsory in general practice in Denmark in 2014). A Danish study suggested that the COPD diagnosis is under-recorded in patients admitted with another acute lung-related diagnosis than COPD [185]. It would therefore seem that all lung-related diagnosis established in hospitalised patients should be considered to identify those who have COPD. Examining the population aged 55 years and up, we noticed that the identification rate rose, which represents an argument for including age in the algorithm.

5.1.1.5 Conclusion on the development of an algorithm to identify patients with COPD

In conclusion, further development of the algorithm with added indicators or age-specific application might increase its PPV and its sensitivity when used in practice populations. Still, we found that the algorithm was validated and had a reasonable predictive power for use in our trial. We also found that it can be used to identify the people with a possible COPD diagnosis at the more advanced stages of disease who may benefit more from a targeted intervention.

THE INTERVENTION – AN ACTIVE IMPLEMENTATION MODEL FOR A DISEASE MANAGEMENT PROGRAMME

5.2.1 The development of the intervention

A "diagnostic" analysis to identify factors that most likely will influence the change and guide and inform the choice of dissemination and implementation of change is needed for any attempt to bring change, according to Grol and Jones [186]. We reviewed the literature in order to be well-acquainted with the current knowledge about implementation of change in primary care settings where several stakeholders are involved, and we updated our knowledge of the current treatment and coordination of health care for patients with COPD.

Qualitative information gathered from two focus groups with patients and three interviews with health professionals shed further light on what the stakeholders thought was important to ensure the best care possible for patients living with COPD. On this basis, we developed an active implementation model for a disease management programme for COPD including professional-directed interventions, organisational interventions and patient-related interventions to support self-management; this was described in Paper II.

5.2.1.1 Theories

We developed a multifaceted complex intervention for actively implementing a diseases management programme for COPD [187] which was targeted at all three levels involved in the care: hospitals, the municipality and GP practices within a particular Danish municipality. Recent results from a study examining the quality of care for patients with COPD has showed improvement after implementing a nationwide programme for COPD in Denmark [188] and another recent systematic review and meta-analysis reported favourable effects of disease management programmes for COPD both for health outcomes and cost. The effort to design and implement a multifaceted complex intervention

proceeded notwithstanding that a recent report suggested that it might hardly be possible to design a united healthcare system that is also an economic success and this might just be a dream of health professionals [41].

Many researchers have described systematic stepwise approaches to the implementation of change in primary care. The Centre for Quality of Care Research in the Netherlands has a long tradition of investigating novel strategies for implementing change in the provision of healthcare, and Wensing et al used quality circles in a study of the prescribing patterns of primary care physicians and found that quality circles had a modest effect on the quality and cost of prescribing in primary care [189]. Bartholomew suggested that intervention researchers effectively should select and use theory to design, test and report interventions using intervention mapping as a framework [190]; whereas Rowlands et al found that careful modelling would be more useful and appropriate for ensuring outcomes in the practice setting even though they acknowledged that randomised controlled trials for testing healthcare interventions are difficult to design and implement [191]. To assess to which extent the implementation of change in healthcare has been effective within specific settings and has promoted dissemination into other settings, Damschroder et al developed the pragmatic structure entitled Consolidated Framework for Implementation Research (CFIR) from previously described theories and constructs to guide the evaluations and to build on the implementation knowledge [192]. Grol argued that barriers and enablers to change should be identified before the start of the implementation of any healthcare innovation [193]. Others have combined theories from different sciences to develop a model for implementation, for example Greenhalgh who suggests a model for diffusion of innovations in health care settings using social sciences ideas and theories [68]. Oborn et al describe how knowledge translation (KT) [73;194] needs to consider processes at multiple levels including the individual, the organisational and the strategic level, and they outline how management literature on knowledge and learning theories may

inform health services research on KT [195]. Driedger et al [192] explored the possibility of researchers and users working as dyad-pairs in the same organisation when using geographic information systems (GIS) to turn data into useful information and to help decision-making and KT; and they found that maps can play an important role as a decision tool.

Wagner et al developed the CCM early in the 21st century. Within the CCM model, care is evidence-based, planned and proactive, and the model is currently being used with success in several healthcare systems [37 58 39]. The model aims to improve the results of the care for the whole population and it involves a planned and coordinated effort between general practice, hospitals and groups working at the local or municipal level to further health-promotion and rehabilitation [5]. As the disease management programme from the Central Denmark Region [17] was based on these principles, we therefore found it feasible to use the CCM [14;15] in our active implementation model.

5.2.1.1 Our model

The components of our model followed the recommendation of the CCM in which patients are given the right care at the right place at the right time to optimise the use of resources [196].

A recent study investigating how evidence is conceptualised in the National Institute of Health and Clinical Excellence (NICE) [197] argued that evidence cannot stand alone, but requires human judgement to be accepted into evidence-based disease management programme. In our model, we used evidence-based and previously proven effective implementation components, keeping in mind that it was our choice that guided the selection of the components and that other components could have been used and may have been equally effective for the implementation of the disease management programme.

5.2.2 The implementation elements

5.2.2.1 Community

5.2.2.1.1 Policies and resources

We negotiated our implementation strategy with the municipality of Ringkoebing-Skjern, which actively supported the implementation of the strategy by increasing the number of free smoking cessation courses and of self-management courses for patients with COPD during the study period. GPs could then refer more patients with COPD to the care of the municipality. The stronger commitment shown at the municipal level and from the GPs also made it possible to launch initiatives that enhanced patients' ability to cope with their disease in general and to better manage exacerbations [198].

In her thesis, Schiøtz describes how health professionals give very little emphasis to self-management in the Danish healthcare system [199]; a similar observation was made in a recent review of 13 different European countries [63]. In our study, the self-management courses took an appreciatory approach with dialogue between the patient and the health professional about the patient's range of choices and opportunities, available treatment options and the patient's readiness to change habits. The emphasis was on participatory activities with dialogue-based knowledge exchange to encourage the patient to develop competences to act. Previously, courses had been conducted in the hospitals using a more teacher/pupil-oriented approach and the present participatory approach was therefore new to the municipality and developed during the study period. The novelty of the courses might have made the health professionals both more active and more interested in conducting the courses, on the one hand, and, on the other hand, it may have made them more insecure because they were chartering new territory. However, in our study it was clearly

an asset to run courses in which the health professionals were both actively involved and enthusiastic, and the GPs were happy to have professional support in the self-management support provision to patients.

We negotiated a surcharge with the Region on care services delivered to patients newly discharged with COPD irrespective of the patient's age to accommodate for literature findings that there is an association, although modest, between remuneration and improvement in care processes [200] and because a previously negotiated agreement for reimbursement to GPs for joint homevisits with the community nurse to citizens aged 75+ who had recently been discharged had proved successful in terms of health care service provision[201]. The agreement involved a shared care approach where the GP and the community nurse employed by the municipality met together with the patient and planned future care which aimed to raise both the patient's and the health professionals' sense of a united, coherent and proactive healthcare system [202;203].

5.2.2.1.2 Self-management support

To enhance self-management support and drawing on the research by Stockley [153;171], we designed an action card (See Appendix II in Paper II) with sputum advice which had previously shown to reduce the number of acute admissions [204]. Our expansion of the advice on the card consisted in advice on how to behave in case of a worsening of the symptoms of cough, breathlessness and/or sputum production using the green-yellow-red action plan recommended in the CCM [205]. We developed the card together with a leaflet, and we expected the GP practices to hand out this material to the relevant patients. We might have increased the use and knowledge of the card had we sent it to the identified patients with COPD; they could have brought the card with them to get guidance on its use at their next follow-up visit. We would then have

empowered the patient to make the decision on using the card and not given the health professionals the right to decide who was eligible for a card and who was not. However, we found it essential that the patients benefited from the health professionals' guidance on the use of the card, wherefore we chose to let the GP practices deliver the action card to the relevant patients.

We wanted to inspire and encourage family, friends and patients to talk openly about the disease by providing disease-specific knowledge and therefore developed a webpage that had produced promising results in a study of engagement in diabetes management [206]. We did consider that patients with COPD and diabetes would be different, especially in terms of age, and that they might therefore use the Internet differently. However, as the website was also aimed at family, friends and health professionals, we considered it to be an important knowledge dissemination tool that could easily be accessed by the users [169].

5.2.2.2 Health system

5.2.2.2.1 Delivery system design

To enable the GP practices to contact the community nurses to plan joint homevisits if needed, we introduced a system whereby the hospital department informed GP practices immediately by fax upon discharge of one of their patients who had been admitted with COPD [172]. The discharge was also communicated via the usual Internet-based communication between the hospital and the GP practices. GPs preferred to receive a fax and found that the presence of a piece of paper with details of the discharged patient on the GP's desk was more convenient than a note in a long list of electronic communication between hospitals and the full GP practice. Although it was an extra effort for the hospital departments to fax information, they took it on during the study period on condition that if the two people who had been instructed in faxing

summaries for intervention patients were not at work, the fax would not be sent and then the knowledge would not be transferred to the GP practice though the fax and some patients would therefore be discharged without their GP practice having being informed, except in the usual Internet communication. It might have been better to improve the Internet-based communication to have it come at the appropriate time to the GPs and have a system in place where discharges were scrutinised by the GP practices and not only by the GP where the patient was registered as the GP can be away on training or holiday, and the time for a joint homevisit with the community nurse will then be forfeited. The "fax system" had previously been in place for other diseases and worked well wherefore we chose to implement it for discharge of patients with COPD.

Recent literature does not fully support the idea that reimbursement enhances guideline adherence; however, the GPs received a special fee for follow-up visits [17]; and GPs were encouraged to do follow-up visits annually or more frequent if specified by the clinical guideline or if the GP found it feasible [16]. The fee covered the extra time spent with the patient.

It has been argued that it is important for quality improvement that the strategies used for disease management regularly are audited, evaluated and adjusted and we advised the GP practices to implement such evaluations every 3rd month [66]. We allowed the GP practices to choose their own way of evaluating and auditing their COPD care instead of having a uniform evaluation approach. This allowed for incorporating the evaluation into the system of evaluation already in place in the different GP practices; however, we could not be entirely sure that the GP practices spent time on the adjustments and auditing.

5.2.2.2.2 Organisation of healthcare

The general practices were encouraged to organise their routines of delegating work so that practice staff did part of the follow-up visits and the monitoring of

patients with COPD in order to make use of each health professional's unique skills and knowledge and hence optimise the time used by the GPs [66]. To avoid repeating tests or procedures, several practices designed written manuals. At one of the meetings with the GP practices, a GP introduced the written manuals from his practice developed to share the care for patients with COPD between the health professionals. The manual was online as well and could be used freely. We could have expected all practices to use these manuals where all the tasks in the COPD care were distributed between the professional groups. However, the number of practice staff and GPs was not the same across the various clinics and we therefore found it better to allow each practice to adjust and develop their own manuals.

5.2.2.2.3 Decision support

We arranged for extra access to expert knowledge by allowing general practices to draw on a local consultant in lung diseases both for advice and for practice consultations as Grimshaw, Eccles and Walker described that the use of a local specialist or opinion leader may have some effect where a change in behaviour is sought [207]. Few of the GPs contacted this specialist for advice during the study period, and it is therefore possible that the update on medication and interaction with the hospital at one of the Breakthrough meetings might have satisfied the GPs' need for expert knowledge. Another possibility is that they might not have encountered situations where they needed expert advice, or it could be that just the very reassurance that a specialist was available if needed was enough.

To allow the GP easy access to up-to-date evidence and local advice from specialists in lung diseases, we made Podcasts for consultations with smoking cessation, instructions in the use of spirometry and a follow-up consultation, and made this advice and these recommendations available on the website [169].

The Internet contains ample examples of English instructions with updated advice from specialists, but to our knowledge there are no updates on COPD care in Danish. Given the rapid development within IT technologies, today we would have developed an app for smartphone use. In this way, we would also have been able to trace if the GPs actually used the updates or preferred other means of accessing the information.

5.2.2.2.4 Clinical information system

Better disease control demands precise identification of the population in question [66]. We therefore provided each GP with a list of their patients with COPD. The patients were identified by a previously developed COPD algorithm [140]. The identification of the patients enabled the GPs to provide follow-up visit to the patients with COPD. The provided lists were not complete, and the GPs added those patients the algorithm had missed.

The GPs expressed that they would like to receive feedback on the patient's progress from the municipality's health centres when a patient with COPD had finished a course at one of the centres. A form for this purpose was developed in collaboration between the staff at the health centres, the patients, the GPs and the research group. This exchange of information often enhanced mutual respect and knowledge of each other's professions, and it improved the patients' feeling of being cared for within the context of a united healthcare system [208-210]. The development of the form for this exchange also highlighted the different cultures, i.e. GPs say patients, and municipalities say citizen. It was a new experience for the participants to share information, and the recognition that all partners possessed useful information about the patients' progress was enlightening both to the GPs and the staff at the municipal health centre. During the study period, this knowledge exchange created a shared feeling of

responsibility towards the provided care. Once Internet-based communication between the municipality and the GP practice becomes common, it is expected to allow for an easier way of communicating about the patients between the two healthcare providers and it may make the patient a party to the information exchange.

5.2.3. The processes of active implementation

The aim of the study guided the choice of intervention strategies, as did our knowledge which was based on literature and the actual conditions in Ringkoebing-Skjern municipality. We planned that the randomised study should be performed in a municipality where the GPs were accustomed to sharing experiences. In order to have an independent group uninfluenced by the spillover effect [116] [117], we also included the neighbouring municipality, the municipality of Ikast-Brande and its GP practices and their patients.

5.2.3.1 Motivation

GP practices randomised to the intervention group were invited to participate. In this way, we made sure that the participating practices were interested in improving their care for their patients with COPD. Motivation plays an important role when implementing change in practice. [211] When two practices declined the invitation, we therefore decided to perform both an as-treated analysis where these two practices served as control practices to measure the effectiveness of the intervention model and an intention-to-treat analysis.

5.2.3.2 Local opinion leader

We chose to have the local GP member of the steering group (Lars Foged, GP) introduce the study both to the GP practices and to the municipality because he

is a local, respected opinion leader [212]. The effectiveness of using a local opinion leader is inevitably tied to the participants' perception, and maybe even preconception, of that person's personality and the message conveyed. Still, we considered this to have only a negligible effect on the local uptake of the intervention and therefore considered this to involve no major disturbance.

5.2.3.3 Continuing medical education and Breakthrough Series

To provide further education and enhance knowledge of the disease management programme, we organised four continuing medical education (CME) meetings [213] with the GPs and the other health professionals from the GP practices in which the Breakthrough Series were used [60;155]. Other implementation strategies could have been used as discussed in the section on theories; However, CME meetings with Breakthrough Series were considered appropriate for the present purpose because this approach allowed for adjustments along the way and was in line with a review of CME where the use of interactive methods was generally more effective than traditional lectures in changing GPs performance and in improving patient care [198].

5.2.3.4 Reimbursement

In order to improve the participation rate, the GP practices were reimbursed for the time they spent on the CME meetings [201] as we expected that reimbursement would work as an incentive to attend the meetings [214].

The fee for joint homevisits with the community nurse might not have influenced the proactive change for the GP practices as there is limited evidence of any change of behaviour owing to the extra payment for services rendered [201;215-219].

5.2.3.5 Academic detailing

A facilitator (MS) visited the GP practices to discuss and assess any challenges they may have encountered during the implementation of the disease management programme [172] [220]. Using academic detailing to induce changes in GPs' behaviour has previously been shown to be efficient, especially in smaller practices [168;221;222]. A Cochrane review found a small, but consistent change when the strategy was used in face-to-face meetings [223]; in a paper discussing this Cochrane review, Vedsted et al recommend that academic detailing be used subject to close monitoring [220]. This was precisely what we did by visiting practices to discuss the challenges experienced in each practice and to ensure continued implementation of the disease management programme, and by using telephone calls to keep momentum and contact.

The municipality health centre and the community nurses were introduced to the project at staff meetings; and during the study period, the project leader (MS) regularly visited the municipality's health centre to discuss project progress and the communication with GP practices. We could have chosen to keep contact just by email and telephone, but we found it vitalising to have personal contact with the involved health professionals who were very enthusiastic about the project of implementing new courses and the new way of working with GP practices. We could have had more people than just one person, the project leader, take the contacts and pay visits both to the GP practices and to the municipality. Still, we decided to deploy only one person to this task to strengthen the continuous and coherent implementation process and to keep the information centralised.

5.2.4 Our active implementation of a disease management programme

We aimed to get the GPs and the practices to be proactive and to take responsibility for the population from their practice who had COPD. The disease management programme was designed to draw maximally on the most up-to-date knowledge of which care would benefit patients with COPD the most and it was developed in partnership with the stakeholders from the healthcare system and the patients. We found no reason to dispute the validity and comprehensiveness of the disease management programme and therefore went ahead with its implementation.

Testing of the active implementation model in a few GP practices before conducting the randomised controlled trial might have produced valuable input to inform the intervention. However, such input would depend of the size of the GP practices, and a pilot study encompassing a representative sample of urban, rural, small and big practices would hardly be feasible from an economic perspective and it could not possibly be conducted within the time limit of the present PhD study. However, we did allow for adjustments along the way to suit local needs and we used qualitative methods to localise the intervention as also the MRC recently suggested [224] [225], and we might therefore consider this study a pilot study.

Parts of the programme were implemented better than other parts. The intervention GP practices followed the programme and proactively performed follow-up consultation and spirometries resulting in a decline in the number of GP consultations and a tendency towards decreased use of hospital services. The use of out-of-hours services and emergency department remained the same. This could indicate that the already established collaboration on healthcare in Ringkoebing-Skjern municipality had worked to optimise these two services, or

that even more focus should be on the use of these two services in a future implementation model.

Many more intervention patients than expected were referred to the courses at the health centre; and the intervention patients were more satisfied with their care than control patients. Very few patients had received the action card that would help them respond themselves to exacerbations. This suggests that we should have focused more on patient empowerment. This also became clear from the PACIC questionnaire which showed that the implementation of the programme did not change the score either on the problem-solving/contextual counselling scale or on the follow-up/coordination of care support scale. Thus, the programme apparently affected neither the way health professionals support patients in coping with the challenges of their disease, nor the way they interact with other healthcare providers involved in COPD care.

It is possible that it is simply too demanding for Danish health professionals to share care considerations with other healthcare sites and with the patients themselves; in this respect, Danish health professionals are no different from many other European health professionals [63]. We could have aimed the intervention directly at the patients by inviting all identified patients for courses encouraging patient empowerment. However, the active implementation model did actually implement the disease management programme better than the usual implementation strategy.

THE STUDY DESIGN

5.4. The study design

The study is a prospective, multicenter intervention study conducted as a block- and cluster-randomised trial in Ringkoebing-Skjern municipality; to control for spillover effect, patients from a comparable municipality acted as a "blinded" external control group [116] [117].

5.4.1 The block and cluster randomisation

In Ringkoebing-Skjern municipality, there is a long tradition for active CME groups for GPs and a good working relationship between the different GP practices and there would therefore be a risk of a spillover effect in the internal control group. To have a control group totally unaffected by our active implementation strategy, we established the external control group in Ikast-Brande municipality.

We chose a randomised design for this study as it is considered one of the most reliable study designs for obtaining information about the clinical effect of interventions and one of the best ways to compare the efficacy of different interventions [121] [122] [123]. Randomised trials are most often conducted under experimental, optimal conditions, in which case they generally provide information about the efficacy of an intervention rather than about its effectiveness, which is appraised when the intervention is implemented in the daily practice life [125] [126].

In randomised studies, comparability between the groups at baseline is secured by randomisation, and the internal validity is strengthened by increasing the size of the study populations [127]. An equal distribution of baseline characteristics in the different groups can only be expected if many clusters are randomised to each group. A lager study than the present with more practices and more

patients would naturally have provided further evidence of the effect of the active implementation, and although we intended to include enough clusters to obtain sufficient power to detect an effect of the intervention in the present study, we must concede that the dimensioning of the study was given by the borders of the municipalities; the aim of the power calculation was accordingly to evaluate whether the study could be used for meaningful research. The number of patients identified supplied us with sufficiently power to proceed with the study and to detect an effect of the active implementation model.

Cluster randomisation decreases the statistical power compared with studies where the randomisation is performed at the level of the individuals [128;129]. We found that individual patient randomisation would not be suitable for this study as part of the intervention targeted the GP (the head of the cluster). If we had chosen individual patient randomisation, one GP would potentially have patients randomised both to the intervention and to the control group. It is very difficult to have just one GP in a GP practice with more doctors participate in the intervention group without any contamination, but it is possible to actively implement the disease management programme for the whole GP practice. We therefore chose a GP setting as our cluster and therefore block-randomised the GPs (all solo practices were one block; practices with two GPs were another block and practices with three or more GPs formed the last block).

5.4.2 The blinding

As the intervention required active involvement of the participating GP practice in CME and a reorganisation of the routines in their practices, the allocation of both GPs and patients was open and well-known to the GPs and the health professionals in both municipalities and at the hospitals and to the researchers in the intervention and the control groups. The patients belonging to the intervention group were sent a flyer together with the questionnaires and a

poster was on display in the intervention practices with information about the study. For the external control group, only the researchers knew the allocation. We could have had a bigger research group which would have given us to the possibility of blinding the researchers performing the analysis. However, for the present study, the size of the research group did not allow for the blinding of the analyst.

5.4.3 Sampling of GP practices and patients

In order to balance the clusters in the intervention and the control group, the GP practices in Ringkoebing-Skjern municipality were block-randomised into three groups, the first with solo-practices, the second with GP practices with two GPs and the third with GP practices that had three or more GPs. Two practices declined the invitation to participate. This might create some selection bias, wherefore the primary analysis was an intention-to-treat analysis and the sensitivity analysis a per-protocol analysis where data from the patients from these two GP practices were removed. As the focus in this study was on effectiveness, it was a natural decision to allocate the two GP practices to the control group and to perform an as-treated analysis to measure the effect in patients who actually received the active implementation of the disease management programme [127 226] as well.

We used a strategy targeting the organisational level and hence faced the problem often encountered in health services research that it is not possible to randomise each individual patient as each patient is registered with a GP and GPs often work together in GP practices. Therefore, the patients were cluster-randomised to the same group as that to which their GPs belonged. The cluster randomisation may pose problems because of unequal distribution of confounders [127]; by adjusting for variance, the cluster design was accounted for in the analysis.

Patients who died were excluded from the registry study. That could potentially represent a bias if they predominantly were from one of the groups; that was not so as the excluded patients were largely evenly distributed among the three groups. We expected that the randomisation would ensure that the number of patients moving outside of the municipality during the study period, being too ill to participate, seeking research protection or dying would be equally represented in the groups. If these event frequencies were unbalanced, it would naturally influence the results. Between the study start at 1 November 2008 and 1 November 2009 when the second questionnaire was sent, these events happened for 5.6% of the patients in the intervention group, for 5.6% in the control group and for 6.8% of the patients in the external control group; hence, the events were fairly evenly distributed between the groups.

5.4.4 Outcome variables

We assessed the outcome of the intervention through valid and countable variables all registered in highly valid registries [174-177] (see section on data quality), all relevant and accessible for our research like the number of planned and additional preventive consultations, the number of spirometries performed, the number of conventional consultations, the consumption of out-of-hours services, the consumption of emergency department services, the number of admissions with and without a lung-related diagnosis, the number of readmissions and the number of bed-days. We also evaluated the effect of the intervention with PACIC to determine the patients' assessment of the change in care in line with other research where there is a focus on patients' recorded outcome measures. It would have been interesting to evaluate the effect of the intervention for patients in terms of more qualitative variables like quality of life, sense of coherence and self-efficacy [227]. Likewise, it would have been interesting to evaluate the effect of the intervention for the health professionals involved both in the GP practices and in the municipality's health centre and for

the municipality's community nurses. Such analyses would have extended the study considerably and would certainly have their place in studies with a longer study period than the present study.

Several other strengths and weaknesses of the study are discussed in detail in Papers III and IV.

DATA QUALITY

5.5 Register data

The data were provided by the DNHISR and the PAS; both registers collect data for the purpose of reimbursement. Danish GPs receive 75% of their salaries from a fee-for-services scheme; thus, both the registry and the healthcare provider have a financial interest in maximum register validity, [228] [136] and any under- or over-reporting is likely to be minimal; moreover, we have no reason to believe that any over- or under-reporting should differ between the groups.

Data from the PAS are used to register all patient contacts to the hospitals and the data are fed into the DNPR [229]. Registrations in the DNPR are the basis for payment for the services provided by the public hospitals, and the registrations are therefore assumed to be complete. The DNPR is considered a unique data source. We used data on patients who had been registered with the ICPC code for COPD or other lung–related diagnosis, both as a main diagnosis and as a side diagnosis as it is often difficult to determine which one is the main diagnosis for patients with COPD.

Data were also collected from the Regional Prescription Registry which feeds its data into the DNPR. This registry has an automated bar-coded-based data entry mechanism which corresponds to the Nordic article number and which links the registry to other registries with information about the drug; thus inter/intra-observer and information bias are very unlikely [139] [176]. The record keeping is considered to be consistent as it is reimbursement-driven, and the register-based data on drug use have been shown to be consistent [176].

QUESTIONNAIRES

5.6.1 Patient questionnaires

We used previously developed and validated scales for most of the patient questionnaires.

The PACIC [141] is validated in a Danish setting [142] and we therefore considered it applicable for the study of chronic disease in Danmark. The Danish Patients Evaluate Practice (DANPEP) [143] is widely used to assess the patients' experience of their GP practice, just like the EQ-5D [230] instrument is used to assess the patients' health-related quality of life. The MRC's dyspnoea scale is the most widely used instrument for assessing COPD status and therefore affords us with the possibility of comparing our results with those of other studies [145].

To enhance the validity of the questionnaires, previously used items on patients' relation to smoking, use of medication, support and socio-economy were used. The questions were carefully discussed with patients, GPs and health professionals and this approach served to optimise the content validity of the questionnaires [147].

5.6.2 Response rates

The response rate was 68.5% in the baseline questionnaire sent to patients identified by the COPD algorithm, and there was no difference between responders and non-responders regarding age and gender. A total of 72.8% (1,445) of the responding patients confirmed their COPD diagnosis. A year later, some had died or sought research protection, and 1,383 patients were sent a follow-up questionnaire. The response rate was 83.6%. We expected the most ill people to have the lowest response rate; our expectation was confirmed in the sense that those who did not answer the follow-up questionnaire had lower mean scores on the MRC's dyspnoea scale than the respondents. This may have

influenced the scores of the PACIC result, and we chose to only analyse those 53.8% of the responders to the follow-up questionnaire who had answered at least 50% of all PACIC questions in both questionnaires. In no way could we reject that these 53.8% of the patients was a selected group who answered at least half instead of some or no PACIC questions at all, and they may not be representative of the full population. We were interested in making a comparison between groups, and the risk of selection connected to randomisation group - "double-skewed drop-out" – was therefore considered to be minimal.

5.6.3 Processing of questionnaire data

Most questions in the questionnaires were answered by filling out the selected multiple- or single-choice fields. Entry fields used were marked for correction by the computer in TELEform. For questions where only one answer was needed, the computer was set to only accept one answer. Each question was set to be checked and validated by the assistant who scanned all the questionnaires.

The error rate for TELEform automated forms processing was shown to be very low in a validation study [151] where manual entry was compared with automatic data capturing (2.4 per 10,000 fields), and the validity of the automated process was comparable to that of double manual data entry. In the present study, we validated the scanning procedure by having the data manager from the IT department scan 30 of the baseline patient questionnaires into TELEform a second time. There were 103 questions in each questionnaire which were answered by choice fields; there were 546 fields to check for errors. We found an error frequency of 0.37% as only two errors were detected.

Questionnaires were scanned and verified by TELEform, and all the unique serial numbers in the Access database were subsequently compared with the

serial numbers on the received paper versions of the questionnaires. A few questionnaires were discovered that were not in the database and they were accordingly added. For each individual patient, we checked and validated that the unique serial number of the questionnaire received matched the number in the Access database. If more than one unique serial number matched a number in the database, the first number received was the one to be registered and the second paper copy was clipped together with the registered copy for safekeeping. To minimise intra-observer variation, the coding was done only by MS who also controlled each questionnaire before the scanning. Just one person, CGJ, scanned the questionnaires and she had profound knowledge of the process. This procedure served to maximise the completeness and accuracy of the questionnaire data.

ANAYSIS

5.7 Analysis strategies

We considered different methods for analysing the data, both for the development of the COPD algorithm, the healthcare utilisation and the PACIC outcome.

5.7.1 Analysis for COPD algorithm – Paper I

In Paper I, we calculated the sensitivity, the specificity as well as the PPV and the negative predictive values (NPV) when developing the COPD algorithm. A high specificity of the algorithm will be a strength as it will ensure that people who have been hospitalised with a lung-related diagnosis, been prescribed lung-related medication or had a spirometry test for other diagnoses will not unnecessarily be suspected of having COPD. We decided to use the overall prevalence of 9% for COPD in Denmark as suggested by Hansen et al [157]. They had standardised the prevalence to the Danish population based on their study of a stratified sample of 4,757 people out of 299,000 Danes aged 45-84 years. Loekke et al [7] suggested a prevalence of 14.3%, which applied to people aged 35 and above; furthermore, this prevalence was calculated on the basis of a study of a much smaller sample than the previous study. We therefore found it relevant to use the prevalence reported by Hansen et al in our study. The algorithm in its present form had the best properties for people at age 55 or older. The relatively low PPV for younger groups may be explained by the inclusion of many patients with asthma.

5.7.2 Analysis of contacts to the healthcare system

Thomsen and Parner [160] argue that evaluation of healthcare contacts from first events alone often misses large amounts of potentially important data and may

produce different results than an evaluation that includes all events, and that an individual rate model that includes a parameter of an unspecified individual event distribution might be the natural choice when analysing longitudinal data of contacts to the healthcare system. Therefore, they conclude that an analysis of healthcare contacts should include both first and recurrent events, and it should use a model appropriate to these data which is what we did when we examined the effect of the active implementation model in the intervention group by comparing the differences with the differences in both the control and the external control groups. To draw maximum strength from the randomisation, we used an intention-to-treat analysis (i.e. the two practices that declined the invitation to be in the interventions group were analysed as intervention practices). Then to measure the effectiveness of the implementation, we performed both a per-protocol analysis and an as-treated analysis as sensibility analysis where data from the two practices that declined to participate were removed for the per-protocol analysis; and for the as-treated analysis, the two practices were analysed as belonging to the control group.

5.7.3 Analysis of patients' evaluation – Paper IV

In Paper IV, we used an as-treated analysis to examine the patients' evaluation of their care because we wanted to examine the effectiveness of the intervention, and in an as-treated analysis the patients will be analysed as intervention patients if they received the "treatment", in this case the active implementation, and as control patients if they act as controls. We recorded the mean PACIC scores for each dimension and the total score for each group at baseline and at follow-up. The change in difference of means scores when the control and external control group were compared with the intervention group was calculated, and the change in mean scores between the control and the external control groups was analysed. We also compared the difference between the

mean difference in change in scores for the corresponding pairwise comparisons between the intervention, the control and the external control groups. In this paper, we used an intention-to-treat analysis as a sensibility analysis together with a per-protocol analysis. In other papers where the PACIC questionnaire has been used to evaluate the patients' assessment of their care [231] [232] [233] [234], the PACIC was used to assess the care at a given time and not in the longitudinal perspective we used in this study. We found it beneficial to assess the change in patients' assessment using this approach.

STATISTICAL PRECISION

5.8 Power calculation

In the randomised study, the Ringkoebing-Skjern municipality was chosen as the area of investigation as the study had to be sufficiently large to accommodate the variance of outcome and the risk of random errors [235], but also sufficiently small to allow it to be accommodated within the cost and time limits of a PhD project. The sample size was calculated to allow us to achieve a change in the proportion of patients having a yearly follow-up consultation for their chronic disease from 50% to 60% with 80% power at the 0.05 significance level. This meant that we needed a total of 816 patients with 408 in each group to be included in the study; and with a design effect of 1.6, we would need a total of 1,306 patients for the study.

A design effect of 1.6 is, admittedly, hypothesised on a clinical common-sense background and not the result of a strict literature-driven and academic calculation, but it should be emphasised that this figure is used exclusively for the power calculation and has no influence on the reported analyses. As was the case for design effect, there was no solid scientific argument for expecting a follow-up frequency of 50%, nor to qualify why an increase of 10% should mark the limit for clinical relevance. We found that it is not uncommon that power calculations rest on such loose guesstimates or assumptions. However, because the dimensioning of the study was basically given by the municipality engaging in the study, we probably exhibited a little less than the usual precision.

BIAS IN RELATION TO THE RANDOMISED STUDY

5.9.1 Study design

A randomised study is considered one of the strongest and most powerful study designs [122] [236] [161]. When randomly allocating a patient or a cluster, e.g. a GP practice, to either the intervention group or the control group in a trial, each unit has an equal probability of 0.5 of being allocated to either group. The characteristics of the patient or the cluster do not influence to which group the allocation goes. In the present study, we arranged the GP practices in three blocks with solo-practices, practices with two GPs and practices with three or more GPs; and we randomly allocated the practices to either intervention or control group and thus minimised any allocation bias.

5.9.2 Selection bias

Selection bias is the systematic difference between the group selected and the full group from which the selected study group stems [237]. We identified the patients with COPD in the same manner, i.e. using the validated COPD algorithm [140], and we therefore have no reason to believe that the patients who were registered with a GP practice that was randomised to the intervention group should be any different from those registered with a GP practice randomised to the control group. However, the data from the questionnaire survey may suffer from selection bias as there is a higher likelihood that a patient responds if he or she was identified by three criteria in the COPD algorithm than by just two criteria or one criterion. This leads us to believe that the proportion of respondents was larger among those who had a verified diagnosis that among those who had no verified diagnosis; thus assuming it was the patients who were the most ill from the disease who responded to the questionnaires.

5.9.3 Information bias

Information bias is a systematic error that stems from errors in data or in the analysis. In the present study, we used the COPD algorithm to identify patients with COPD for the study. This may have introduced information bias to the registry part of the study as the analysis was performed for the whole identified population, and the algorithm identified 72.8% of the patients with COPD in the baseline questionnaire survey. In the validation of the COPD algorithm, we entered cases in which the GPs were in doubt as to whether the patient had COPD or not and classified them as positive cases, but it could actually be that the answer was positive for another lung-related disease; which would then introduce an information bias into the study.

5.9.4 Confounding

The participants in the study were block-randomised by chance to either the intervention or the control arm to minimise the differences in baseline characteristics. This procedure was chosen to avoid confounding [237]. For the present trial, we considered that any attempt on the part of the Central Denmark Region to implement their disease management programme for COPD would deploy the same approach in the whole of Ringkoebing-Skjern municipality and not just in those GP practices that were randomised to any one of the two groups. The added external control group of Ikast-Brande municipality enhanced the strength of our study in that we ensured that we had a control group where there was no spillover effect as the GPs attended different CME groups and the municipality offered different kinds of support for the patients with COPD.

GENERALISABILITY

5.10 Internal and external validity

The internal validity discussed above is essential to the external validity of the study, and the generalisability of the study rests, among others, on its internal validity. However, other aspects of the generalisation must also be considered. Most if not all of the interventions conducted in this study are transferable to daily clinical practice and the experimental condition can thus be considered almost analogous to everyday conditions in general practice. The Ringkoebing-Skjern municipality is a rural municipality with some bigger towns and a large population; it can therefore be considered representative of the setting found in most other Danish municipalities. On the other hand, it is a municipality where there is a tradition for a good working relationship between GPs, the municipality and the hospitals; there has also traditionally been a high level of participation in CME which may have minimised the effect of our intervention as the ceiling effect would have been reached. This could explain why we did not find the expected effect of the introduction of the programme on the use of the out-of-hours service and the emergency department services.

However, we do find that the results may apply to other countries or health care organisations within countries with a similar organisation of their healthcare system where GPs act as gatekeepers to the rest of the healthcare system, e.g. within the other Nordic countries, the UK and Kaiser Permanente.

ETHICS

5.11 Ethical considerations

Careful considerations were given to the ethical aspects of the present study. We have used internationally recognised procedures for scientific studies in the planning of the study and thoroughly discussed sending a questionnaire to individuals implying that they could have COPD even though the accompanying letter stressed that we could be mistaken. We ensured that no patient received less care than they would normally receive during the intervention period and that nobody was exposed to any risk. A few individuals who were contacted raised this issue, but many more contacted us with positive comments on how they appreciated that CODP and their care were at the centre of a scientific study. The studies in the present thesis have undergone thorough examination by the Multi-Practice Committee of the Danish Society of General Practitioners and the Association of Danish General Practitioners, the Danish Data Protection Agency and the Danish National Board of Health, and they were approved by all these bodies. According to the Scientific Ethics Committee for the Central Denmark Region, the Biomedical Research Ethic Committee System Act did not apply to the present project. We therefore found it ethically sound to proceed with the study.

CHAPTER 6

DISCUSSION OF RESULTS

This chapter briefly discusses the main results presented in Papers I-IV

OVERALL DISCUSSION OF THE STUDY

This chapter discusses our experiences when developing our active implementation model and our results in relation to the literature; special focus is devoted to the strengths and weaknesses and lessons learned.

6.1.1 Aim

We wanted to test a model for implementation of a disease management programme for chronic disease, in casu COPD, and to investigate the effect of the implementation on healthcare utilisation and patients' evaluation of their care.

6.1.2 Identification of patients

To target the right people for intervention and intensified care, we developed and validated an algorithm which identified patients with COPD who had already been in contact with the healthcare system. The algorithm was used to identify patients in the real-life setting of Ringkoebing-Skjern municipality and a neighbouring municipality. Close to three-quarters of the identified patients had a verified COPD diagnosis, a percentage that rose with the age of the population.

6.1.3 The intervention – an active implementation model

To improve care and adherence to the disease management programme and the clinical guidelines, we developed an implementation model using the guidance of MCR for the development of complex interventions. The active

implementation model was based on the CCM, Breakthrough Series; both the elements and the processes of the model were visualised in a PatPlot.

6.1.4 The effect of the intervention on healthcare utilisation and the patients' evaluation

The effect of the active implementation of the disease management programme was tested by measuring GPs' adherence to the disease management programme in terms of specific services routinely reported to Danish registries. The GP practices showed good adherence to the disease management programme. This resulted in a decline in the number of ordinary GP consultations and a tendency towards decreased use of hospital services. Use of the out-of-hours services did not change as a result of the active implementation of the programme although patients from the control group made increased use of these services. No effect on the use of emergency department services was registered. Furthermore, we evaluated the effect of the model on the patients' evaluation of the concerted effort from the healthcare system. According to the patients' PACIC questionnaire answers, the active implementation of the disease management programme for COPD meant that they received better care.; when the dimensions were considered individually, no effect was observed for Problem solving and Follow-up dimensions.

COMPARING DISEASE MANAGEMENT PROGRAMMES

6.2.1 Promoting disease management programmes

Starfield has championed the value and need for better primary care by asking the rhetorical question which healthcare is the better; the one referring 10% or the one referring 40% of the patients from primary care to specialist care. While not answering this question, she represents convincing arguments that the lowest cost and the healthiest populations are found in countries with the strongest primary care sectors. This certainly amounts to a good argument for placing the GP practice as a coordinator of care for patients with chronic conditions [20].; not least because the measure system proposed by Starfield is designed specifically to identify patients with coexistences of multiple diseases rather than a single disease. The identification of patients with the diseases instead of just identification of a disease will enable targeted care for the patients with disease at the moderate and severe state who will benefit the most from treatment.

A recent report from the Capital Region of Denmark found that patients and relatives had the impression that there was very little or no coordination between the different sectors, the patients did not feel that they were being heard when they needed acute care, and neither patients nor relatives had the impression that anyone within the healthcare system had the overview and were coordinating their care [31]. Based on the literature, we would suggest that the GP were the coordinator to ensure an overview of the examinations and to provide the patients with some sort of security that the healthcare system actually takes care of them as requested by the patients themselves and by their relatives [31]. We accordingly focused our intervention strategy on improving care for patients with COPD and targeted the GP practices.

6.2.2 Continuing medical education and adjustments

We expected that focused education of GPs and the other health professionals in the GP clinic would improve their adherence to the COPD clinical guideline and the disease management programme, especially where the potential for improvement is high [238]; however, a nurse-led intervention in GP practices in Australia found no influence on the health-related quality of life although there was evidence of improved quality of care [239]. A recent study identified the following important barriers to adherence to COPD guidelines among primary care providers: poor familiarity with the recommendations, low self-efficacy and time constrains [240]. We therefore used a design for inclusion of GP practices that minimised the clinicians' engagement in the research while maximising their clinical input and which made participation attractive to the GPs and their practice staff as this approach had been successfully pursued by other researchers [241].

A Canadian Health Technology Assessment investigated perceptions of COPD over the course of the disease among patients with COPD and their relatives and healthcare providers. It was found that patients might not realise that COPD is incurable and fatal, and even some GPs did not consider the disease to be fatal. Smokers may not really agree with the idea that smoking worsens COPD; the disease runs a course that calls for continuity and flexibility to respond to the unpredictable, yet increasing demand of the disease over time [242]. Implementation of a disease management programmes like that of the Central Denmark Region for COPD may, indeed, be an expedient response to this situation which demands continuous follow-up on the patient and the disease progression, and a continuous response adjusted to this situation on the part of the healthcare system. We therefore used the Central Denmark Region's disease

management programme for COPD and accommodated for adjustments using the Breakthrough Series.

6.2.3 Effect of disease management programmes

A recent systematic literature review of the economic impact of disease management programmes for COPD found a favourable outcome both for costs and on health outcomes [187], especially in patients with severe COPD. In the present study, we used the provided services as a measure of economic effect. Further economic analysis of the effect of the individual components of the intervention could have been performed and the economic effect of the present study could have been compared to the effect of similar disease management programmes in other countries. However, it fell outside the scope of the present study to perform an economic analysis. The result of another literature review found that an intervention should be tailored to the severity of the disease to maximise the economic outcome of the intervention [243]. In the present study, the health professionals were not specifically requested to stratify the patients according to the seriousness of their disease although it was mentioned in the clinical guideline. It might have altered the use of secondary care if the health professionals who delivered the care had been encouraged to allocate more frequent follow-up consultations to the patients with COPD in the advanced stages.

Costs may also be saved if adequate and appropriately planned homecare can be arranged so that patients may be discharged as early as possible. Thus, a Dutch study reported economic gain from early discharge and, moreover, the patients who had been discharged early were just as satisfied with their treatment as those who had stayed longer in hospital [244]. This finding suggests that patients can be discharged early with adequate and appropriate homecare planned in

joint homevisits of GPs and community nurses as we had allowed for in our study.

An active implementation approach was adopted in the present study because it was assumed to be more efficient than a passive strategy. This assumption was backed by the findings of Döpp et al. who reported that a passive, multifaceted implementation of a dementia programme offered by the community's occupational therapist was less effective than an active implementation programme [245]. The high degree of adherence to the disease management programme on the part of the GPs in the present study also proved our assumption right

6.2.4 Patient centred care and involvement

Although the design of the present study fell short of being fully participatory, we did include patients and health professionals alike in the development of both questionnaires and the active implementation model. It is possible that even further involvement would have meant that interactions between GPs, health professionals and patients changed even more and became more in the direction of 'proactive' like in the My Own Health Report study which aimed to have primary care practices systematically collect patient-reported information and provide patients with needed advice, goal setting and counselling [246]. Patients have a strong desire to participate and be engaged in activities related to their own lives. The importance of enabling patients to 'participate' rather than just 'do' should be taken into account when planning and delivering patient-centred interventions across the whole care spectrum [247].

IDENTIFYING PATIENTS WITH COPD THE COPD ALGORITHM

6.3 Algorithms to identify patients at risk of having COPD

An algorithm developed in New Mexico, US used healthcare utilisation data to identify people at risk of having COPD [184]. The health care organisation provided services from primary care clinics, speciality centres and hospitals to totalling 350,000 members. The algorithm identified 2,219 cases at risk in the claims records. The cases of possible COPD were identified from their use of healthcare services during the two years prior to their COPD diagnosis. The cases were age- and sex-matched to three controls who did not have a COPD diagnosis in their claims record [184]. The total control cohort counted 5,790 patients. Stepwise conditional logistic regression equations were used to identify the indicators of COPD from hospital admissions, outpatient encounters and outpatient pharmacy prescription during 24 and 12 month before the first diagnosis of COPD. Those indicators that were most strongly associated with a diagnosis of COPD were put into the discriminant function algorithm. A total of 19 factors were included into the algorithm. It was examined if exacerbations could enhance the performance of the algorithm; however, exacerbations had no significant influence and were therefore not included in the final algorithm. To test the sensitivity, specificity and positive PPV of the algorithm, it was applied to the validation group's 1998 and 1999 claims records and compared with their clinical diagnoses. The algorithm was further validated in 200 medical records from the validation group where the algorithm had identified the patients likely to have COPD but never having had a clinical diagnosis. Furthermore, the medical records of 200 patients who had a clinical diagnosis of COPD but had not been identified by the algorithm were examined. The algorithm was applied to the validation group's 1998 and 1999 claims records. In this group, the algorithm correctly identified 2,240 patients out of 3,704 (60.5%) with COPD

(PPV of 25%) within a total population of 41,428 people who were 40 years or older [184]. Similar to our findings, the PPV increased with age; and when the algorithm was used for people who were 65 years old or older, the PPV improved to 38% with a sensitivity of 64%. The authors expressed that that the clinical characteristics of the population in the insurance scheme might be slightly different from those of other populations, just like the health professionals in the organisation are likely to be different from health professionals working in other settings [184]. However, it was concluded that the algorithm can be used as a tool to efficiently identify a large number of people with an increased risk of having a debilitative and progressive respiratory condition and that it might enhance the algorithm to add information on the patient's tobacco use [184]. Similarly, we developed the present COPD algorithm knowing that it would identify patients with obstructive lung disease and not only patients with COPD. We did not consider including information on patients' smoking status as we used data from registries that did not include patient-reported information on smoking status.

A case-control study conducted in the same US setting found that the use of antibiotics, cardiac medication and lung-related medication was significantly higher for patients with COPD than for patients in the control group [248]. The final algorithm, which identified patients with COPD with a sensitivity of 60% and a specificity of 70%, was tested in two more managed care databases. One of the databases contained information on more than 3 million people in the United States, and the other had patient-level information on more than 5 million people, also in the United States. The algorithm performed similarly in the two groups and similarly to the group in which it was developed; and the PPV rose substantially when the population was limited to people who were 65 years old or older, although the sensitivity remained the same. They [248] concluded that the algorithm served its purpose well, particularly by identifying

those patients whose COPD had advanced the most and who therefore needed care the most. This was also the characteristic of the algorithm developed for the present study. The authors also concluded that the algorithm that was based only on the use of medications performed less well than the algorithm that deployed both in- and out-patient data and use of medication [248].

Our decision to use multiple data sources to design the algorithm was hence rooted partly in the experience from similar undertakings reported by other researchers [184] [248]. A third study sought to identify cohorts of patients with asthma for the purpose of healthcare research and population monitoring [249]; this study used GP data and found that adding hospital data to their algorithm improved its ability to detect such patients. These studies support our idea that patients with COPD may be identified from administrative data from hospitals, GPs and pharmacies; and that such an approach may be feasible in proactive care designed for care improvement and research purposes.

A recent Danish study suggested that COPD is under-recorded and that many patients with COPD are admitted with acute lung-related diagnoses other than COPD [185]. Hence, we speculate that it may be necessary to use the diagnosis for all lung-related diseases to identify those who have COPD. To identify patients with COPD, we developed an algorithm from registry data that have been shown to be highly valid [136] [139]. The algorithm used three variables derived from registries containing data on hospital use, redeemed medication and spirometries performed in the GP practices. We tested the algorithm both among GPs and patients, and it identified between 30% and 97% of the COPD population depending on the age of the population. Inclusion of many patients with asthma may explain the relatively low PPV of the algorithm in younger people, and age may be a variable that should be included in the algorithm in the future. The high specificity of the developed algorithm ensures that people

will not be unnecessarily investigated for COPD even if they have been in contact with the healthcare system.

THE COMPLEX INTERVENTION – AN ACTIVE IMPLEMENTATION MODEL FOR A DISEASE MANAGEMENT PROGRAMME

6.4.1 Comparisons with other studies

The implementation of change in healthcare is subject to the realities of the political and organisational setting which may be either conducive or obstructive to change. In a report on the collaboration between municipalities in Denmark and researchers, both sides mentioned the need to implement evidence-based practice based on the experienced needs and resources. We found that the Ringkoebing-Skjern municipality and the Central Denmark Region were very supportive and accommodating in the development of this intervention. The health professionals took part in the development of the active implementation model and its adjustments and they mustered support and a high level of motivation along the way and, not least, economic and political support [250 251].

In any change process, the leaders need to advocate for a new practice and key alliances must be forged [252]. The leader must also support stakeholders in their new practice, while involving external and independent people to inspire the implementation of the change [251]. The Municipality and the regional authorities consistently placed responsibility for the implementation with the Research Unit for General Practice which improved the prospects of successful implementation [250;253].

A recent report from the Capital Region of Denmark found that patients and relatives had the impression that there was very little or no coordination between the different sectors; the patients did not feel that they were being heard when they needed acute care; and neither patients nor relatives had the impression that anyone within the healthcare system had an overview and were coordinating their care [254]. This report underscored the necessity for improved

coordination of care. Our model where the GP acts as the coordinator of the care and where more Internet-based communication between providers is coming in place will hopeful over time make it clearer who is the coordinator of the patients' care so that patients and relatives may experience that there is someone who has an overview of their care in the healthcare system [255].

Current recommendations [88] state that implementations need to draw on multiple components, each targeting different areas and actors; and Grimshaw et al described that that interventions with at least one element from the CCM improved clinical outcomes and the processes of care [256].; other studies have shown that a combination of different components enhances the probability for successful implementation of change [257]. We used theory and established elements in the initial planning phase. We covered those areas which the CCM identified as essential to produce change in healthcare settings where prepared, proactive practice teams interact with informed and activated patients [14 15 59]. We integrated suggestions from focus group interviews with patients in the municipality and from individual interviews with health professionals both from the GP practices, the municipality's health centre and the hospitals. This allowed us to adapt the intervention to the local setting before the cluster randomised trial was launched.

Dutch patients evaluated their care better when they were treated in GP practices which followed a disease management programme for a single disease similar to the programme in our study [234]. A European study which evaluated the approach of twelve different countries to the implementation and evaluation of disease management programmes found that most of the countries evaluated the results for patient population with a single chronic disease and measured clinical processes, patient behaviour and satisfaction, cost and healthcare

utilisation during one to three years. In the present study, we also focused on a single disease (COPD) in the disease management programme for COPD [258].

To ensure long-term effect, it is essential to be able to adjust and evaluate the changes implemented and the use of the Breakthrough Series which allows general practices continually to adjust and evaluate the components in the model [155]. Such continual improvement is particularly important in an interactive healthcare setting where three partners - hospital, municipality and general practitioners – are involved, not at least to ensure long-term effect.

In their description of the development of an educational intervention, Maindal et al. state that there seems to be little agreement on the key tasks involved in the development of complex interventions [142]. Using the PaTPlot to illustrate the contents and the timeline of the complex intervention was helpful in the present study.

The use of an opinion leader to disseminate or introduce evidence-based practice in GP practices was successful in the present study where our opinion leader - the local well-respected GP, Lars Foged - introduced the study to his colleagues at the introduction meeting [259]. To disseminate information about the clinical guideline and the disease management programme, we held four meetings with the GP practices and the GPs were remunerated for the time they spent on these meetings as a US study had identified time spent without economic compensation as one of the barriers to GP adherence[214].

The approach of having one person (MS) undertake all the contact to the stakeholders may have been instrumental in achieving some changes, but it might have blocked others as compliance could be influenced by personality preferences even if we do know that practice facilitation is an established way of

implementing change in primary care settings as also shown in a recent randomised trial of delivery of care consistent with the CMM [260].

A representative pilot study was not performed even if it might have given valuable input to the design of the implementation programme. This would have required a longer study period and would not have been feasible either from a time or from an economic perspective. Instead, we allowed for adjustments along the way using the Breakthrough Series, and we found it highly productive to use qualitative methods to localise the intervention, as also recently suggested by the British Medical Research Council [64].

Reviews have shown that integrated care programmes have positive effects on the quality of care [11]. In a Dutch study [35,66], national guidelines for general practice were implemented by post and by post with outreach visitors. The Dutch study found both more extensive use of the clinical guidelines and higher awareness of their existence, whichever intervention was used. However, offering the general practices a range of components to choose between in a catalogue of possibilities instead of enforcing a fixed intervention may have strengthened the GP practices' ownership and have ensured greater commitment to the implementation, and we expected the GP practices to have chosen the components they found most relevant.

The implementation of an integrated education programme in primary care in Barcelona, Spain, reported improvements in dietary, exercise and smoking habits, but no reduction in the number of exacerbations or hospital admissions [261]. In our study, the intervention increased the number of follow-up consultations, and patients from intervention practices used less daytime GP consultations and fewer intervention patients with confirmed COPD were readmitted to hospital.

In a Norwegian study, Ogden et al. measured implementation components ten years after the introduction of two evidence-based programmes [262] and found that the change had been continuous and perpetual. That is precisely what we expect that we will find in a longer perspective because we used several elements from the CCM, and we expect that the results will accrue owing to the cumulative effect of the implementation strategy rather than to the effect of each individual component.

A review of the delivery of disease management programmes in Australia found that it was important to focus on self-management with patient education and motivational counselling to improve the patients' use of the healthcare system and their evaluation of the care. The review also found that combinations of multidisciplinary team and patient education improved patient outcomes and that health professionals needed evidence-based guidelines and other educational material to improve their adherence to disease management programmes [263]. In a qualitative study in 13 European countries, most of the responders said that self-management support was an important but still underdeveloped goal, and the Dutch providers found that it was not an integral part of their routine [259]. An important step towards understanding how to encourage both patients and health professionals to engage in productive interactions might be to involve patients in their capacity as the "experts" they are in being patients and then improve the support for the emotional management in care for patients with chronic conditions. Another study found that personal support from health professionals was highly valued by patients with coronary heart disease and helped them overcome negative social influences and cultural norms [264]. An Australian study of self-management support in general practice found that a broader systemic approach is needed, including a collaborative approach between providers, a range of self-

management support options, training of general practice staff, and changes to the organisation of services and the way in which they relate to each other [265]. The Ringkoebing-Skjern Municipality provided the course "How to manage your COPD". The course was developed in partnership between patients and health professionals and it used a new concept for delivering patient courses in which the patients and the health professionals interacted and had to actively solicit one another's collaboration across formal and informal diversities using creativity, perseverance and humour. This was a collaboration of five municipalities in the western part of the Central Denmark Region in developing new educational methods, and this project would fit well into the network asked for by European researchers to address the challenges of chronic illness care [266].

We developed the action card and the website to support self-management and much can surely be done to develop the use of this support even further as very few (i.e. twelve) of the patients mentioned that they had received an action card. It is possible that a better understanding of how to encourage both patients and health professionals to engage in productive interactions could put to shame [63] the conclusion of the review of 13 European countries that European healthcare is talking the talk of patient participation but far from walking the walk.

In our study, we involved patients in the focus groups to explore where they experienced a need for improvement in the care from the healthcare system. Involving patients and carers in the planning of the care for a chronic disease may enhance joint decision-making and goal setting which is where our model needed a stronger focus. Involvement of patients and health professionals is, however, not a novel feature in general practice research. Hence, a previous thesis explored how such participatory advanced care planning could engage hope and address barriers experienced by GPs and patients and their families [267].

Several literature reviews have found that effective implementation strategies must include multifaceted interventions, actively engage the health professionals and include process models [268] [269]. In a Danish PhD thesis, the CCM was found to be useful in the Danish healthcare system; and even if the author found that the effect was context-dependent, CCM did improve the quality of care services as also reported in our study which found that multifaceted intervention and extensive cooperation enhanced GPs' adherence to the disease management programme and made patients more satisfied with their care [270].

Ham has suggested ten characteristics and four implementations strategies to achieve a high performance level in a chronic care system as he does not find the CCM to be sufficient [271]. Many of these features also characterised our study; for example, Ham's interventions strategies were similar to ours though we might have given further emphasis to his third strategy for how to handle incentives to support the implementation. Thus, the issue of awarding good outcomes is on the agenda in the forthcoming round of negotiations on delivery of healthcare services between the regions and the GPs. It requires political will and diligence to avoid an inappropriate expansion of specialist care while ensuring a flow of resources that is conducive to the development of the primary care sector and the introduction of new care models appropriate to our day and age where chronic conditions are on the rise.

Support from central policy makers is essential in changing care provision as evidenced by the success of the Veterans Association in the US in shifting most of their care to primary care and enhancing the quality of outpatient services while encouraging the healthcare to be delivered on an outpatient rather than an inpatient basis, and then reducing their use of hospitals admissions [272]. Likewise, the recommendations from the Danish National Health Board on care for

chronic diseases and for COPD [99;273] were instrumental to the development of the disease management programme for COPD in the Central Denmark Region.

Another implementation strategy suggested by Ham [271] is community engagement, and he uses examples from New Zeeland and Seattle, USA, to illustrate that patients with the poorest health were difficult to reach in ways other than through the community. An opportunity to trail new and innovative approaches in a project where nine towns in the UK were given money from the government to develop community-based environmental interventions to prevent obesity were forfeited as the requirements were that they used evidence-based practice; the chance to implement truly innovative programmes failed out of fear of failure; more time for development, implementation and evaluation of future initiatives and no restrictions were the suggestions for more innovative developments [274].

In a systematic review, Legare et al pointed towards the tendency of GPs to select those patients they believe can follow the programmes [275], and Giesen emphasises the importance of targeting the programmes to the receivers' need [276]. A pilot study of a big integrated care project in North West London aiming to integrate primary, acute, community, mental health and social care for people with diabetes and those over 75 years recently found that after a year they had successfully created a shared strategic vision and had obtained some evidence of changes in care processes. Like in our study, they found no significant reductions in the use of emergency services [277]. The same study also recommends that sufficient time should be allowed for evaluation of the interventions and that mixed methods should be used for the evaluation of the projects. We made no qualitative assessment of our study; and it is likely that a qualitative assessment may have enhanced the evaluation of the active implementation model, for example if we had conducted interviews or focus

groups meetings with the stakeholders, i.e. the municipality politicians and the leader of the healthcare centre, GPs, other health professionals and patients.

Evidence-based practice has been a buzz word for the past 20 years, and a recent review of the literature found that although there were some barriers to the implementation of evidence-based practice to improve the quality of health care, the general attitude is that proved and research-based practice it mostly welcomed into the daily life of health professionals as an important means to improve the quality of patient care; the introduction should be supported by professional, educational and managerial role models like the components we included in the active implementation model [278]. When patients received structured chronic illness care, good practice management and organisation of care, their assessment of the care they received became more positive according to a study investigating 140 GP practices from five European countries (Austria, Germany, the Netherlands, Switzerland and the United Kingdom)[279]. A regional project investigating the implementation of a disease management programme in Holland for patients with COPD found that there was a significant improvement in health utility and in the quality aspect of care when the programme included self-management, disease control, dissemination of information about the disease, self-reported smoking status and patient evaluation of the care received. Similarly, a North American study found that disease management programmes improved patients' health and quality of life [280]. This is similar to our findings which showed more appropriate use of primary care, enhanced adherence to the disease management programme and a higher score on PACIC, which overall indicates that patients were more satisfied with their care [86].

Using the developed and validated COPD algorithm to identify a Danish population of patients with COPD in the municipality of Ringkoebing-Skjern

and actively implementing a disease management programme, we reproduced the finding of an English intervention study that showed a trend towards fewer hospital admissions and less use of hospital beds [281] as described in Paper III.

6.4.2 Strengths and limitations

We used the stringent and transparent approach outlined in the MRC's framework for implementing complex interventions [158] together with the CCM [14 15], The Breakthrough Series [155 60] and the PaTPlot [159]. We thereby developed an active implementation model for a disease management programme introduced in the Central Denmark Region for patients with COPD.

Interpretation of the evidence depends of descriptive information of the intervention which we provided in Paper II. A public health intervention needs to be transparent and transferable in terms of design; and because the intervention has to be complex and context-dependent, the description of the intervention must necessarily be detailed. One study found five questions to stimulate and structure the debate among researchers, funders and policymakers and help make decisions about evaluation within and between complex public health interventions as they evolve from an initial concept to the introduction of full-scale intervention packages [282]. Other authors have pointed out that documentation and evaluation of the implementation and the process of implementation are rarely provided [283]. Established evaluation criteria were not available for all dimensions and all parts of the implementation process. We therefore developed an approach unique to the present study to identify and evaluate knowledge that was generated during the evaluation. It is possible that qualitative research interviews using the five questions mentioned above with patients and health professionals about the effect of the active implementation

would have allowed us to perform a more systematic evaluation; such interviews could not be conducted within the time frame of the present study [284].

The use of a complex intervention based on specific parts of the CCM [14 15] poses a challenge as we were unable to ascribe change to a particular part of the intervention. Furthermore, it is possible that the effect stems from the very complex and multifaceted approach itself rather than from one or a few of its elements [56].

In order to accommodate the analysis to changes over time, we chose to exclude those patients who died during the trial. In the case of large group differences in mortality, this could affect the results of the comparison of healthcare use in either direction. However, given the character of the intervention as well as the disease itself, we assumed that any such difference would be negligible in a short-term perspective.

The results are strengthened by the randomised design of the study, the high number of included GPs and patients, and the use of highly valid administrative data. Analyses of the register-based results have been performed both for the group identified by the COPD algorithm based on administrative data and for the CD group in which patients confirmed their COPD diagnosis. An added strength is that the results and the trends in the bigger group were confirmed by the results in the group where the diagnosis was certain.

Patients whose GPs belonged to an intervention practice gave a more favourable assessment of the care they received than patients whose GPs belonged to the internal control group and to the external control group. The active implementation changed the way patients assessed their overall care in general and how they assessed patient activation, delivery system design and decision support and goal setting in particular.

The results in the present study are in line with those presented in a review where all interventions were associated with improvement in adherence to the disease management programme. They are also in agreement with the results of a study where substantial improvements in processes and outcomes were associated with the implementation a disease management programme for diabetes. Similarly, a review evaluating the efficacy of the CCM components showed that disease management programmes with two or more components from the CCM had used hospitals less than those who had implemented only a single component [285] [286].

The multifaceted intervention we developed as our active implementation model was effective in inducing change in general practice; an observation which is in line with the suggestions in a recent review [285] [202].

CHAPTER 7

CONCLUSIONS AND FUTURE RESEARCH

This chapter draws some of main conclusions from the study and suggests future research

CONCLUSIONS

7.1 Overall aim

Pursuant to the overall aim of this study, we developed an active implementation model for a disease management programme where we used COPD as a model disease. We tested the model in a block- and cluster-randomised controlled trial, and the findings in this thesis indicate that the use of healthcare resources, which we used as a proxy for economy, was optimised when GP practices, the municipality and the hospitals adopted the disease management programme for COPD. Furthermore, the patients' evaluation of their care for COPD improved as a result of the active implementation of the programme.

7.1.1 The individual aims

We fulfilled the aims listed in Chapter 2 and the following conclusions can be drawn

1.
The developed COPD algorithm had a sufficient PPV to be used as a screening tool and was instrumental in identifying those patients who will benefit from proactive care and those who needed integrated care for their chronic disease the most.

2.
Using the step-wise procedure recommended by the MRC for development of complex interventions was a feasible approach for design of a model for actively implementing a disease management programme where COPD could be used as a model disease.

3.

The multifaceted implementation of a disease management programme for COPD made general practice follow the programme and proactively perform follow-up consultations and spirometries. This resulted in a decline in the number of GP consultations and a tendency towards decreased use of hospital services. The amount of out-of-hours services requested remained the same although patients from the control group increased their use of these services. No effect on the use of the emergency department was found.

4.

According to their answers in the PACIC instrument, patients gave a more positive evaluation of the care they received for their COPD after the active implementation of the disease management programme for COPD focusing on the GP's role as a care coordinator and on patient self-management.

FUTURE RESEARCH

7.2 Spin-off research

Suggestions for spin off research that is needed in the light of the conclusions drawn from the present study are listed below:

7.2.1 Identification of patients

The present study developed an algorithm to identify patients who are already using services from the healthcare system and therefore have advanced-stage COPD; a challenge for future research is to create valid clinical databases that may be used to identify patients with early stages of COPD to enable a stratified clinical follow-up. One strategy could be to offer spirometry to all current smokers attending the GP's clinic. An encouraging development in Denmark is the development of "Data Capture", i.e. the ongoing registration in a central database of ICPC codes from GPs' records [287]. The implementation of this system is mandatory as from 2014 and this initiative gives unique possibilities for quality development and follow-up research, and it may be used to refine the algorithms to identify patients.

7.2.2 GPs role in the health system

The present thesis has underlined the importance of general practices assuming a role as the coordinator of care for patients with COPD. Compared with the control groups, patients in our intervention group gave a more positive evaluation of the care they received, and more patients were allocated to the right level of care, which meant a more optimal use of healthcare resources. This finding calls for more implementation and feasibility studies. Moreover, long-term follow-up studies are required to fine-tune the intervention for implementation in a normal daily healthcare setting. Furthermore, we need

more studies to investigate the GP's role and how general practice influences the combined care effort for chronic diseases involving general practice, the municipality, the hospitals and the patients as stakeholders. A special challenge will be to gear the system's ability to handle patients with multimorbidity in which COPD is one of the diseases [288].

7.2.3 Interventions

Future research should focus on how implementation strategies can be developed that include effective components targeting change in healthcare delivery. This research should explore which intervention components are best and which combinations are most effective seen from both a disease and a patient perspective. We need further large-scale intervention studies to find ways of optimising the health-related quality of life.

7.2.4 Quality improvement

We need further large-scale intervention studies to find ways of optimising the triple aim for quality improvement – improve the health of the population, improve the patient satisfaction and reduce cost per patient – where special emphasis should be paid to patients' quality of life and self-management [289-291]. In the present study, we measured healthcare utilisation as a proxy for economic evaluation, but detailed and more comprehensive economic and cost-effect analyses are needed that include the costs of the implementation and measurements of the economic aspect of the active implementation of optimised healthcare for patients with COPD.

7.2.5 Multimorbidity

As stated before, the present thesis points to the need for research of other chronic diseases and multimorbidity; but in a wider context, it also calls for more research into different ways to create a comprehensive healthcare system where all stakeholders acquire new skills in clinical coordination to the best benefit of patients.

7.2.6 Self-management

Further research should focus on the effect of and ways to improve the municipalities' provision of courses and individual counselling sessions and the effect of these initiatives on the patients' self-management. Such research should take into consideration the different courses and services provided by the hospitals and municipalities and focus on those activities that maximise patient benefit. There is an ongoing, very exciting development in the use of IT as a tool to ensure self-care and empowerment of patients and as a means to ensure better shared care between health care providers. There is an urgent need for research in best practices of the use of this technology for patients with COPD from a disease, a patient and a system perspective.

7.2.7 Long time studies

The study period lasted two years and it could well be that the effect would have been a different one if the intervention had been studied over a longer period; our findings in this randomised study and the success of similar programmes for other chronic diseases highlight the potential and the need for larger and longer-lasting studies with implementation activities as close as possible to daily life in GP practices.

CHAPTER 8

PERSPECTIVES

This chapter sets the study into perspective

PERSPECTIVES

8.1.1 Organisation spin-off

The research in the present thesis should ideally have spin-off effects that improve the education of health professionals and support research and development and organisation of healthcare provision. An approach where the stakeholders, i.e. general practice, municipality and hospitals, are jointly responsible for providing care to patients living with one or more chronic disease and that deploys CCM in which the GP acts as a coordinator of care could be introduced in the education of future GPs and other related health professionals. In a joint healthcare system, this would make the practitioners better equipped to cope with an integrated care approach early in their career.

The politicians and other decision makers must continue their strategic support for this initiative where forces are joined to provide meaningful courses for the patients and where the professionals continually take each individual patient as their starting point and dare use themselves in the interaction.

8.2.1 Self-management

One great challenge for general practice and other health professionals will be to incorporate self-management with a focus on ways to empower patients with COPD and their relatives. Sharing some of the responsibility for the care and maintenance of the patient's health status with the patients themselves is a new challenge for health professionals, and it would be interesting to investigate how this is best achieved and the consequences this has for the health professionals' perception of themselves as caregivers. A new balance between the GP as individual caregiver for patients attending his clinic and the GP as a person responsible for the health of all persons in the target group in his catchment area might be considered. This is also the case for the balance between the reactive

and the proactive doctor role. The doctor meets the patients attending to the patient's needs in the classic reactive role, but a more proactive preventive role may enhance and guide self care and improve the overall care. Clarification of the ethical, societal and economic aspects of such reengineering of the goals for the GP and the healthcare is needed. Like changing the semantics to "people with chronic disease" which might induce a different partnership for the management of the disease than the traditional "patient with chronic disease". One could hope that the change in healthcare will be sustained and that the use of health care services will change even further when self-management becomes more of an established routine both for patients and health professionals.

8.3.1 The future

The implications of the present study reach far beyond the condition, COPD, we initially set out to study. They have a bearing on future research and support an active, planned and focused strategy for implementing disease management programmes where the GPs is the coordinator of health care for patients with one or more chronic diseases or other clinical conditions that demand long-term coordination of care.

Donabedian introduced the perspective that patients' evaluation of their care was an outcome of health care evaluation already in 1960s [42]. In the 2000s, McKee stated as obvious that health improvement should be the primary purpose of any health intervention and the primary criterion for judging its value and that improved health represents an economic as well as a health benefit [28]. Patients gave a more positive evaluation of the care they received for their COPD using the PACIC instrument after the active implementation of the disease management programme for COPD focusing on the GP's role as a care coordinator and patient self-management. This finding and our finding that the

use of hospital services is influenced by the active implementation may collectively inform future policies about healthcare for patients with COPD.

Thus, the results of the present thesis support the idea of designing active implementation strategies for the implementation of new healthcare programmes and in a wider context it supports efforts to further develop a comprehensive healthcare system with a good task distribution between different providers and with an integration of all efforts to enable the best possible outcomes for patients with chronic diseases.

CHAPTER 9

ENGLISH SUMMARY

This chapter offers a brief summary in English

ENGLISH SUMMARY

This PhD thesis is based on the project "The effect of an active implementation of a disease management programme for COPD" carried out in the Central Denmark Region from 2008 to 2012. The thesis is based on four papers and focuses on the collaboration in the care for patients with COPD.

9.1 Introduction

The vision of a healthcare system centred on the patient is entertained both at political and administrative levels and, not least, by health care professionals. It follows that the quality of the healthcare system should be appraised according to clinical/medical criteria and that patients' voices should be heard. Besides good communication and professional treatment, patients want continuity and coordination of their care. The Danish municipal reform in 2007 delegated responsibility for prevention, rehabilitation and treatment of Danish citizens to the municipalities; this implied the task of creating a structure where the basic features were more interdisciplinary and better coordinated intersectorial pathways within the healthcare system. The thesis examined how such structures were created in a concerted care effort between Ringkoebing-Skjern Municipality, the Central Denmark Region and local general practitioners in order to optimize the care for patients with chronic obstructive pulmonary disease (COPD) and to ensure high-quality care services and avoid disease progression and complications and a worsening of the chronic condition and to reap experience from the management of COPD to inform healthcare efforts targeting other major chronic diseases.

There is only scarce evidence of the effectiveness of disease management programmes and their implementation in complex primary care settings where GP practices, municipalities and hospitals are expected to work together to

provide care for citizens with chronic conditions. It seems that active, theory-driven implementation outperforms other implementation strategies. In 2008, the Central Denmark Region implemented a disease management programme for COPD which presented a unique opportunity to test an active implementation model against a usual implementation model.

9.2 Aims

The overall aim of the present thesis is to describe how a theory-based intervention model can guide the selection of components in a complex implementation process and how the model can form the basis for a randomised trial.

The specific aims were:

- To develop an algorithm for identifying patients with COPD from administrative data
- To describe the development of an active implementation model based on the Medical Research Council's (MRC's) model for designing complex interventions and the Chronic Care Model (CCM)
- To test the effect of an active implementation of a disease management programme on health utilisation in a randomised trial set-up
- To test the effect of active implementation of a disease management programme on patients' assessment of their care in a randomised trial set-up

9.3 Methods

Paper I

An algorithm was developed in three steps to identify COPD patients from three different GP and patient populations. The algorithm was based on hospital and prescription data drawn from highly valid registries.

Paper II

An intervention was designed to ensure active implementation of a disease management programme for patients with COPD. The intervention was developed on the basis of the principles of the CCM and targeted professionals, organisation and patients while aiming to support self-management and to give general practice main responsibility for coordinating treatment and follow-up. A multifaceted implementation strategy using Breakthrough Series, academic detailing and patient lists was used.

Papers III and IV

A block- and cluster-randomised study was performed to test the active implementation model and to measure its effect in terms of the healthcare utilisation and the quality of the care and patients' assessment of their care.

9.4 Results

An algorithm based on administrative data on hospital and prescription use was developed and validated; its strength was sufficient to warrant its use as a tool to identify patients with COPD.

Using the MRC's model for developing complex interventions, a multifaceted implementation strategy for a disease management programme for COPD using Breakthrough Model, CME, academic detailing and patient lists was developed based on principles outlined in the CCM.

The active implementation model was tested in a randomised controlled trial. The patients found improved quality of their care; and healthcare services were used in accordance with the disease management programme.

9.5 Conclusion and perspectives

Coordinated care for patients with COPD orchestrated by the GPs ensures better patient assessments of the received care and changes the patterns of healthcare utilisation. This thesis contributes with new knowledge of how patients with COPD can be identified from administrative data. Further studies to develop the algorithm are needed.

Combining a theoretical model for complex interventions and the CCM and choosing specific implementation strategies proved to be a feasible approach in the implementation of a practice-based active implementation targeting a COPD disease management programme.

Awarding general practice a prime role as a care and self-management support coordinator in a COPD programme that involved active implementation of a disease management guidelines was successful on two counts: patients evaluated the quality of their care better and the use of healthcare resources changed with GPs adhering to the programme and a tendency to decreased use of hospital services.

The gained scientific knowledge of how general practice, municipalities and hospitals can collaborate on providing efficient and effective care when the healthcare system is the proactive partner can be used to implement programmes for other chronic diseases, and it raises more questions on how the complex model can be optimised further and targeted differently. The economic prospects of the implementation can be investigated further likewise the socio-economic influence of the implementation.

CHAPTER 10

DANSK RESUMÉ

This chapter offers a summary of the thesis in Danish

Denne ph.d.-afhandling er baseret på projektet "Effekten af en aktiv implementering af et forløbsprogram for kronisk obstruktiv lungelidelse – KOL", der blev gennemført i Region Midtjylland fra 2008 til 2012. Afhandlingen er baseret på fire artikler og fokuser på samarbejdet om patienter med kronisk obstruktiv lungelidelse - KOL.

10.1 Introduktion

Visionen om et sundhedsvæsen centreret om patienten er både det politiske, det administrative og det sundhedsprofessionelle mål for et godt sundhedssystem. Kvaliteten og standarden af det faglige niveau skal være i top, og patienterne skal inddrages i beslutninger om deres helbred. Foruden god kommunikation og professionel behandling ønsker patienter kontinuitet i koordineringen af deres omsorg. Den danske strukturreform fra 2007 uddelegerede ansvaret for forebyggelse, rehabilitering og genoptræning af borgere til kommunerne. Dette krævede nye strukturer, som i deres natur måtte være mere interdisciplinære og bedre koordinerende mellem sektorerne for at kreere klare forløb i sundhedsvæsenet. Denne afhandling undersøger, hvordan sådanne strukturer blev skabt ved en fælles indsats mellem Ringkøbing-Skjern kommune, Region Midtjylland og almen praksis for at optimere omsorgen for patienter med KOL. Det overordnede formål for denne indsats var at sikre en høj kvalitet i omsorgen samt undgå udvikling af sygdommen og komplikationer samt at erhverve erfaring fra varetagelsen af KOL til brug for sundhedsvæsenets indsatser over for andre store kroniske sygdomme.

Der foreligger ikke omfattende bevis for effektiviteten af forløbsprogrammer og især ikke for deres implementering i komplekse sundhedsvæsener, hvor almen praksis, kommuner og hospitaler forventes at samarbejde om omsorgen for patienter med kroniske lidelser. Det lader til, at aktive teoribaserede

implementeringer overgår andre implementeringsforsøg. I 2008 implementerede Region Midtjylland et forløbsprogram for KOL, det gav en unik mulighed for at teste en aktiv implementering imod den gængse.

10.2 Formål

Det overordnede formål med denne afhandling er at beskrive, hvordan en interventionsmodel baseret på teori kan guide udvælgelsen af komponenter i en kompleks implementeringsproces, og hvordan modellen kan afprøves i et lodtrækningsforsøg.

De underordnede formål var:

- At udvikle en algoritme for at identificere patienter med KOL ud fra registerdata.
- At beskrive udviklingen af en aktiv implementeringsmodel baseret på det britiske Medical Research Councils model for udvikling af komplekse interventioner og kronikermodellen.
- At afprøve den aktive implementeringsmodel for et forløbsprogram i et lodtrækningsforsøg og beskrive effekten for brug af sundhedsydelser.
- At afprøve den aktive implementeringsmodel for et forløbsprogram i et lodtrækningsforsøg og beskrive effekten for patienternes evaluering af deres omsorg.

10.3 Metoder

Studie I: En algoritme blev udviklet i tre stadier for at identificere patienter med KOL, og den blev afprøvet i tre forskellige populationer. Algoritmen var baseret på data om brug af hospital og medicin for lungerelaterede lidelser fra valide registre.

Studie II: En intervention blev designet for at sikre en aktiv implementering af et forløbsprogram for patienter med KOL var baseret på kronikermodellens

principper. Interventionen var rettet mod sundhedsprofessionelle, organisationen og patienterne, den stræbte mod at støtte egenomsorgen og at give almen praksis rollen som koordinator af omsorgen. Der blev brugt en multifaceteret strategi, som bygger på Gennembrudsmodellen, face-to-face møder, efteruddannelse i almen praksis og patientidentifikation.

Studie III og IV: Et blok- og klynge-lodtrækningsstudie blev gennemført for at teste effekten af den aktive implementeringsmodel for brug af sundhedsydelser og patienternes evaluering af omsorgen.

10.4 Resultater

Der blev udviklet og valideret en algoritme baseret på data fra brug af hospital og medicin for lungerelaterede lidelser. Algoritmen havde tilstrækkelig styrke til at kunne bruges som et værktøj til at identificere patienter med KOL.

Det britiske Medical Research Councils model for udvikling af komplekse interventioner var grundlaget for udviklingen af en multifaceteret implementeringsstrategi for et forløbsprogram for KOL. Baseret på principper fra kronikermodellen blev der benyttet Gennembrudsmodel, face-to-face møder, efteruddannelse og identifikation af patienter.

Den aktive implementeringsmodel blev afprøvet i et lodtrækningsforsøg. Patienterne fandt, at deres omsorg var bedre, og brugen af sundhedsydelserne ændrede sig som forudset med almen praksis, der fulgte forløbsprogrammet og en tendens til mindre brug af hospitalerne.

10.5 Konklusion og perspektiver

Koordineret omsorg for patienter med KOL, hvor almen praksis er omdrejningspunkt og tovholder, sikrer, at patienterne evaluerer deres omsorg bedre, og brugen af sundhedsydelser ændres og bliver mere hensigtsmæssig.

Denne afhandling tilføjer ny viden om patienter med KOL og om implementering af forandring i et komplekst sundhedsvæsen. Flere studier om udviklingen af den udviklede og validerede algoritme er nødvendige for at fintune algoritmen.

Kombinationen af en teoribaseret model for komplekse interventioner og kronikermodellen samt valg af specifikke implementeringsstrategier viste sig at være en brugbar tilgang til implementering af praksisbaseret aktiv implementering af et målrettet forløbsprogram for KOL.

Den erhvervede videnskabelige viden om, hvordan almen praksis, kommuner og hospitaler kan samarbejde om at levere kompetent og effektiv omsorg med almen praksis som tovholder kan bruges til at implementere forløbsprogrammer for andre kroniske sygdomme. Der bliver også rejst spørgsmål om, hvordan den komplekse model yderligere kan optimeres og målrettes anderledes. Det økonomiske aspekt af implementeringen bør undersøges yderligere, og tilsvarende bør den socioøkonomiske indflydelse af den aktive implementation.

CHAPTER 11

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CHAPTER 12

APPENDICES

APPENDIX I

I.1 Baseline questionnaire

Dette spørgeskema er sendt til borgere, der har en praktiserende læge i Ringkøbing-Skjern Kommune og som muligvis har en kronisk lungesygdom. Din læge eller en anden i sundhedsvæsenet har måske fortalt dig, at du har astmatisk bronkitis, rygerlunger, emfysem, slidte lunger eller noget lignende. Det er det, der under ét hedder KOL.

Vi skal understrege, at vi ikke ved noget, som du ikke allerede selv har fået at vide, og at vores henvendelse til dig kan skyldes en fejlregistrering.

Skulle du IKKE have en kronisk lungesygdom, beklager vi meget henvendelsen, og beder dig blot sætte kryds i boksen nederst på siden.

Hvis du har en kronisk lungesygdom, vil vi bede dig udfylde dette spørgeskema.

Vi vil bede dig - med en blå eller sort pen - at sætte et kryds i boksen ved det svar, der umiddelbart passer bedst på dig.

Hvis du sætter et kryds det forkerte sted, skal du strege det forkerte ud og sætte et nyt kryds.

Eksempel: Korrekt afkrydsning: Fortrudt afkrydsning:

Du er velkommen til at kontakte os, hvis du er i tvivl eller har spørgsmål.

Projektansvarlig Margrethe Smidth

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Forskningsenheden for Almen Praksis Bartholins Allé 2

8000 Århus

Hvis du IKKE har en Kronisk Obstruktiv Lungelidelse – KOL – beklager vi denne henvendelse og beder dig returnere skemaet i den vedlagte svarkurvert til Forskningsenheden for Almen Praksis i Århus.

☐ Jeg har IKKE KOL og returnerer skemaet i vedlagte svarkuvert. Portoen er betalt.

NÅR VI SKRIVER KOL, KRONISK OBSTRUKTIV LUNGELIDELSE, DÆKKER DET UDTRYK

SOM KRONISK BRONKITIS, EMFYSEM, RYGERLUNGER, SLIDTE LUNGER OG LIGNENDE.

1. DIT HELBRED

a. Hvor længe har du haft KOL?

☐☐ år ☐☐ måneder

b. Hvem fortalte dig først, at du har KOL?
Sæt kun ét kryds.

- ☐ Min praktiserende læge
- ☐ Klinikpersonalet i min lægepraksis
- ☐ Sygehuslæge
- ☐ Privatpraktiserende speciallæge
- ☐ En anden, hvem? _____

c. Har du inden for <u>de sidste 12 måneder</u> haft en eller flere af nedenstående sygdomme?
Sæt gerne flere krydser, hvis det er relevant.

- ☐ Forhøjet blodtryk, åreforkalkning, hjertekrampe, blodprop eller hjerneblødning
- ☐ Aldersdiabetes/type 2-sukkersyge
- ☐ Slidgigt, leddegigt, diskusprolaps, rygsygdom eller dårlig ryg
- ☐ Psykisk sygdom eller mentale forstyrrelser
- ☐ Migræne eller hyppig hovedpine
- ☐ Kræft
- ☐ Forbigående psykisk lidelse, fx let depression eller angst
- ☐ Andet, hvad?_____ ☐☐☐

d. Hvordan synes du, at dit helbred er alt i alt?
Sæt kun ét kryds.

- ☐ Fremragende
- ☐ Vældigt godt
- ☐ Godt
- ☐ Mindre godt
- ☐ Dårligt

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2. DIN HVERDAG

a. Hvor svær er din åndenød, når du anstrenger dig?
Sæt kun ét kryds - i den boks, der passer bedst på dig.

- ☐ Jeg får kun åndenød, når jeg anstrenger mig meget
- ☐ Jeg får kun åndenød, når jeg skynder mig op ad en lille bakke
- ☐ Går langsommere end andre i samme alder på grund af åndenød eller må stoppe for at få luft ved almindelig gang i fladt terræn
- ☐ Jeg stopper op for at få vejret efter cirka 100 meter eller efter få minuters gang på stedet
- ☐ Jeg har for meget åndenød til at forlade mit hjem, eller jeg får åndenød, når jeg tager mit tøj af eller på

b. Hvor mange nætter i løbet af den sidste uge har du haft problemer med at falde i søvn på grund af KOL?
Sæt kun ét kryds.

- ☐ Jeg har ikke haft problemer med at falde i søvn på grund af KOL
- ☐ Nogle få nætter
- ☐ Flere nætter
- ☐ Hver eneste nat

c. Hvor mange nætter i løbet af den sidste uge er du vågnet om natten på grund af KOL?
Sæt kun ét kryds.

- ☐ Jeg er slet ikke vågnet om natten på grund af KOL
- ☐ Nogle få nætter
- ☐ Flere nætter
- ☐ Hver eneste nat

d. Hvor meget motion får du i løbet af en dag?
Ved motion menes al bevægelse i dagligdagen. Havearbejde, gåture og lign. er også motion.
Sæt kun ét kryds.

- ☐ Mindre end et kvarter pr. dag
- ☐ Et kvarter til en halv time pr. dag
- ☐ En halv time til en time pr. dag
- ☐ Mere end en time pr. dag

e. Hvordan vurderer du din fysiske form alt i alt?
Sæt kun ét kryds.

- ☐ Fremragende
- ☐ Vældig god
- ☐ God
- ☐ Mindre god
- ☐ Dårlig

f. Hvor vigtigt er det for dig at være mere fysisk aktiv, end du er nu?
Sæt kun ét kryds.

- ☐ Meget
- ☐ Noget
- ☐ Lidt
- ☐ Ikke vigtigt
- ☐ Ved ikke

3. NEDENFOR SPØRGER VI IGEN OM DIN HVERDAG

Du synes måske, at vi spørger om det samme som andre steder. Afkryds alligevel fem steder.

Sæt kun ét kryds ud for det af de tre udsagn inden for hver kategori, der passer bedst på dig.

Bevægelighed	☐ Jeg har ingen problemer med at gå omkring
	☐ Jeg har nogle problemer med at gå omkring
	☐ Jeg er bundet til sengen
Personlig pleje	☐ Jeg har ingen problemer med min personlige pleje
	☐ Jeg har nogle problemer med at vaske mig eller klæde mig på
	☐ Jeg kan ikke vaske mig eller klæde mig på
Sædvanlige aktiviteter Arbejde, studie, husarbejde, familie- eller fritidsaktiviteter.	☐ Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter
	☐ Jeg har nogle problemer med at udføre mine sædvanlige aktiviteter
	☐ Jeg kan ikke udføre mine sædvanlige aktiviteter
Smerter/ubehag	☐ Jeg har ingen smerter eller ubehag
	☐ Jeg har moderate smerter eller ubehag
	☐ Jeg har ekstreme smerter eller ubehag
Angst/depression	☐ Jeg er ikke ængstelig eller deprimeret
	☐ Jeg er moderat ængstelig eller deprimeret
	☐ Jeg er ekstremt ængstelig eller deprimeret

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4. HVORDAN DU HAR DET PSYKISK OG FØLELSESMÆSSIGT

Sæt kun ét kryds i hver række.

I de sidste 4 uger hvor meget har du været generet af:	Slet ikke	Lidt	Noget	En hel del	Virkelig meget
At du pludselig blev bange uden grund?	☐	☐	☐	☐	☐
Nervøsitet eller indre uro?	☐	☐	☐	☐	☐
At bekymre dig for meget?	☐	☐	☐	☐	☐
At føle dig nedtrykt?	☐	☐	☐	☐	☐
En følelse af ingenting at være værd?	☐	☐	☐	☐	☐
Tanken om at gøre ende på dit liv?	☐	☐	☐	☐	☐
En følelse af at være fanget i en fælde?	☐	☐	☐	☐	☐
At føle dig ensom?	☐	☐	☐	☐	☐
Selvbebrejdelser?	☐	☐	☐	☐	☐

5. DIG OG SUNDHEDSVÆSENET

Sæt ét kryds på skalaen fra 0-10, hvor 0 er mindst muligt og 10 er mest muligt.

a. Hvor meget støtte giver din praktiserende læge dig til at håndtere din KOL?

Mindst mulig ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Mest mulig

b. Hvor meget ved du om, hvad der skal foregå ved et planlagt besøg om KOL hos din praktiserende læge?

Mindst muligt ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Mest muligt

fortsat ... DIG OG SUNDHEDSVÆSENET

Sæt ét kryds på skalaen fra 0-10, hvor 0 er mindst muligt og 10 er mest muligt.

c. Hvor meget deltager du i beslutningerne om behandlingen af din KOL?

Mindst muligt ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Mest muligt

d. I hvor høj grad oplever du, at sygehuset, kommunen og din praktiserende læge sørger for at dele oplysninger om dig og din KOL?

Mindst muligt ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Mest muligt

6. DIG OG RYGNING

a. Bliver der røget indendørs i dit hjem?
Sæt kun ét kryds.

☐ Ja, hver dag

☐ Ja, mindst en gang om måneden

☐ Nej, aldrig eller næsten aldrig

b. Har du en ægtefælle/samlever, der ryger?
Sæt kun ét kryds.

☐ Ja.

☐ Nej

c. Ryger du?
Sæt kun ét kryds.

☐ Ja, hver dag

☐ Ja, mindst én gang om ugen

☐ Ja, mindst én gang om måneden

☐ Nej, jeg ryger ikke. .....*Gå venligst til spørgsmål* **7.a.** *på side* **7**

d. I hvor mange år har du røget dagligt?

☐☐ år

fortsat ... DIG OG RYGNING.

e. Hvor meget ryger du i løbet af et døgn?

☐☐☐ Antal cigaretter

☐☐☐ Antal cerutter

☐☐☐ Antal cigarer

☐☐☐ Antal pibestop

f. Har din egen læge rådet dig til at holde op med at ryge?
Sæt kun ét kryds.

☐ Ja

☐ Nej

☐ Ved ikke

g. Vil du gerne holde op med at ryge?
Sæt kun ét kryds.

☐ Ja

☐ Nej

☐ Ved ikke

h. Vil du gerne have støtte og hjælp til at holde op med at ryge?
Sæt kun ét kryds.

☐ Ja

☐ Nej

☐ Ved ikke

i. Kender du til rygestopstilbud i din omegn?
Sæt gerne flere krydser.

☐ Ja, hos min praktiserende læge

☐ Ja, hos klinikpersonalet i min lægepraksis

☐ Ja, på apoteket

☐ Ja, på Sundhedscenter Vest i Tarm

☐ Ja, hos en klog kone/mand

☐ Ja, på internettet

☐ Ja, tilbud fra patientforeninger

☐ Ja, andet, hvad?_____

☐ Nej

7. HVORDAN DU BENYTTER SUNDHEDSVÆSENET

a. Hvor ofte har du inden for de seneste 12 måneder besøgt din egen læge på grund af din KOL?
Sæt kun ét kryds.

- ☐ 5 eller flere gange
- ☐ 3-4 gange
- ☐ 1-2 gange
- ☐ Jeg har ikke været hos min egen læge de sidste 12 måneder på grund af KOL

b. Har du inden for de seneste 12 måneder haft en forværring af din KOL, som medførte besøg af en vagtlæge?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

c. Har du inden for de seneste 12 måneder haft en forværring af din KOL, som medførte besøg på en skadestue?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

d. Har du inden for de seneste 12 måneder haft en forværring af din KOL, som medførte indlæggelse på et sygehus?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

8. HVAD DER SKER HOS DIN EGEN PRAKTISERENDE LÆGE

a. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder målt din lungefunktion?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Ved ikke/kan ikke huske

fortsat ... HVAD DER SKER HOS DIN EGEN PRAKTISERENDE LÆGE

b. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder rådet dig til at dyrke mere motion?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

c. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder rådet dig til at holde øje med din vægt?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

d. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder tilbudt dig til at blive vaccineret mod influenza?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

e. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder vist dig, hvordan din inhalator bruges?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke
- ☐ Jeg bruger ikke inhalator

f. Har du en recept på penicillin liggende hjemme, som du kan indløse i tilfælde af forværring af din KOL?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/Ved ikke

9. INFORMATIONER OM DIN MEDICIN

a. Hvornår regulerede en læge sidst medicinen, du tager for din KOL?
Cirka dato.

☐☐ Måned ☐☐☐☐ År ☐ Tager ikke medicin for KOL....*Gå venligst til spørgsmål* **10**

b. Hvordan fik du sidste gang fornyet din recept på medicinen for din KOL?
Sæt kun ét kryds.

- ☐ Ved besøg hos min praktiserende læge
- ☐ Ved telefonsamtale med min praktiserende læge
- ☐ Ved et besøg hos praksispersonalet i min lægepraksis
- ☐ Ved telefonisk henvendelse til praksispersonalet i min lægepraksis
- ☐ På sygehuset
- ☐ Ved et besøg hos privatpraktiserende speciallæge
- ☐ Kan ikke huske

DE NÆSTE SPØRGSMÅL (10-13) ER RET OMFATTENDE. DET VIL NOK VÆRE EN GOD IDE AT TAGE EN PAUSE, FØR DU GÅR I GANG MED DEM, DA VI RIGTIG GERNE VIL HAVE, AT DU BESVARER ALLE SPØRGSMÅL I SKEMAET.

PAUSE

10. DIG OG DIN LÆGEPRAKSIS
Sæt kun ét kryds i hver række.

Når du tænker tilbage på de seneste 12 måneder, hvordan vurderer du så din praktiserende læges praksis med hensyn til:	Dårlig ▼	Nogen-lunde ▼	God ▼	Meget god ▼	Ene-stående ▼	Kan ikke svare ▼
Det ikke-lægelige personales hjælpsomhed?	☐	☐	☐	☐	☐	☐
At få en tid, der passer dig?	☐	☐	☐	☐	☐	☐
At få kontakt med lægepraksis i telefonen?	☐	☐	☐	☐	☐	☐
At få kontakt med lægen i telefonen?	☐	☐	☐	☐	☐	☐
At yde hurtig hjælp ved presserende sygdom?	☐	☐	☐	☐	☐	☐

11. DIG OG DIN PRAKTISERENDE LÆGE

Sæt kun ét kryds i hver række.

Når du tænker tilbage på de seneste 12 måneder, hvordan vurderer du så din praktiserende læge med hensyn til:	Dårlig ▼	Nogen-lunde ▼	God ▼	Meget god ▼	Ene-stående ▼	Kan ikke svare ▼
At få dig til at føle, at der er tid til dig under konsultationen?	☐	☐	☐	☐	☐	☐
At vise interesse for din situation?	☐	☐	☐	☐	☐	☐
At gøre det let for dig at fortælle om dine problemer?	☐	☐	☐	☐	☐	☐
At inddrage dig i beslutninger?	☐	☐	☐	☐	☐	☐
At lytte til dig?	☐	☐	☐	☐	☐	☐
At sørge for hurtigt at lindre dine symptomer?	☐	☐	☐	☐	☐	☐
At hjælpe dig til at få det så godt, at du kan udføre dine normale aktiviteter?	☐	☐	☐	☐	☐	☐
At være omhyggelig ved behandling af dine problemer?	☐	☐	☐	☐	☐	☐
At undersøge dig?	☐	☐	☐	☐	☐	☐
At forklare formålet med undersøgelser og behandlinger?	☐	☐	☐	☐	☐	☐
At tale med dig om dine symptomer og din sygdom, så du føler dig velinformeret?	☐	☐	☐	☐	☐	☐
At hjælpe dig til at håndtere dine følelser omkring dine helbredsproblemer?	☐	☐	☐	☐	☐	☐
At hjælpe dig til at følge lægens råd?	☐	☐	☐	☐	☐	☐
At vide hvad der er blevet sagt og gjort ved tidligere henvendelser til praksis?	☐	☐	☐	☐	☐	☐
At forberede dig på, hvad du kunne forvente af hospital, speciallæge eller andre behandlere?	☐	☐	☐	☐	☐	☐

12. DIN VURDERING AF STØTTEN FRA DIN PRAKTISERENDE LÆGE OG LÆGEPRAKSIS
Sæt kun ét kryds i hver række.

Når jeg inden for de seneste 6 måneder har været til behandling eller kontrol for min sygdom ...	Aldrig ▼	Som regel ikke ▼	Nogle gange ▼	For det meste ▼	Altid ▼
er jeg blevet spurgt om mine egne forslag, når vi lavede en plan for min behandling	☐	☐	☐	☐	☐
har jeg fået valget mellem forskellige behandlinger, som jeg kunne tænke over	☐	☐	☐	☐	☐
er jeg blevet bedt om at fortælle om evt. problemer med den medicin, jeg får, eller dens virkning	☐	☐	☐	☐	☐
har jeg fået udleveret en liste over ting, jeg burde gøre for at forbedre mit helbred	☐	☐	☐	☐	☐
har jeg følt mig tryg ved, at min behandling var godt tilrettelagt	☐	☐	☐	☐	☐
har jeg fået forklaret, hvordan det, jeg selv gør for at passe på mit helbred, påvirker min sygdom	☐	☐	☐	☐	☐
er jeg blevet bedt om at tale om mine egne mål med at tage vare på min sygdom	☐	☐	☐	☐	☐
har jeg fået hjælp til at sætte konkrete mål for, hvordan jeg vil forbedre mine kost- eller motionsvaner	☐	☐	☐	☐	☐
har jeg fået en kopi af planen for min behandling	☐	☐	☐	☐	☐
er jeg blevet opfordret til at deltage i en gruppe eller på et kursus specielt rettet mod, at jeg kan blive bedre til at tage vare på min sygdom	☐	☐	☐	☐	☐
er jeg blevet stillet spørgsmål om mine sundhedsvaner enten direkte eller via et spørgeskema	☐	☐	☐	☐	☐
har jeg været sikker på, at min læge eller sygeplejerske har taget hensyn til mine holdninger og vaner, når de anbefalede forskellige behandlinger	☐	☐	☐	☐	☐
har jeg fået hjælp til at lave en plan for behandlingen, som jeg kan klare at gennemføre i dagligdagen	☐	☐	☐	☐	☐
har jeg fået hjælp til at forberede mig på, hvordan jeg kan tage vare på min sygdom selv i vanskelige perioder	☐	☐	☐	☐	☐

fortsat ... DIN VURDERING AF STØTTEN FRA DIN PRAKTISERENDE LÆGE OG PRAKSIS
Sæt kun ét kryds for hvert udsagn.

Når jeg inden for de seneste 6 måneder har været til behandling eller kontrol for min sygdom....	Aldrig ▼	Som regel ikke ▼	Nogle gange ▼	For det meste ▼	Altid ▼
er jeg blevet spurgt om, hvordan min kroniske sygdom påvirker mit liv	☐	☐	☐	☐	☐
har lægen, sygeplejersken eller andre efterfølgende kontaktet mig for at høre, hvordan det gik	☐	☐	☐	☐	☐
er jeg blevet opfordret til at deltage i aktiviteter i lokalsamfundet, som jeg kunne have gavn af	☐	☐	☐	☐	☐
er jeg blevet henvist til endiætist eller en anden person, der kan rådgive eller undervise om sundhed	☐	☐	☐	☐	☐
har jeg fået forklaret, hvordan mine besøg hos andre læger fx en øjenlæge eller en anden speciallæge, gavner min behandling	☐	☐	☐	☐	☐
er jeg blevet spurgt om, hvordan det er gået, når jeg har været hos andre læger	☐	☐	☐	☐	☐

13. HVORDAN DU OPLEVER SAMARBEJDET OM DIN BEHANDLING
Sæt kun ét kryds for hvert udsagn.

Hvor enig er du i følgende udsagn?	Meget uenig ▼	Uenig ▼	Enig ▼	Meget enig ▼	Ved ikke ▼	Ikke relevant ▼
Jeg oplever, at samarbejdet mellem **min egen læge og hjemmesygeplejersken** fungerer tilfredsstillende	☐	☐	☐	☐	☐	☐
Jeg oplever, at samarbejdet mellem **sygehuset og hjemmesygeplejersken** fungerer tilfredsstillende	☐	☐	☐	☐	☐	☐
Jeg oplever, at **min egen læge** har kendskab, til hvad der sker på sygehuset	☐	☐	☐	☐	☐	☐
Jeg føler, at **min egen læge** er tilstrækkeligt involveret i mit forløb	☐	☐	☐	☐	☐	☐
Jeg oplever, at der er for mange forskellige læger og sygeplejersker involveret i mit forløb	☐	☐	☐	☐	☐	☐

14. DAGLIGDAGEN OG DEN STØTTE DU HAR

a. Hvor ofte er du i kontakt med familie, som du ikke bor sammen med?
Sæt kun ét kryds.

- ☐ Dagligt eller næsten dagligt
- ☐ Et par gange om ugen
- ☐ Et par gange om måneden
- ☐ Sjældnere end et par gange om måneden
- ☐ Aldrig
- ☐ Ved ikke

b. Hvor ofte er du i kontakt med venner og bekendte, som du ikke bor sammen med?
Sæt kun ét kryds.

- ☐ Dagligt eller næsten dagligt
- ☐ Et par gange om ugen
- ☐ Et par gange om måneden
- ☐ Sjældnere end et par gange om måneden
- ☐ Aldrig
- ☐ Ved ikke

c. Har du inden for de seneste 12 måneder været i biografen, til koncert, til familiefest, sammenkomst med venner eller lignende?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/Ved ikke

d. Hvis du har brug for hjælp til praktiske problemer, kan du da regne med at få hjælp fra andre?
Sæt kun ét kryds.

- ☐ Ja, helt sikkert
- ☐ Ja, måske
- ☐ Nej
- ☐ Ved ikke

fortsat ... DAGLIGDAGEN OG DEN STØTTE DU HAR

e. Sker det nogensinde, at du er alene, selv om du mest har lyst til at være sammen med andre?
Sæt kun ét kryds.

- ☐ Ja, ofte
- ☐ Ja, en gang imellem
- ☐ Ja, sjældent
- ☐ Nej
- ☐ Ved ikke

f. Har du et kæledyr, som du føler dig knyttet til?

☐ Ja ☐ Nej

Hvis ja, hvilket?

- ☐ Hund
- ☐ Kat
- ☐ Fugl
- ☐ Andet, hvad?_____

15. GENERELLE OPLYSNINGER OM DIG

a. Hvem bor i din husholdning?
Sæt kun ét kryds.

- ☐ Jeg bor alene
- ☐ Jeg bor sammen med mine børn
- ☐ Jeg bor sammen med min ægtefælle/samlever
- ☐ Jeg bor sammen med børn og ægtefælle/samlever
- ☐ Jeg bor i kollektiv/med venner
- ☐ Jeg bor sammen med andre, hvem?_____

fortsat ... OPLYSNINGER OM NOGLE AF DINE PERSONLIGE FORHOLD

b. Ejer du selv eller andre i din husstand den bolig, du bor i?
Sæt kun ét kryds.

☐ Ja

☐ Nej

c. Ejer du selv eller andre i din husstand en bil?
Sæt kun ét kryds.

☐ Ja

☐ Nej

d. Hvor stor var din husstandsindkomst før skat og andre fradrag sidste år?
Sæt kun ét kryds.

☐ 0 - 99.999 kr.

☐ 100.000 - 249.999 kr.

☐ 250.000 - 449.999 kr.

☐ 450.000 - 700.000 kr.

☐ 700.000 kr. eller mere

☐ Ved ikke

e. Hvilken erhvervsuddannelse har du?
Sæt kun ét kryds. Hvis du har flere uddannelser, så vælg den længstvarende.

☐ Ingen

☐ Et eller flere kortere kurser, fx specialarbejderkurser, arbejdsmarkedskurser

☐ Faglært indenfor et håndværk, handel eller kontor, fx lærlinge- eller EFG-uddannelse

☐ Kort videregående uddannelse under 3 år, fx social- og sundhedsassistent, politibetjent

☐ Mellemlang videregående uddannelse 3-4 år, fx folkeskolelærer, journalist, socialrådgiver

☐ Lang videregående uddannelse på 5 år eller mere, fx civilingeniør, læge, cand.scient., jurist

☐ Andet, hvad?_____

fortsat ... OPLYSNINGER OM NOGLE AF DINE PERSONLIGE FORHOLD

f. Hvad er din nuværende erhvervsmæssige stilling?
Sæt kun ét kryds.

- ☐ Specialarbejder eller ufaglært arbejder
- ☐ Hjemmegående uden andet arbejde
- ☐ Faglært arbejder
- ☐ Funktionær eller tjenestemand
- ☐ Selvstændig erhvervsdrivende eller medhjælpende ægtefælle
- ☐ Lærling, elev, studerende
- ☐ I flexjob som:_____
- ☐ Folkepensionist
- ☐ Førtidspensionist
- ☐ På efterløn
- ☐ Arbejdsløs med understøttelse
- ☐ På kontanthjælp
- ☐ På orlov, fx barselsorlov, uddannelsesorlov eller lignende
- ☐ Andet, hvad?_____

g. Hvor høj er du?

☐☐☐ cm

h. Hvor meget vejer du i hele kilogram/kg?

☐☐☐ kg

Hvis du har noget, du vil uddybe eller tilføje, er du velkommen til at skrive det her:

MANGE TAK FOR DIN HJÆLP

Ved en kronisk lungesygdom, mener vi det, der i daglig tale kaldes for KOL – Kronisk Obstruktiv Lungesygdom. KOL er kendetegnet ved, at du har åndenød, når du anstrenger dig, du hoster og måske har du slim, som kommer med op, når du hoster.

Kronisk betyder, at man skal leve med sygdommen resten af livet. Udviklingen af sygdommen kan bremses, men den forsvinder aldrig helt igen.

Obstruktiv betyder, at luftvejene er forsnævrede, således at transporten af luft kræver et større arbejde af kroppen end normalt.

Når diagnosen KOL bliver stillet, er de fleste over 50 år, men sygdommen er snigende, så man kan have været syg i mange år, før man får diagnosen stillet. Åndenød, når man anstrenger sig, er et typisk tegn på KOL. Åndenøden skyldes, at lungefunktionen er nedsat permanent.

Du kan læse meget mere om KOL på Dansk Lungeforenings hjemmeside om KOL:

http://www.kol.dk

ENDNU ENGANG TAK FOR DIN HJÆLP, OG AT DU DELTAGER I PROJEKTET.

APPENDIX II

II.1 Follow-up questionnaire

Vi sender dette spørgeskema til dig, fordi du sidste år svarede på et lignende spørgeskema omkring dine lunger. Din læge eller en anden i sundhedsvæsenet har måske fortalt dig, at du har astmatisk bronkitis, rygerlunger, emfysem, slidte lunger eller noget lignende. Det er det, der under ét hedder KOL.

Vi skal understrege, at vi ikke ved noget, som du ikke allerede selv har fået at vide.

En del af spørgsmålene er de samme som sidste år, nogle er nye og andre er fjernet. Din situation kan have ændret sig eller være den samme; under alle omstændigheder er det vigtigt, at så mange som muligt svarer for at få det bedste resultat af undersøgelsen.

Derfor vil vi bede dig udfylde dette spørgeskema.

Vi vil bede dig om - med en blå eller sort pen - at sætte et kryds i boksen ved det svar, der umiddelbart passer bedst på dig.

Hvis du sætter et kryds det forkerte sted, skal du bare strege det forkerte ud og sætte et nyt kryds.

Eksempel: Korrekt afkrydsning: Fortrudt afkrydsning:

Du er velkommen til at kontakte os, hvis du er i tvivl eller har spørgsmål.

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NÅR VI SKRIVER KOL, KRONISK OBSTRUKTIV LUNGELIDELSE, DÆKKER DET UDTRYK

SOM KRONISK BRONKITIS, EMFYSEM, RYGERLUNGER, SLIDTE LUNGER OG LIGNENDE.

1. DIT HELBRED

a. Hvordan synes du, at dit helbred er alt i alt?
Sæt kun ét kryds.

- ☐ Fremragende
- ☐ Vældig godt
- ☐ Godt
- ☐ Mindre godt
- ☐ Dårligt

b. Har du inden for de seneste 12 måneder haft en eller flere af nedenstående sygdomme?
Sæt gerne flere krydser, hvis det er relevant.

- ☐ Forhøjet blodtryk, åreforkalkning, hjertekrampe, blodprop eller hjerneblødning
- ☐ Aldersdiabetes/type 2-sukkersyge
- ☐ Slidgigt, leddegigt, diskusprolaps, rygsygdom eller dårlig ryg
- ☐ Psykisk sygdom eller mentale forstyrrelser
- ☐ Migræne eller hyppig hovedpine
- ☐ Kræft
- ☐ Forbigående psykisk lidelse, fx let depression eller angst
- ☐ Andet, hvad?_____

Udfyldes ikke
Til kodning
☐☐☐

2. DIN HVERDAG

a. Hvor svær er din åndenød, når du anstrenger dig?
Sæt kun ét kryds - i den boks, der passer bedst på dig.

- ☐ Jeg får kun åndenød, når jeg anstrenger mig meget
- ☐ Jeg får kun åndenød, når jeg skynder mig op ad en lille bakke
- ☐ Går langsommere end andre i samme alder på grund af åndenød eller må stoppe for at få luft ved almindelig gang i fladt terræn
- ☐ Jeg stopper op for at få vejret efter cirka 100 meter eller efter få minutters gang på stedet
- ☐ Jeg har for meget åndenød til at forlade mit hjem, eller jeg får åndenød, når jeg tager mit tøj af eller på

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fortsat... DIN HVERDAG

b. Hvor mange nætter i løbet af den sidste uge har du haft problemer med at falde i søvn på grund af KOL?
Sæt kun ét kryds.

- ☐ Jeg har ikke haft problemer med at falde i søvn på grund af KOL
- ☐ Nogle få nætter
- ☐ Flere nætter
- ☐ Hver eneste nat

c. Hvor mange nætter i løbet af den sidste uge er du vågnet om natten på grund af KOL?
Sæt kun ét kryds.

- ☐ Jeg er slet ikke vågnet om natten på grund af KOL
- ☐ Nogle få nætter
- ☐ Flere nætter
- ☐ Hver eneste nat

d. Hvor meget motion får du i løbet af en dag?
Ved motion menes al bevægelse i dagligdagen. Havearbejde, gåture og lign. er også motion.
Sæt kun ét kryds.

- ☐ Mindre end et kvarter pr. dag
- ☐ Et kvarter til en halv time pr. dag
- ☐ En halv time til en time pr. dag
- ☐ Mere end en time pr. dag

e. Hvordan vurderer du din fysiske form alt i alt?
Sæt kun ét kryds.

- ☐ Fremragende
- ☐ Vældig god
- ☐ God
- ☐ Mindre god
- ☐ Dårlig

f. Hvor vigtigt er det for dig at være mere fysisk aktiv, end du er nu?
Sæt kun ét kryds.

- ☐ Meget
- ☐ Noget
- ☐ Lidt
- ☐ Ikke vigtigt
- ☐ Ved ikke

3. NEDENFOR SPØRGER VI IGEN OM DIN HVERDAG

Du synes måske, at vi spørger om det samme som andre steder. Afkryds alligevel fem steder.

Sæt kun ét kryds ud for det af de tre udsagn inden for hver kategori, der passer bedst på dig.

Bevægelighed	☐ Jeg har ingen problemer med at gå omkring
	☐ Jeg har nogle problemer med at gå omkring
	☐ Jeg er bundet til sengen
Personlig pleje	☐ Jeg har ingen problemer med min personlige pleje
	☐ Jeg har nogle problemer med at vaske mig eller klæde mig på
	☐ Jeg kan ikke vaske mig eller klæde mig på
Sædvanlige aktiviteter Arbejde, studie, husarbejde, familie- eller fritidsaktiviteter	☐ Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter
	☐ Jeg har nogle problemer med at udføre mine sædvanlige aktiviteter
	☐ Jeg kan ikke udføre mine sædvanlige aktiviteter
Smerter/ubehag	☐ Jeg har ingen smerter eller ubehag
	☐ Jeg har moderate smerter eller ubehag
	☐ Jeg har ekstreme smerter eller ubehag
Angst/depression	☐ Jeg er ikke ængstelig eller deprimeret
	☐ Jeg er moderat ængstelig eller deprimeret
	☐ Jeg er ekstremt ængstelig eller deprimeret

Udfyldes ikke Til kodning ☐☐☐

Udfyldes ikke Til kodning ☐☐☐

4. HVORDAN DU HAR DET PSYKISK OG FØLELSESMÆSSIGT

Sæt kun ét kryds i hver række.

I de sidste 4 uger hvor meget har du været generet af:	Slet ikke	Lidt	Noget	En hel del	Virkelig meget
At du pludselig blev bange uden grund?	☐	☐	☐	☐	☐
Nervøsitet eller indre uro?	☐	☐	☐	☐	☐
At bekymre dig for meget?	☐	☐	☐	☐	☐
At føle dig nedtrykt?	☐	☐	☐	☐	☐
En følelse af ingenting at være værd?	☐	☐	☐	☐	☐
Tanken om at gøre ende på dit liv?	☐	☐	☐	☐	☐
En følelse af at være fanget i en fælde?	☐	☐	☐	☐	☐
At føle dig ensom?	☐	☐	☐	☐	☐
Selvbebrejdelser?	☐	☐	☐	☐	☐

5. DIG OG SUNDHEDSVÆSENET

Sæt ét kryds på skalaen fra 0-10, hvor 0 er mindst muligt og 10 er mest muligt.

a. Hvor meget støtte giver din praktiserende læge dig til at håndtere din KOL?

Mindst muligt ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Mest muligt

b. Hvor meget ved du om, hvad der skal foregå ved et planlagt besøg om KOL hos din praktiserende læge?

Mindst muligt ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Mest muligt

fortsat ... DIG OG SUNDHEDSVÆSENET

Sæt ét kryds på skalaen fra 0-10, hvor 0 er mindst muligt og 10 er mest muligt.

c. Hvor meget deltager du i beslutningerne om behandlingen af din KOL?

Mindst muligt ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Mest muligt

d. I hvor høj grad oplever du, at sygehuset, kommunen og din praktiserende læge sørger for at dele oplysninger om dig og din KOL?

Mindst muligt ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Mest muligt

6. DIG OG RYGNING

a. Bliver der røget indendørs i dit hjem?
Sæt kun ét kryds.

- ☐ Ja, hver dag
- ☐ Ja, mindst en gang om måneden
- ☐ Nej, aldrig eller næsten aldrig

b. Har du en ægtefælle/samlever, der ryger?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej

c. Ryger du?
Sæt kun ét kryds.

- ☐ Ja, hver dag
- ☐ Ja, mindst én gang om ugen
- ☐ Ja, mindst én gang om måneden
- ☐ Nej, men jeg har røget
- ☐ Nej, jeg ryger ikke

d. I hvor mange år har du røget dagligt?

☐☐ år

☐ Jeg har aldrig røget

fortsat ... DIG OG RYGNING

KUN FOR RYGERE
Hvis du ikke ryger på nuværende tidspunkt, så gå venligst videre til spørgsmål 7.

e. Hvor meget ryger du i løbet af et døgn?

☐☐☐ Antal cigaretter
☐☐☐ Antal cerutter
☐☐☐ Antal cigarer
☐☐☐ Antal pibestop

f. Har din egen læge rådet dig til at holde op med at ryge?
Sæt kun ét kryds.

☐ Ja
☐ Nej
☐ Ved ikke

g. Vil du gerne holde op med at ryge?
Sæt kun ét kryds.

☐ Ja
☐ Nej
☐ Ved ikke

h. Vil du gerne have støtte og hjælp til at holde op med at ryge?
Sæt kun ét kryds.

☐ Ja
☐ Nej
☐ Ved ikke

i. Kender du til rygestoptilbud i din omegn?
Sæt gerne flere krydser.

☐ Ja, hos min praktiserende læge
☐ Ja, hos klinikpersonalet i min lægepraksis
☐ Ja, på apoteket
☐ Ja, på Sundhedscenter Vest i Tarm
☐ Ja, hos en klog kone/mand
☐ Ja, på internettet
☐ Ja, tilbud fra patientforeninger
☐ Ja, andet, hvad?_____
☐ Nej

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7. HVORDAN DU BENYTTER SUNDHEDSVÆSENET

a. Hvor ofte har du inden for de seneste 12 måneder besøgt din praktiserende læge på grund af din KOL?

- ☐ 5 eller flere gange
- ☐ 3-4 gange
- ☐ 1-2 gange
- ☐ Jeg har ikke været hos min egen læge de seneste 12 måneder på grund af KOL

b. Har du inden for de seneste 12 måneder haft en forværring af din KOL, som medførte besøg af en vagtlæge?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

c. Har du inden for de seneste 12 måneder haft en forværring af din KOL, som medførte besøg på en skadestue?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

d. Har du inden for de seneste 12 måneder haft en forværring af din KOL, som medførte indlæggelse på et sygehus?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

8. HVAD DER SKER HOS DIN PRAKTISERENDE LÆGE

a. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder målt din lungefunktion?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

fortsat ... HVAD DER SKER HOS DIN PRAKTISERENDE LÆGE

b. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder rådet dig til at dyrke mere motion?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

c. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder rådet dig til at holde øje med din vægt?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

d. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder tilbudt dig at blive vaccineret mod influenza?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

e. Har din egen læge eller praksispersonalet inden for de seneste 12 måneder vist dig, hvordan din inhalator bruges?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke
- ☐ Jeg bruger ikke inhalator

f. Har du en recept på penicillin liggende hjemme, som du kan indløse i tilfælde af forværring af din KOL?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

fortsat... HVAD DER SKER HOS DIN PRAKTISERENDE LÆGE

g. Har du inden for de seneste 12 måneder været indkaldt til en kontrol for din KOL hos din praktiserende læge?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

h. Ved du, hvornår du skal til en kontrol for din KOL hos din praktiserende læge?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Har ikke en aftale om kontrol for min KOL
- ☐ Kan ikke huske/ved ikke

i. Har din praktiserende læge eller praksispersonalet givet dig en PEP-fløjte?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

j. Har din praktiserende læge eller praksispersonalet givet dig et handlingskort, hvor du kan se, hvad du skal gøre, hvis din KOL bliver værre?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

k. Har din praktiserende læge eller praksispersonalet inden for de seneste 12 måneder henvist dig til kommunens rygestopkurser?
Sæt kun ét kryds.

- ☐ Ikke aktuelt, jeg ryger ikke
- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

l. Har din praktiserende læge inden for de seneste 12 måneder henvist dig til et forløb for KOL på sundhedscenteret?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

9. INFORMATIONER OM DIN MEDICIN

a. Hvornår regulerede en læge sidst den medicin, du tager for din KOL?
Cirka tidspunkt.

☐☐ Måned ☐☐☐☐ År ☐ Tager ikke medicin for KOL....*Gå venligst til spørgsmål* **10**

b. Hvordan fik du sidste gang fornyet din recept på medicinen for din KOL?
Sæt kun ét kryds.

- ☐ Ved et besøg hos min praktiserende læge
- ☐ Ved en telefonsamtale med min praktiserende læge
- ☐ Ved et besøg hos praksispersonalet i min lægepraksis
- ☐ Ved en telefonsamtale med praksispersonalet i min lægepraksis
- ☐ På sygehuset
- ☐ Ved et besøg hos privatpraktiserende speciallæge
- ☐ Kan ikke huske

DE NÆSTE SPØRGSMÅL (10-13) ER RET OMFATTENDE. DET VIL NOK VÆRE EN GOD IDE AT TAGE EN PAUSE, FØR DU GÅR I GANG MED DEM, DA VI RIGTIG GERNE VIL HAVE, AT DU BESVARER ALLE SPØRGSMÅL I SKEMAET.

PAUSE

10. DIG OG DIN LÆGEPRAKSIS
Sæt kun ét kryds i hver række.

Når du tænker tilbage på de seneste 12 måneder, hvordan vurderer du så din praktiserende læges praksis med hensyn til:	Dårlig ▼	Nogen-lunde ▼	God ▼	Meget god ▼	Ene-stående ▼	Kan ikke svare ▼
Det ikke-lægelige personales hjælpsomhed?	☐	☐	☐	☐	☐	☐
At få en tid, der passer dig?	☐	☐	☐	☐	☐	☐
At få kontakt med lægepraksis i telefonen?	☐	☐	☐	☐	☐	☐
At få kontakt med lægen i telefonen?	☐	☐	☐	☐	☐	☐
At yde hurtig hjælp ved presserende sygdom?	☐	☐	☐	☐	☐	☐

11. DIG OG DIN PRAKTISERENDE LÆGE

Sæt kun ét kryds i hver række.

Når du tænker tilbage på de seneste 12 måneder, hvordan vurderer du så din praktiserende læge med hensyn til:	Dårlig ▼	Nogen-lunde ▼	God ▼	Meget god ▼	Ene-stående ▼	Kan ikke svare ▼
At få dig til at føle, at der er tid til dig under konsultationen?	☐	☐	☐	☐	☐	☐
At vise interesse for din situation?	☐	☐	☐	☐	☐	☐
At gøre det let for dig at fortælle om dine problemer?	☐	☐	☐	☐	☐	☐
At inddrage dig i beslutninger?	☐	☐	☐	☐	☐	☐
At lytte til dig?	☐	☐	☐	☐	☐	☐
At sørge for hurtigt at lindre dine symptomer?	☐	☐	☐	☐	☐	☐
At hjælpe dig til at få det så godt, at du kan udføre dine normale aktiviteter?	☐	☐	☐	☐	☐	☐
At være omhyggelig ved behandling af dine problemer?	☐	☐	☐	☐	☐	☐
At undersøge dig?	☐	☐	☐	☐	☐	☐
At forklare formålet med undersøgelser og behandlinger?	☐	☐	☐	☐	☐	☐
At tale med dig om dine symptomer og din sygdom, så du føler dig velinformeret?	☐	☐	☐	☐	☐	☐
At hjælpe dig til at håndtere dine følelser omkring dine helbredsproblemer?	☐	☐	☐	☐	☐	☐
At hjælpe dig til at følge lægens råd?	☐	☐	☐	☐	☐	☐
At vide hvad der er blevet sagt og gjort ved tidligere henvendelser til praksis?	☐	☐	☐	☐	☐	☐
At forberede dig på, hvad du kunne forvente af hospital, speciallæge eller andre behandlere?	☐	☐	☐	☐	☐	☐

12. DIN VURDERING AF STØTTEN FRA DIN PRAKTISERENDE LÆGE OG LÆGEPRAKSIS

Sæt kun ét kryds i hver række.

Når jeg inden for de seneste 6 måneder har været til behandling eller kontrol for min sygdom ...	Aldrig ▼	Som regel ikke ▼	Nogle gange ▼	For det meste ▼	Altid ▼
er jeg blevet spurgt om mine egne forslag, når vi lavede en plan for min behandling	☐	☐	☐	☐	☐
har jeg fået valget mellem forskellige behandlinger, som jeg kunne tænke over	☐	☐	☐	☐	☐
er jeg blevet bedt om at fortælle om evt. problemer med den medicin, jeg får, eller dens virkning	☐	☐	☐	☐	☐
har jeg fået udleveret en liste over ting, jeg burde gøre for at forbedre mit helbred	☐	☐	☐	☐	☐
har jeg følt mig tryg ved, at min behandling var godt tilrettelagt	☐	☐	☐	☐	☐
har jeg fået forklaret, hvordan det, jeg selv gør for at passe på mit helbred, påvirker min sygdom	☐	☐	☐	☐	☐
er jeg blevet bedt om at tale om mine egne mål med at tage vare på min sygdom	☐	☐	☐	☐	☐
har jeg fået hjælp til at sætte konkrete mål for, hvordan jeg vil forbedre mine kost- eller motionsvaner	☐	☐	☐	☐	☐
har jeg fået en kopi af planen for min behandling	☐	☐	☐	☐	☐
er jeg blevet opfordret til at deltage i en gruppe eller på et kursus specielt rettet mod, at jeg kan blive bedre til at tage vare på min sygdom	☐	☐	☐	☐	☐
er jeg blevet stillet spørgsmål om mine sundhedsvaner enten direkte eller via et spørgeskema	☐	☐	☐	☐	☐
har jeg været sikker på, at min læge eller sygeplejerske har taget hensyn til mine holdninger og vaner, når de anbefalede forskellige behandlinger	☐	☐	☐	☐	☐
har jeg fået hjælp til at lave en plan for behandlingen, som jeg kan klare at gennemføre i dagligdagen	☐	☐	☐	☐	☐
har jeg fået hjælp til at forberede mig på, hvordan jeg kan tage vare på min sygdom selv i vanskelige perioder	☐	☐	☐	☐	☐

fortsat ... DIN VURDERING AF STØTTEN FRA DIN PRAKTISERENDE LÆGE OG LÆGEPRAKSIS
Sæt kun ét kryds i hver række.

Når jeg inden for de seneste 6 måneder har været til behandling eller kontrol for min sygdom....	Aldrig	Som regel ikke	Nogle gange	For det meste	Altid
er jeg blevet spurgt om, hvordan min kroniske sygdom påvirker mit liv	☐	☐	☐	☐	☐
har lægen, sygeplejersken eller andre efterfølgende kontaktet mig for at høre, hvordan det gik	☐	☐	☐	☐	☐
er jeg blevet opfordret til at deltage i aktiviteter i lokalsamfundet, som jeg kunne have gavn af	☐	☐	☐	☐	☐
er jeg blevet henvist til en diætist eller en anden person, der kan rådgive eller undervise om sundhed	☐	☐	☐	☐	☐
har jeg fået forklaret, hvordan mine besøg hos andre læger, fx en øjenlæge eller en anden speciallæge, gavner min behandling	☐	☐	☐	☐	☐
er jeg blevet spurgt om, hvordan det er gået, når jeg har været hos andre læger	☐	☐	☐	☐	☐

13. HVORDAN DU OPLEVER SAMARBEJDET OMKRING DIN BEHANDLING
Sæt kun ét kryds i hver række.

Hvor enig er du i følgende udsagn?	Meget uenig	Uenig	Enig	Meget enig	Ved ikke	Ikke relevant
Jeg oplever, at samarbejdet mellem **min egen læge og hjemmesygeplejersken** fungerer tilfredsstillende	☐	☐	☐	☐	☐	☐
Jeg oplever, at samarbejdet mellem **sygehuset og hjemmesygeplejersken** fungerer tilfredsstillende	☐	☐	☐	☐	☐	☐
Jeg oplever, at **min egen læge** har kendskab til, hvad der sker på sygehuset	☐	☐	☐	☐	☐	☐
Jeg føler, at **min egen læge** er tilstrækkeligt involveret i mit forløb	☐	☐	☐	☐	☐	☐
Jeg oplever, at der er for mange forskellige læger og sygeplejersker involveret i mit forløb	☐	☐	☐	☐	☐	☐

14. DAGLIGDAGEN OG DEN STØTTE DU HAR

a. Hvor ofte er du i kontakt med familie, som du ikke bor sammen med?
Sæt kun ét kryds.

- ☐ Dagligt eller næsten dagligt
- ☐ Et par gange om ugen
- ☐ Et par gange om måneden
- ☐ Sjældnere end et par gange om måneden
- ☐ Aldrig
- ☐ Ved ikke

b. Hvor ofte er du i kontakt med venner og bekendte, som du ikke bor sammen med?
Sæt kun ét kryds.

- ☐ Dagligt eller næsten dagligt
- ☐ Et par gange om ugen
- ☐ Et par gange om måneden
- ☐ Sjældnere end et par gange om måneden
- ☐ Aldrig
- ☐ Ved ikke

c. Har du inden for de seneste 12 måneder været i biografen, til koncert, til familiefest, sammenkomst med venner eller lignende?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej
- ☐ Kan ikke huske/ved ikke

d. Hvis du har brug for hjælp til praktiske problemer, kan du da regne med at få hjælp fra andre?
Sæt kun ét kryds.

- ☐ Ja, helt sikkert
- ☐ Ja, måske
- ☐ Nej
- ☐ Ved ikke

fortsat ... DAGLIGDAGEN OG DEN STØTTE DU HAR

e. Sker det nogensinde, at du er alene, selv om du mest har lyst til at være sammen med andre?
Sæt kun ét kryds.

- ☐ Ja, ofte
- ☐ Ja, en gang imellem
- ☐ Ja, sjældent
- ☐ Nej
- ☐ Ved ikke

15. OPLYSNINGER OM NOGLE AF DINE PERSONLIGE FORHOLD

a. Hvem bor i din husholdning?
Sæt kun ét kryds.

- ☐ Jeg bor alene
- ☐ Jeg bor sammen med mine børn
- ☐ Jeg bor sammen med min ægtefælle/samlever
- ☐ Jeg bor sammen med børn og ægtefælle/samlever
- ☐ Jeg bor i kollektiv/med venner
- ☐ Jeg bor sammen med andre, hvem?_____

b. Ejer du selv eller andre i din husstand den bolig, du bor i?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej

c. Ejer du selv eller andre i din husstand en bil?
Sæt kun ét kryds.

- ☐ Ja
- ☐ Nej

fortsat ... OPLYSNINGER OM NOGLE AF DINE PERSONLIGE FORHOLD

d. Hvad er din nuværende erhvervsmæssige stilling?
Sæt kun ét kryds.

- ☐ Specialarbejder eller ufaglært arbejder
- ☐ Hjemmegående uden andet arbejde
- ☐ Faglært arbejder
- ☐ Funktionær eller tjenestemand
- ☐ Selvstændig erhvervsdrivende eller medhjælpende ægtefælle
- ☐ Lærling, elev, studerende
- ☐ I flexjob som:_____
- ☐ Folkepensionist
- ☐ Førtidspensionist
- ☐ På efterløn
- ☐ Arbejdsløs med understøttelse
- ☐ På kontanthjælp
- ☐ På orlov, fx barselsorlov, uddannelsesorlov eller lignende
- ☐ Andet, hvad?_____

Udfyldes ikke Til kodning ☐☐☐

Hvis du har noget, du vil uddybe eller tilføje, er du velkommen til at skrive det her:

TAK FOR DIN HJÆLP

Med en kronisk lungesygdom mener vi det, der i daglig tale kaldes for KOL – Kronisk Obstruktiv Lungesygdom. KOL er kendetegnet ved, at du har åndenød, når du anstrenger dig, du hoster og måske har du slim, som kommer med op, når du hoster.

Kronisk betyder, at man skal leve med sygdommen resten af livet. Udviklingen af sygdommen kan bremses, men den forsvinder aldrig helt igen.

Obstruktiv betyder, at luftvejene er forsnævrede, således at transporten af luft kræver et større arbejde af kroppen end normalt.

Når diagnosen KOL bliver stillet, er de fleste over 50 år, men sygdommen er snigende, så man kan have været syg i mange år, før man får diagnosen stillet. Åndenød, når man anstrenger sig, er et typisk tegn på KOL. Åndenøden skyldes, at lungefunktionen er nedsat permanent.

Du kan læse mere om KOL og projektet på hjemmesiden:

http://kol.au.dk

MANGE TAK FOR DIN HJÆLP, OG FOR AT DU DELTAGER I PROJEKTET

APPENDIX III

III.1 flyer sent to intervention patients together with baseline questionnaire

APPENDIX IV

IV.1 Agendas for CME meetings with GP practices

PROGRAM FOR DEN 16.SEPTEMBER 2009

Mødested: Sundhedscenter Vest, Kirkegade 3, 6880 Tarm

Mødetid: 17 00 til 19 30

Program:

17 00 – 17 10 Velkomst. Praktiserende læge Lars Foged

17 10 – 17 30 Introduktion af forløbet for projektet og områder for intervention.
Assisterende forskningsleder læge Peter Vedsted ph.d.

17 30 – 17 50 Vigtigheden af et sammenhængende sundhedsvæsen.
Professor praktiserende læge Frede Olesen Dr.med.Sc.

17 40 – 18 00 Hvad vil projektet indebære for hver praksis.
Ph.d. studerende fysioterapeut Margrethe Smidth

18 00 – 19 30 Lokale nyheder. Praktiserende læge Lars Foged.

Der vil være en pause med forfriskninger indlagt på passende tid.

Forskningsenheden for Almen Praksis- Bartholins Allé 2- 8000 Århus- m.smidth@alm.au.dk-89 42 60 20

PROGRAM FOR DEN 3. DECEMBER 2009

Mødested: Sundhedscenter Vest, Kirkegade 3, 6880 Tarm

Mødetid: 17 00 til 19 30

Tilmelding: Venligst mail eller ring senest mandag 30.november 2009 om, hvem der kommer torsdag den 3. december 2009, så forplejningen kan være parat. m.smidth@alm.au.dk eller telefon 89 42 60 20

Program:

17 00 – 17 12 Velkommen og opsummering

17 10 – 17 30 Behandling af patienter med KOL. Overlæge Erik Juul Jensen dr.med. Lungemedicinsk afdeling. Regionshospitalet Holstebro.

17 30 – 17 40 KOL lærings- og mestringsforløb. Udviklingskonsulent Susanne Rystok. Sundhedscenter Vest. Tarm.

17 40 – 18 00 Eksempel på praktisk brug af Gennembrudsmetoden til at implementere tiltag i praksis. Professor Peter Vedsted ph.d. Forskningsenheden for Almen Praksis. Århus.

18 00 – 19 30 Arbejde i praksisgrupper med det praksistiltag, som I har besluttet jer for.

Der vil være en pause med forfriskninger indlagt på passende tid.

Forskningsenheden for Almen Praksis- Bartholins Allé 2- 8000 Århus- m.smidth@alm.au.dk-89 42 60 20

PROGRAM FOR ONSDAG DEN 3. FEBRUAR 2010

Mødested:
Lokale 1, Ringkøbing Rådhus, 6950 Ringkøbing – indgangen ved den lille parkeringsplads ud mod vandet er åben.

Mødetid:
17 00 til 19 30

Tilmelding:
Vil I være flinke og maile eller ringe **senest mandag 1. februar 2010** med besked om, hvem og hvor mange, der kommer onsdag den 3. februar 2010, så forplejningen kan være parat. m.smidth@alm.au.dk eller telefon 89 42 60 20. Det ser ud til at vi kan blive næsten fuldtallige.

Formål med dette 2. gennembrudsmøde:
Vi skal på mødet høre om de initiativer - PDSA-cirkler - I har arbejdet konkret med. For mindst én PDSA cirkel og gerne flere skal vi dele de erfaringer alle praksis har og på tværs af faggrupper. Disse erfaringer skal alle kunne tage med hjem i praksis og arbejde videre med..

Program:

17 00 – 17 15 Velkommen, venteværelsesplakat, PEP fløjter og opsummering.

17 15 – 17 45 Delt i en gruppe med praksispersonale og en med praktiserende læger.

En fra hver praksis fremlægger kort, hvad og hvordan deres PDSA cirkel har fungeret og er blevet justeret.

17 45 – 17 50 Individuel refleksion og nedskrivning af de 3 vigtigste ting hver enkelt har hørt fra de andre.

17 50 – 18 15 Udveksling og organisering i temaer af alles vigtigste ting.

18 15 – 18 45 Let anretning.

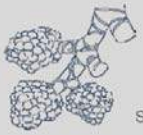
18 45 – 19 00 De store linjer fra temaerne.

19 00 – 19 25 **DEN** ting jeg går i gang med.

19 25 – 19 30 Opsummering og nærmeste fremtid.

Forskningsenheden for Almen Praksis- Bartholins Allé 2- 8000 Århus- m.smidth@alm.au.dk-89 42 60 20

FORSKNINGSENHEDEN FOR ALMEN PRAKSIS Århus



sundhedscenter Vest

PROGRAM FOR TORSDAG DEN 15.APRIL 2010

Mødested:
Sundhedscenter Vest, Kirkegade 3, 6880 Tarm

Mødetid:
17 00 til 19 30

Tilmelding:
Vil I være flinke og maile eller ringe **senest tirsdag den 13.april 2010** med besked om, hvem og hvor mange, der kommer torsdag den 15.april 2010, så forplejningen kan være parat. m.smidth@alm.au.dk eller telefon 89 42 60 20.

Program:

17 00 – 17 15 Velkommen og opsummering.

17 15 – 17 30 Erfaren patient Bente Andersen fortæller om sin hverdag og sin opfattelse af Sundhedsvæsenet.

17 30 – 17 45 Hvordan opfordres og rådgives patienter til egenomsorg?

17 45 – 18 00 Hvad synes jeres patienter om, hvad der foregår i praksis?
Et hurtigt kig på den første dataindsamling med sammenligning af jeres og "de andres" praksis – interventionspraksis sammenlignet med kontrolpraksis

18 00 – 18 30 Let forfriskning

18 30 – 18 40 En måde at registrere rygere på. Sygeplejerske Inger Lis Hansen

18 40 – 18 50 En måde at få årskontrollerne sat i system

18 50 – 19 00 Opsamling af, hvad der er sket på 4 møder og i den mellemliggende tid.
Hvordan vi håber, det ser ud om et ½ år.

19 20 – 19 30 Hvordan fortsætter projektet med dataindsamling og resultat opgørelse.

Tak for denne gang.

.

Forskningsenheden for Almen Praksis- Bartholins Allé 2- 8000 Århus- m.smidth@alm.au.dk-89 42 60 20

APPENDIX V

V.1. Folder with Action card

HOLD ØJE MED DINE SYMPTOMER

GRØNNE SYMPTOMER:

- Fortsæt din normale behandling.

GULE SYMPTOMER:

- Hold øje med dine symptomer
- Brug din PEP-fløjte ofte.
- Lav dine åndedrætsøvelser ofte.
- Tag din anfaldsmedicin regelmæssigt op til maksimum.

RØDE SYMPTOMER:
eller efter 2 døgn med maksimum anfaldsmedicin.

- Tag maksimal anfaldsmedicin og start prednisolonkur.
- Kontakt en læge med henblik på akut vurdering og behandling.

Prednisolonkur: Tag prednisolon, som din læge har udskrevet i forvejen:

Dosering:

HANDLING / SYMPTOM	GØR	GØR MERE	GØR MEGET
ÅNDENØD	Normal som jeg plejer	Mere end jeg plejer	Meget mere end jeg plejer
HOSTE	Normal som jeg plejer	Mere end jeg plejer	Meget mere end jeg plejer
SLIM	Normal som jeg plejer	Mere end jeg plejer	Meget mere end jeg plejer
HVAD DU SKAL GØRE	FORTSÆT NORMAL BEHANDLING	TAG ANFALDS-MEDICIN TIL MAXIMUM	ANFALDSMEDICIN + START PREDNISOLON + KONTAKT LÆGE


DINE EGNE OPLYSNINGER
KONTAKT TLF.NR.
Din praktiserende læge:
Lungemedicinsk specialist el. sygeplejerske:
MEDICIN
Daglig medicin og dosering:
Antibiotika og dosering:
Bronkieudvidende medicin (anfaldsmedicin) via inhalator eller spray:
Maksimum antal sug/pust pr. dag:

SLIM

Kontroller farven på dit slim.

Host dit slim ud på et stykke hvidt papir.

Hvis slimet har ændret farve til gullig-grønt, skal du tage antibiotika. Enten har du en recept eller så skal du hurtigst muligt få fat på en.

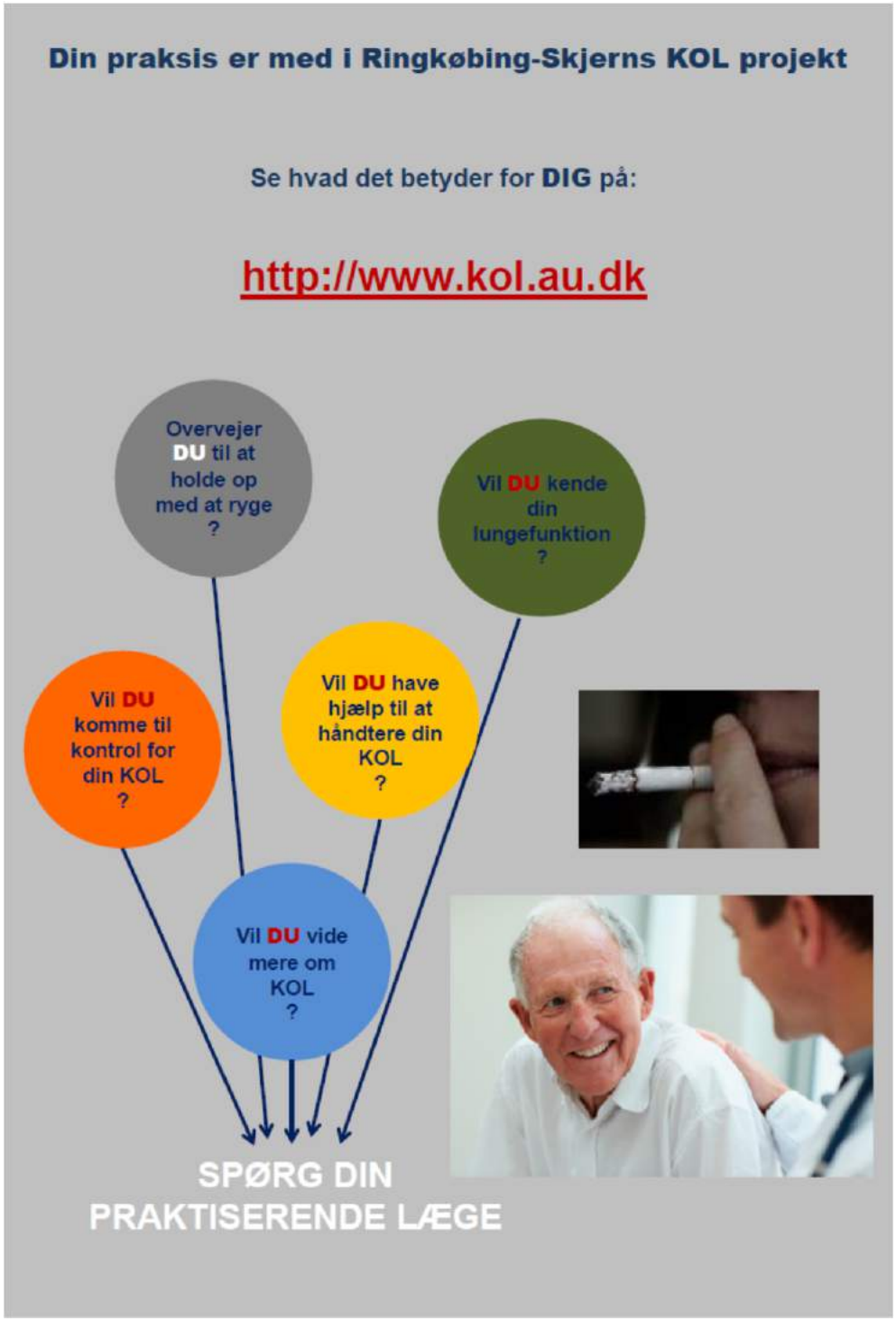
Blod i dit slim behøver ikke betyde, at du skal tage antibiotika. Kontakt din egen læge for at diskutere det.

Startet på antibiotika? Drøft snarest behandlingen med din læge.

Ha' kortet på dig, så du altid kan holde øje med, hvordan du har det.

APPENDIX VI

VI.1 Poster for waiting areas



APPENDIX VII

VII.1 Referral form from GPs to health centre

sundhedscenter Vest
sammen om sundhed

Henvisning til Sundhedscenter Vest

CPR: Dato for henvisning
Navn:
Adresse:
Postnr. og by:
Telefon - hvor borgeren træffes:
E-mail:

Henvisende Læge (navn, adr., tlf. og mail):

Kort beskrivelse af hvorfor borgeren henvises til Sundhedscenter Vest:

Nuværende rygestatus: ☐ ikke ryger ☐ ryger

Borgeren henvises med henblik på en afklarende samtale til (sæt kryds):

At få hjælp til at tabe sig: (overvægtige gravide og BMI over 35) ☐

At få hjælp til at holde op med at ryge: ☐

At få hjælp til et alkoholproblem: ☐

At få hjælp til et stofmisbrug: ☐

Borgeren henvises med henblik på en afklarende samtale til at få redskaber til at klare hverdagen med (sæt kryds):

KOL: ☐
Borgerens sidst målte FEV_1 noteres her:

Type 2 diabetes: ☐

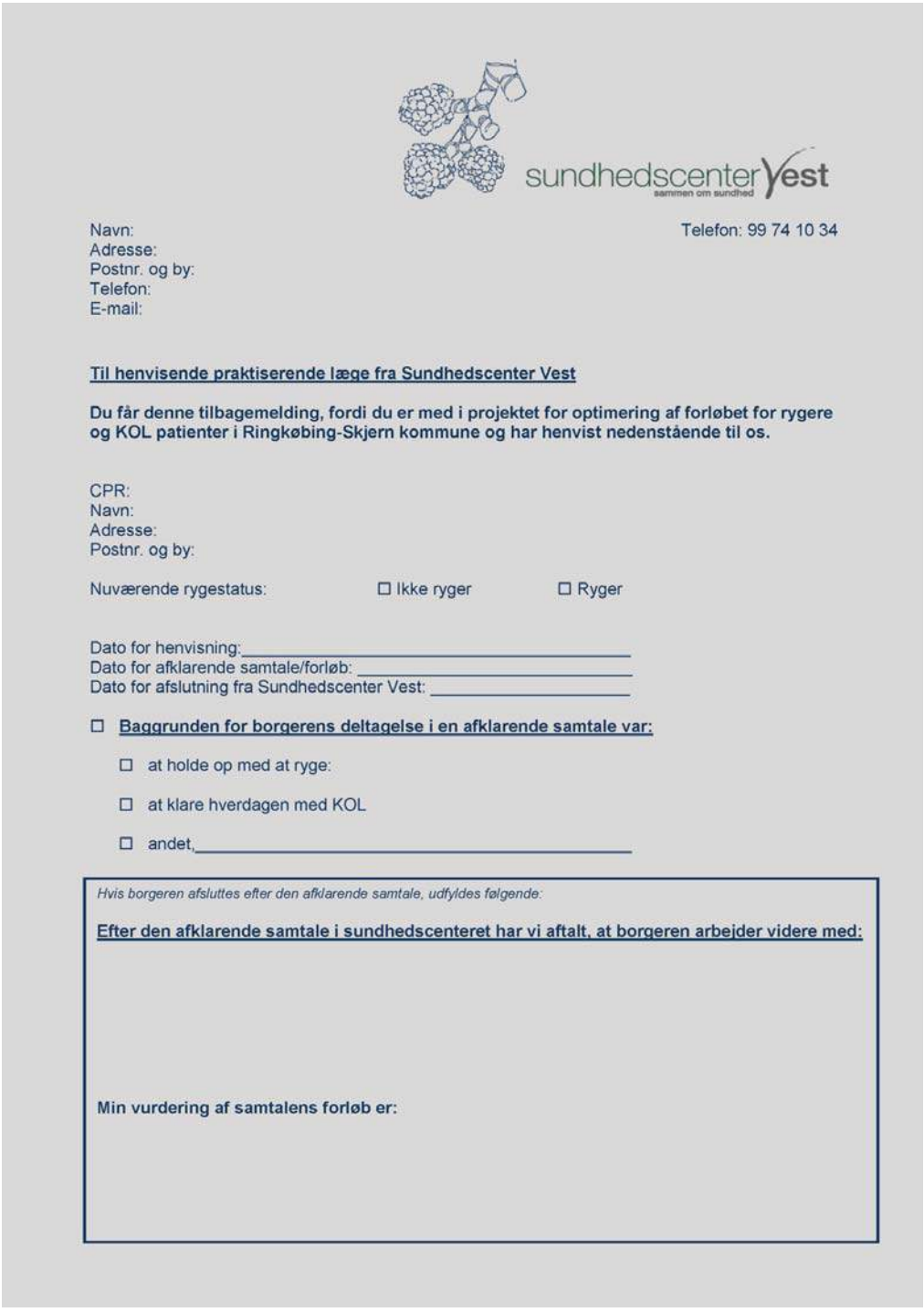
Kræft: (borgere over 18 år) ☐

Hjertesygdom: ☐

Ved spørgsmål kan Sundhedscenteret kontaktes på telefon 99 74 10 34
Henvisningen kan sendes pr. mail til Sundhedscentervest@rksk.dk eller pr. post til Sundhedscenter Vest, Kirkegade 3, 6880 Tarm eller til fax. 9737 6966
På www.sundhedscenter-vest.dk eller www.praksis.dk vil du kunne finde en beskrivelse af de enkelte tilbud.

Borgeren kontaktes senest 14 dage efter henvisninger er modtaget med henblik på en afklarende samtale.

VII.2. Feed-back form from health centre to GP



sundhedscenter Vest
sammen om sundhed

Navn:
Adresse:
Postnr. og by:
Telefon:
E-mail:

Telefon: 99 74 10 34

Til henvisende praktiserende læge fra Sundhedscenter Vest

Du får denne tilbagemelding, fordi du er med i projektet for optimering af forløbet for rygere og KOL patienter i Ringkøbing-Skjern kommune og har henvist nedenstående til os.

CPR:
Navn:
Adresse:
Postnr. og by:

Nuværende rygestatus: ☐ Ikke ryger ☐ Ryger

Dato for henvisning:_____
Dato for afklarende samtale/forløb: _____
Dato for afslutning fra Sundhedscenter Vest: _____

☐ **Baggrunden for borgerens deltagelse i en afklarende samtale var:**

- ☐ at holde op med at ryge:
- ☐ at klare hverdagen med KOL
- ☐ andet,_____

Hvis borgeren afsluttes efter den afklarende samtale, udfyldes følgende:

Efter den afklarende samtale i sundhedscenteret har vi aftalt, at borgeren arbejder videre med:

Min vurdering af samtalens forløb er:

Hvis borgeren har deltaget i et rygestopstilbud, udfyldes følgende:

☐ **Borgeren har deltaget i dette tilbud for at stoppe med at ryge:**

Min vurdering af forløbet er:

Hvis borgeren har deltaget i et lærings- og mestringsforløb, udfyldes følgende:

☐ **Borgeren har deltaget i et forløb for håndtering og mestring af KOL, og har nu sat disse mål for følgende:**

- **At leve med sin kroniske sygdom:**
- **At håndtere smerter, træthed, angst og andre symptomer:**
- **Motion:**
- **Kost:**
- **Håndtering af medicin:**
- **Hjælpemidler – PEP fløjte, ilt….**
- **Netværksdannelse:**
- **Yderligere bemærkninger til deltagelse i forløbet:**

Med venlig hilsen _____

APPENDIX VIII

VIII.1 Sub-group analysis for the FI population – Intention-to-treat

Intention to treat analysis - Rates and rate ratios (RRs) for specific variable for patients identified by the COPD algorithm

Rate and RRs for planned preventive consultations, additional preventive consultations, spirometries performed at GP practices and out-of-hours contacts as well as for patients who were admitted and patients in contact with emergency department. The RRs are presented with 95% confidence intervals (95% CI).

N=2,736	Intervention (N=877)	Control (N=767)	Ext. control (N=1,092)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
Number of patients who had a planned preventive consultation						
2008	0.30 [0.23;0.39]	0.21 [0.16;0.29]	0.22 [0.13;0.37]	1.39 [0.93;2.07] p=0.110	1.37 [0.75;2.49] p=0.303	0.99 [0.54;1.80] p=0.970
2009	0.41 [0.32;0.55]	0.14 [0.15;0.26]	0.25 [0.15;0.42]	2.19 [1.44;3.31] p<0.001	1.65 [0.91;2.97] p=0.097	0.75 [0.41;1.37] p=0.355
RR	1.40 [1.03;1.90] p=0.033	0.89 [0.76;1.02] p=0.100	1.16 [0.93;1.45] p=0.176	1.58 [1.12;2.22] p=0.009	1.20 [0.82;1.76] p=0.343	0.76 [0.59;0.99] p=0.042
Number of patients who had an additional preventive consultation						
2008	0.12 [0.05;0.28]	0.06 [0.02;0.13]	0.09 [0.05;0.16]	2.13 [0.64;7.10] p=0.220	1.30 [0.47;3.61] p=0.611	0.61 [0.22;1.68] p=0.342
2009	0.19 [0.10;0.36]	0.07 [0.03;0.16]	0.10 [0.05;0.19]	2.78 [0.94;8.20] p=0.064	1.83 [0.73;4.59] p=0.200	0.68 [0.22;1.93] p=0.444
RR	1.54 [0.96;2.49] p=0.075	1.18 [0.69;2.02] p=0.542	1.10 [0.76;1.59] p=0.612	1.31 [0.64;2.67] p=0.465	1.40 [0.77;2.57] p=0.272	1.07 [0.56;2.06] p=0.831
Number of patients who had a spirometry performed at the GP						
2008	0.29 [0.23;0.36]	0.20 [0.15;0.27]	0.20 [0.15;0.26]	1.44 [1.00;2.07] p=0.050	1.48 [1.04;2.09] p=0.028	1.03 [0.68;1.54] p=0.905
2009	0.35 [0.27;0.47]	0.20 [0.14;0.28]	0.17 [0.12;0.25]	1.80 [1.14;2.85] p=0.011	2.06 [1.28;3.33] p=0.003	1.14 [0.68;1.92] p=0.613
RR	1.23 [0.95;1.59] p=0.115	0.98 [0.81;1.20] p=0.854	0.88 [0.68;1.22] p=0.449	1.25 [0.91;1.73] p=0.173	1.40 [0.92;2.13] p=0.117	1.11 [0.76;1.64] p=0.578
Number of patients who used out-of-hours services						
2008	0.30 [0.26;0.35]	0.30 [0.26;0.35]	0.32 [0.28;0.35]	0.98 [0.81;1.18] p=0.806	0.94 [0.80;1.10] p=0.417	0.96 [0.80;1.15] p=0.659
2009	0.29 [0.27;0.31]	0.30 [0.28;0.33]	0.28 [0.25;0.31]	0.95 [0.85;1.05] p=0.325	1.03 [0.91;1.17] p=0.653	1.09 [0.95;1.24] p=0.211
RR	0.97 [0.88;1.06] p=0.447	0.99 [0.87;1.14] p=0.932	0.88 [0.78;0.99] p=0.036	0.97 [0.83;1.14] p=0.718	1.10 [0.94;1.28 p=0.223	1.14 [0.95;1.37] p=0.169
Number of patients who were admitted with a lung-related diagnosis						
2008	0.06 [0.05;0.08]	0.06 [0.04;0.08]	0.07 [0.05;0.09]	1.11 [0.71;1.73] p=0.636	0.92 [0.69;1.24] p=0.598	0.83 [0.52;1.33] p=0.438
2009	0.05 [0.04;0.07]	0.05 [0.04;0.06]	0.07 [0.06;0.09]	1.13 [0.83;1.53] p=0.453	0.73 [0.55;0.98] p=0.035	0.65 [0.50;0.85] p=0.002
RR	0.87 [0.70;1.07] p=0.183	0.86 [0.52;1.42] p=0.547	1.09 [0.90;1.33] p=0.373	1.01 [0.58;1.75] p=0.967	0.79 [0.59;1.06] p=0.113	0.78 [0.46;1.35] p=0.379
Number of patients who were admitted to hospital with another diagnosis						
2008	0.22 [0.19;0.26]	0.20 [0.16;0.24]	0.22 [0.20;0.24]	1.10 [0.86;1.40] p=0.450	0.99 [0.82;1.20] p=0.952	0.91 [0.73;1.12] p=0.349
2009	0.22 [0.19;0.26]	0.22 [0.20;0.24]	0.24 [0.21;0.26]	0.98 [0.82;1.17] p=0.802	0.93 [0.76;1.12] p=0.438	0.94 [0.83;1.08] p=0.430
RR	1.00 [0.88;1.13] p=0.998	1.12 [0.96;1.31] p=0.141	1.07 [0.96;1.20] p=0.216	0.90 [0.73;1.09] p=0.253	0.93 [0.79;1.10] p=0.408	1.05 [0.86;1.27] p=0.800
Number of patients who visited the emergency department						
2008	0.06 [0.05;0.08]	0.08 [0.07;0.10]	0.10 [0.08;0.13]	0.75 [0.53;1.05] p=0.095	0.62 [0.44;0.87] p=0.005	0.82 [0.63;1.08] p=0.153
2009	0.07 [0.06;0.09]	0.08 [0.07;0.09]	0.10 [0.09;0.12]	0.96 [0.72;1.27] p=0.760	0.74 [0.56;0.98] p=0.033	0.77 [0.63;0.95] p=0.015
RR	1.18 [0.82;1.69] p=0.367	0.92 [0.68;1.26] p=0.631	0.98 [0.79;1.22] p=0.882	1.28 [0.80;2.05] p=0.310	1.20 [0.79;1.82] p=0.394	0.94 [0.65;1.36] p=0.741

VIII.1 Sub-group analysis for the EI population – Intention-to-treat

Intention to treat analysis - Count and incidence rate ratios (IRRs) for specific variables for patients identified by the COPD algorithm

Counts and IRRs for joint homevisits, conventional consultations, contacts to out-of-hours services, admissions, bed days and readmissions. The IRRs are presented with 95% confidence intervals (95%CI)

N= 2,736	Intervention (N=877)	Control (N=767)	Ext. control (N=1,092)	Intervention vs. control IRR	Intervention vs. ext control IRR	Control vs. ext control IRR
Joint home visits						
2008	0.002 [0.000;0.012]	0 visits	0.003 [0.001;0.007]	#	0.62 [0.10;3.78] p=0.604	#
2009	0.005 [0.001;0.021]	2 visits	0.003 [0.001;0.007]	#	1.63 [0.39;6.92] p=0.505	#
IRR	2.60 [1.63;4.14] p<0.001	#	0.99 [0.55;1.76] p=0.962	#	2.63 [1.23;5.64] p=0.012	#
Consultations with GP (daytime)						
2008	7.06 [6.26;7.97]	7.32 [6.25;8.59]	6.61 [6.10;7.16]	0.96 [0.79;1.18] p=0.721	1.07 [0.94;1.27] p=0.367	1.08 [0.91;1.29] p=0.258
2009	6.78 [6.16;7.46]	7.92 [6.51;9.62]	6.80 [6.28;7.35]	0.86 [0.69;1.06] p=0.157	1.00 [0.88;1.13] p=0.966	1.16 [0.94;1.44] p=0.155
IRR	0.96 [0.91;1.02] p=0.153	1.08 [1.03;1.14] p=0.004	1.03 [0.98;1.08] p=0.275	0.89 [0.82;0.96] p=0.003	0.93 [0.87;1.00] p=0.072	1.05 [0.98;1.13] p=0.182
Contacts to out-of-hours services						
2008	0.66 [0.50;0.88]	0.63 [0.52;0.77]	0.63 [0.54;0.73]	1.05 [0.75;1.46] p=0.780	1.05 [0.77;1.44] p=0.749	1.00 [0.78;1.29] p=0.978
2009	0.66 [0.53;0.83]	0.72 [0.60;0.86]	0.61 [0.53;0.71]	0.91 [0.70;1.21] p=0.543	1.08 [0.83;1.41] p=0.548	1.18 [0.94;1.49] p=0.157
IRR	1.00 [0.87;1.15] p=0.987	1.14 [1.03;1.25] p=0.002	0.97 [0.83;1.14] p=0.722	0.88 [0.74;1.03] p=0.117	1.03 [0.83;1.28] p=0.780	1.18 [0.98;1.41] p=0.085
Admissions with a lung-related diagnosis						
2008	0.10 [0.07;0.13]	0.11 [0.08;0.14]	0.13 [0.09;0.21]	0.91 [0.63;1.33] p=0.633	0.73 [0.44;1.23] p=0.237	0.80 [0.48;1.33] p=0.394
2009	0.09 [0.07;0.11]	0.12 [0.08;0.17]	0.15 [0.12;0.18]	0.75 [0.50;1.12] p=0.161	0.58 [0.44;0.78] p<0.001	0.78 [0.53;1.14] p=0.200
IRR	0.91 [0.69;1.22] p=0.537	1.11 [0.85;1.44] p=0.435	1.15 [0.81;1.63] p=0.447	0.82 [0.56;1.20] p=0.323	0.80 [0.51;1.26] p=0.333	0.97 [0.64;1.47] p=0.881
Admissions with another diagnosis						
2008	0.44[0.35;0.56]	0.40 [0.36;0.46]	0.42 [0.37;0.48]	1.10 [0.85;1.42] p=0.470	1.06 [0.81;1.37] p=0.677	0.96 [0.80;1.15] p=0.666
2009	0.42 [0.35;0.51]	0.52 [0.48;0.57]	0.49 [0.44;0.53]	0.81 [0.66;0.99] p=0.038	0.86 [0.70;1.06] p=0.150	1.06 [0.92;1.22] p=0.411
IRR	0.95 [0.76;1.20] p=0.686	1.29 [1.13;1.48] p<0.001	1.17 [1.00;1.37] p=0.047	0.74 [0.57;0.96] p=0.025	0.81 [0.62;1.07] p=0.146	1.10 [0.90;1.36] p=0.351
Bed days						
2008	1.87 [1.42;2.47]	1.78 [1.51;2.09]	1.91 [1.46;2.51]	1.05 [0.76;1.45] p=0.754	0.98 [0.67;1.43] p=0.911	0.93 [0.67;1.29] p=0.658
2009	2.14 [1.77;2.59]	2.57 [2.04;3.23]	2.39 [1.94;2.95]	0.83 [0.62;1.12] p=0.229	0.90 [0.68;1.18] p=0.437	1.07 [0.78;1.47] p=0.655
IRR	1.14 [0.87;1.50] p=0.338	1.44 [1.05;1.98] p=0.022	1.25 [0.93;1.68] p=0.143	0.79 [0.52;1.20] p=0.274	0.92 [0.60;1.38] p=0.676	1.16 [0.75;1.78] p=0.513
Readmissions*						
2008	0.09 [0.06;0.13]	0.10 [0.08;0.12]	0.08 [0.05;0.14]	0.92 [0.60;1.43] p=0.719	1.08 [0.58;2.02] p=0.804	1.17 [0.70;1.95] p=0.541
2009	0.08 [0.06;0.12]	0.14 [0.11;0.17]	0.14 [0.11;0.17]	0.61 [0.40;0.93] p=0.022	0.60 [0.40;0.90] p=0.014	0.99 [0.74;1.33] p=0.961
IRR	0.92 [0.57;1.51] p=0.755	1.40 [1.18;1.68] p<0.001	1.66 [1.11;2.49] p=0.014	0.66 [0.39;1.11] p=0.116	0.56 [0.30;1.05] p=0.070	0.84 [0.55;1.30] p=0.447
Contact to outpatient services with a lung-related diagnosis						
2008	0.15 [0.10;0.20]	0.18 [0.14;0.24]	0.18 [0.12;0.26]	0.80 [0.52;1.23] p=0.312	0.82 [0.49;1.38] p=0.457	1.03 [0.63;1.66] p=0.919
2009	0.18 [0.10;0.33]	0.23 [0.17;0.32]	0.23 [0.16;0.34]	0.80 [0.41;1.56] p=0.516	0.80 [0.40;1.59] p=0.523	0.99 [0.61;1.63] p=0.984
IRR	1.27 [0.71;2.25] p=0.419	1.26 [0.89;1.80] p=0.118	1.31 [1.18;1.45] p<0.001	1.00 [0.50;1.98] p=0.999	0.97 [0.54;17.6] p=0.920	0.97 [0.67;1.41] p=0.875

* A readmission was defined as an acute admission within 30 days of the last admission.

\# Too few visits undertaken to do any analysis.

VIII.2 Sub-group analysis for the EI population – Per-protocol

Per protocol analysis - Rates and rate ratios (RRs) for specific variable for patients identified by the COPD algorithm

Rate and RRs for planned preventive consultations, additional preventive consultations, spirometries performed at GP practices and out-of-hours contacts as well as for patients who were admitted and patients in contact with emergency department. The RRs are presented with 95% confidence intervals (95% CI).

N= 2,624	Intervention (N=765)	Control (N=767)	Ext. control (N=1,092)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
Number of patients who had a planned preventive consultation						
2008	0.29 [0.21;0.40]	0.22 [0.16;0.29]	0.22 [0.13;0.37]	1.35 [0.88;2.06] p=0.173	1.33 [0.72;2.47] p=0.366	0.99 [0.54;1.81] p=0.969
2009	0.44 [0.33;0.58]	0.19 [0.14;0.26]	0.25 [0.15;0.43]	2.29 [1.51;3.48] p<0.001	1.72 [0.95;3.12] p=0.072	0.75 [0.41;1.38] p=0.356
RR	1.51 [1.12;2.03] p=0.007	0.89 [0.77;1.02] p=0.100	1.16 [0.93;1.45] p=0.177	1.70 [1.22;2.37] p=0.002	1.30 [0.89;1.88] p=0.171	0.76 [0.59;0.99] p=0.043
Number of patients who had an additional preventive consultation						
2008	0.10 [0.04;0.29]	0.06 [0.02;0.13]	0.09 [0.05;0.16]	1.82 [0.47;7.03] p=0.385	1.11 [0.34;3.65] p=0.858	0.61 [0.22;1.68] p=0.342
2009	0.18 [0.09;0.38]	0.07 [0.03;0.16]	0.10 [0.05;0.19]	2.75 [0.88;8.59] p=0.081	1.81 [0.68;4.84] p=0.238	0.66 [0.22;1.93] p=0.445
RR	1.79 [1.00;3.20] p=0.051	1.18 [0.69;2.02] p=0.543	1.10 [0.76;1.59] p=0.613	1.51 [0.68;3.34] p=0.306	1.62 [0.81;3.23] p=0.170	1.07 [0.56;2.06] p=0.831
Number of patients who had a spirometry performed at the GP						
2008	0.30 [0.24;0.37]	0.20 [0.15;0.27]	0.20 [0.15;0.26]	1.49 [1.03;2.17] p=0.035	1.53 [1.07;2.18] p=0.019	1.03 [0.68;1.54] p=0.906
2009	0.38 [0.29;0.50]	0.20 [0.14;0.28]	0.17 [0.12;0.23]	1.93 [1.24;3.02] p=0.004	2.21 [1.38;3.54] p=0.001	1.14 [0.68;1.92] p=0.614
RR	1.27 [0.98;1.65] p=0.074	0.98 [0.81;1.20] p=0.853	0.88 [0.63;1.22] p=0.448	1.29 [0.93;1.80] p=0.123	1.44 [0.95;2.20] p=0.088	1.12 [0.76;1.64] p=0.578
Number of patients who used out-of-hours services						
2008	0.30 [0.27;0.33]	0.30 [0.26;0.35]	0.32 [0.28;0.35]	1.00 [0.83;1.19] p=0.959	0.95 [0.82;1.09] p=0.432	0.95 [0.79;1.15] p=0.593
2009	0.29 [0.26;0.31]	0.30 [0.28;0.32]	0.28 [0.25;0.31]	0.95 [0.85;1.06] p=0.386	1.03 [0.90;1.18] p=0.674	1.08 [0.95;1.23] p=0.232
RR	0.96 [0.89;1.02] p=0.190	1.00 [0.87;1.15] p=0.984	0.88 [0.78;0.99] p=0.036	0.96 [0.82;1.12] p=0.578	1.09 [0.95;1.20] p=0.228	1.14 [0.95;1.37] p=0.169
Number of patients who were admitted with a lung-related diagnosis						
2008	0.06 [0.05;0.07]	0.06 [0.04;0.09]	0.07 [0.05;0.09]	1.10 [0.71;1.69] p=0.676	0.91 [0.68;1.21] p=0.514	0.83 [0.52;1.33] p=0.435
2009	0.05 [0.04;0.06]	0.05 [0.04;0.06]	0.07 [0.06;0.09]	1.04 [0.75;1.44] p=0.830	0.67 [0.50;0.91] p=0.011	0.65 [0.49;0.85] p=0.002
RR	0.80 [0.65;1.01] p=0.062	0.86 [0.51;1.42] p=0.547	1.09 [0.90;1.33] p=0.372	0.94 [0.54;1.65] p=0.841	0.74 [0.55;1.00] p=0.046	0.78 [0.45;1.35] p=0.378
Number of patients who were admitted to hospital with another diagnosis						
2008	0.22 [0.18;0.26]	0.20 [0.16;0.24]	0.22 [0.20;0.24]	1.08 [0.84;1.39] p=0.556	0.98 [0.80;1.20] p=0.824	0.91 [0.74;1.11] p=0.347
2009	0.22 [0.18;0.26]	0.22 [0.21;0.24]	0.24 [0.21;0.26]	0.97 [0.79;1.17] p=0.732	0.92 [0.74;1.13] p=0.405	0.95 [0.83;1.08] p=0.428
RR	1.01 [0.88;1.15] p=0.929	1.12 [0.96;1.31] p=0.141	1.07 [0.96;1.20] p=0.215	0.89 [0.73;1.10] p=0.290	0.94 [0.79;1.12] p=0.463	1.05 [0.86;1.27] p=0.644
Number of patients who visited the emergency department						
2008	0.06 [0.04;0.08]	0.08 [0.07;0.10]	0.10 [0.08;0.13]	0.72 [0.49;1.05] p=0.086	0.59 [0.40;0.86] p=0.006	0.82 [0.63;1.08] p=0.154
2009	0.07 [0.05;0.10]	0.08 [0.07;0.09]	0.10 [0.09;0.12]	0.93 [0.68;1.27] p=0.642	0.72 [0.52;0.98] p=0.037	0.77 [0.63;0.95] p=0.016
RR	1.19 [0.78;1.83] p=0.417	0.92 [0.68;1.26] p=0.614	0.98 [0.79;1.22] p=0.882	1.29 [0.76;2.18] p=0.340	1.21 [0.75;1.95] p=0.428	0.94 [0.65;1.37] p=0.742

VIII.2 Sub-group analysis for the EI population – per-protocol

Per protocol analysis - Count and incidence rate ratios (IRRs) for specific variables for patients identified by the COPD algorithm

Counts and IRRs for joint homevisits, conventional consultations, contacts to out-of-hours services, admissions, bed days and readmissions. The IRR are presented with 95% confidence intervals (95%CI)

N= 2,624	Intervention (N=765)	Control (N=767)	Ext. control (N=1,092)	Intervention vs. control IRR	Intervention vs. ext control IRR	Control vs. ext control IRR
Joint home visits						
2008	0.002 [0.000;0.014]	0 visits	0.003 [0.001;0.007]	#	0.69 [0.11;4.27] p=0.692	#
2009	0.005 [0.001;0.024]	2 visits	0.003 [0.001;0.007]	#	1.68 [0.37;7.74] p=0.505	#
IRR	2.39 [1.68;3.42] p<0.001	#	0.99 [0.55;1.76] p=0.963	#	2.43 [1.21;4.85] p=0.012	#
Consultations with GP (daytime)						
2008	7.22 [6.34;8.21]	7.32 [6.25;8.58]	6.61 [6.11;7.17]	0.99 [0.80;1.21] p=0.887	1.01 [0.94;1.27] p=0.260	1.10 [0.93;1.32] p=0.257
2009	6.90 [6.22;7.66]	7.91 [6.52;9.62]	6.80 [6.29;7.36]	0.87 [0.70;1.08] p=0.217	1.01 [0.89;1.16] p=0.823	1.16 [0.94;1.43] p=0.155
IRR	0.96 [0.90;1.02] p=0.152	1.08 [1.03;1.14] p=0.004	1.03 [0.98;1.08] p=0.274	0.88 [0.82;0.96] p=0.003	0.93 [0.86;1.01] p=0.070	1.05 [0.98;1.13] p=0.142
Contacts to out-of-hours services						
2008	0.68 [0.51;0.91]	0.63 [0.51;0.77]	0.63 [0.54;0.73]	1.08 [0.76;1.53] p=0.648	1.09 [0.78;1.51] p=0.612	1.00 [0.78;1.29] p=0.976
2009	0.68 [0.53;0.86]	0.72 [0.60;0.86]	0.61 [0.53;0.71]	0.94 [0.70;1.25] p=0.674	1.11 [0.84;1.47] p=0.467	1.18 [0.94;1.49] p=0.157
IRR	0.99 [0.86;1.14] p=0.897	1.14 [1.05;1.24] p=0.002	0.97 [0.83;1.14] p=0.724	0.87 [0.73;1.02] p=0.094	1.02 [0.82;1.27] p=0.855	1.18 [0.98;1.42] p=0.085
Admissions with a lung-related diagnosis						
2008	0.10 [0.07;0.13]	0.11 [0.08;0.14]	0.13 [0.08;0.21]	0.91 [0.63;1.33] p=0.643	0.73 [0.44;1.22] p=0.236	0.80 [0.48;1.32] p=0.390
2009	0.09 [0.07;0.11]	0.12 [0.08;0.17]	0.15 [0.13;0.19]	0.74 [0.49;1.13] p=0.162	0.57 [0.42;0.79] p=0.001	0.78 [0.53;1.14] p=0.193
IRR	0.90 [0.66;1.21] p=0.482	1.11 [0.85;1.44] p=0.444	1.15 [0.81;1.62] p=0.438	0.81 [0.55;1.20] p=0.296	0.78 [0.49;1.25] p=0.302	0.97 [0.64;1.46] p=0.866
Admissions with another diagnosis						
2008	0.44 [0.34;0.56]	0.40 [0.36;0.46]	0.42 [0.37;0.48]	1.08 [0.81;1.43] p=0.602	1.04 [0.78;1.38] p=0.809	0.96 [0.80;1.15] p=0.662
2009	0.43 [0.35;0.52]	0.52 [0.48;0.57]	0.49 [0.44;0.55]	0.81 [0.66;1.01] p=0.059	0.86 [0.69;1.08] p=0.192	1.06 [0.92;1.22] p=0.403
IRR	0.98 [0.77;1.24] p=0.853	1.29 [1.13;1.48] p<0.001	1.17 [1.00;1.37] p=0.047	0.75 [0.57;0.99] p=0.046	0.83 [0.63;1.11] p=0.215	1.10 [0.90;1.36] p=0.347
Bed days						
2008	1.87 [1.36;2.55]	1.78 [1.52;2.08]	1.92 [1.47;2.52]	1.05 [0.74;1.49] p=0.790	0.97 [0.65;1.46] p=0.887	0.93 [0.68;1.27] p=0.633
2009	2.14 [1.73;2.64]	2.57 [2.05;3.24]	2.39 [1.94;2.94]	0.83 [0.61;1.13] p=0.240	0.89 [0.67;1.20] p=0.453	1.08 [0.79;1.47] p=0.637
IRR	1.15 [0.84;1.56] p=0.390	1.45 [1.06;1.97] p=0.019	1.24 [0.92;1.67] p=0.149	0.79 [0.51;1.23] p=0.297	0.92 [0.60;1.42] p=0.714	1.16 [0.76;1.79] p=0.488
Readmissions*						
2008	0.09 [0.06;0.14]	0.10 [0.08;0.12]	0.08 [0.05;0.13]	0.89 [0.55;1.44] p=0.636	1.05 [0.53;2.03] p=0.877	1.18 [0.72;1.93] p=0.512
2009	0.09 [0.07;0.13]	0.14 [0.11;0.17]	0.14 [0.11;0.17]	0.67 [0.45;0.99] p=0.045	0.66 [0.46;0.96] p=0.029	0.99 [0.74;1.33] p=0.971
IRR	1.05 [0.66;1.67] p=0.838	1.40 [1.18;1.67] p<0.001	1.67 [1.12;2.49] p=0.012	0.75 [0.46;1.23] p=0.250	0.63 [0.34;1.16] p=0.139	0.84 [0.55;1.29] p=0.426
Contact to outpatient services with a lung-related diagnosis						
2008	0.17[0.12;0.23]	0.18 [0.14;0.24]	0.18 [0.12;0.27]	0.91 [0.60;1.38] p=0.651	0.93 [0.56;1.55] p=0.776	1.02 [0.63;1.66] p=0.925
2009	0.20 [0.11;0.36]	0.23 [0.17;0.32]	0.23 [0.16;0.34]	0.85 [0.42;1.69] p=0.638	0.84 [0.41;1.73] p=0.639	0.99 [0.61;1.63] p=0.983
IRR	1.18 [0.66;2.13] p=0.574	1.28 [0.89;1.80] p=0.185	1.30 [1.17;1.45] p<0.001	0.93 [0.47;1.87] p=0.845	0.91 [0.50;1.66] p=0.752	0.97 [0.67;1.41] p=0.881

* A readmission was defined as an acute admission within 30 days of the last admission.

Too few visits undertaken to do any analysis.

VIII.3 Sub-group analysis for the EI population – As-treated

As treated analysis - Rates and rate ratios (RRs) for specific variable for patients identified by the COPD algorithm

Rate and RRs for planned preventive consultations, additional preventive consultations, spirometries performed at GP practices and out-of-hours contacts as well as for patients who were admitted and patients in contact with emergency department. The RRs are presented with 95% confidence intervals (95% CI).

N= 2,736	Intervention (N=765)	Control (N=879)	Ext. control (N=1,092)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
Number of patients who had a planned preventive consultation						
2008	0.29 [0.21;0.40]	0.23 [0.18;0.30]	0.22 [0.13;0.37]	1.24 [0.83;1.86] p=0.299	1.33 [0.72;2.47] p=0.367	1.07 [0.60;1.93] p=0.815
2009	0.44 [0.33;0.58]	0.20 [0.15;0.26]	0.25 [0.15;0.42]	2.17 [1.47;3.20] p<0.001	1.72[0.95;3.11] p=0.072	0.79 [0.44;1.42] p=0.436
RR	1.51 [1.122;2.03] p=0.007	0.86 [0.75;0.99] p=0.036	1.16 [0.93;1.45] p=0.176	1.75 [1.26;2.43] p=0.001	1.30 [0.89;1.88] p=0.171	0.74 [0.57;0.96] p=0.023
Number of patients who had an additional preventive consultation						
2008	0.10 [0.04;0.29]	0.08 [0.04;0.16]	0.09 [0.05;0.16]	1.29 [0.37;4.50] p=0.692	1.11 [0.34;3.64] p=0.858	0.87 [0.36;2.08] p=0.747
2009	0.18 [0.09;0.38]	0.08 [0.04;0.17]	0.10 [0.05;0.19]	2.21 [0.78;6.21] p=0.134	1.81 [0.68;4.83] p=0.237	0.82 [0.31;2.16] p=0.687
RR	1.79 [1.003;3.20] p=0.051	1.04 [0.70;1.55] p=0.841	1.10 [0.76;1.59] p=0.612	1.71 [0.85;3.47] p=0.135	1.62 [0.81;3.23] p=0.169	0.95 [0.55;1.63] p=0.844
Number of patients who had a spirometry performed at the GP						
2008	0.30 [0.24;0.37]	0.20 [0.16;0.26]	0.20 [0.15;0.26]	1.48 [1.05;2.09] p=0.026	1.53 [1.07;2.18] p=0.019	1.03 [0.70;1.52] p=0.863
2009	0.38 [0.29;0.50]	0.19 [0.14;0.27]	0.17 [0.12;0.25]	1.96 [1.29;2.96] p=0.002	2.21 [1.38;3.53] p=0.001	1.13 [0.69;1.86] p=0.629
RR	1.27 [0.98;1.65] p=0.073	0.96 [0.80;1.16] p=0.676	0.88 [0.63;1.22] p=0.448	1.32 [0.96;1.82] p=0.088	1.44 [0.95;2.20] p=0.087	1.09 [0.75;1.59] p=0.646
Number of patients who used out-of-hours services						
2008	0.30 [0.27;0.33]	0.30 [0.26;0.35]	0.32 [0.28;0.35]	1.00 [0.83;1.19] p=0.959	0.95 [0.82;1.09] p=0.432	0.95 [0.79;1.15] p=0.593
2009	0.29 [0.26;0.31]	0.30 [0.28;0.32]	0.28 [0.25;0.31]	0.95 [0.85;1.06] p=0.386	1.03 [0.90;1.18] p=0.674	1.08 [0.95;1.23] p=0.232
RR	0.96 [0.89;1.02] p=0.190	1.00 [0.87;1.15] p=0.984	0.88 [0.78;0.99] p=0.036	0.96 [0.82;1.12] p=0.578	1.09 [0.95;1.20] p=0.228	1.14 [0.95;1.37] p=0.169
Number of patients who were admitted with a lung-related diagnosis						
2008	0.06 [0.05;0.07]	0.06 [0.04;0.08]	0.07 [0.05;0.09]	1.06 [0.72;1.58] p=0.761	0.91 [0.68;1.21] p=0.509	0.85 [0.55;1.32] p=0.477
2009	0.05 [0.04;0.06]	0.05 [0.04;0.06]	0.07 [0.06;0.09]	0.94 [0.68;1.31] p=0.717	0.67 [0.50;0.91] p=0.010	0.71 [0.54;0.94] p=0.017
RR	0.80 [0.65;1.01] p=0.062	0.91 [0.58;1.45] p=0.699	1.09 [0.90;1.33] p=0.373	0.89 [0.53;1.47] p=0.639	0.74 [0.55;0.99] p=0.046	0.84 [0.51;1.38] p=0.482
Number of patients who were admitted to hospital with another diagnosis						
2008	0.21 [0.18;0.26]	0.20 [0.17;0.24]	0.22 [0.20;0.24]	1.05 [0.83;1.33] p=0.703	0.98 [0.80;1.20] p=0.817	0.93 [0.77;1.12] p=0.458
2009	0.22 [0.18;0.26]	0.22 [0.21;0.24]	0.24 [0.21;0.26]	0.96 [0.79;1.16] p=0.670	0.92 [0.74;1.13] p=0.403	0.95 [0.84;1.09] p=0.493
RR	1.01 [0.88;1.15] p=0.925	1.10 [0.95;1.27] p=0.200	1.07 [0.96;1.20] p=0.216	0.92 [0.75;1.11] p=0.378	0.94 [0.79;1.12] p=0.466	1.02 [0.85;1.23] p=0.800
Number of patients who visited the emergency department						
2008	0.06 [0.04;0.08]	0.08 [0.07;0.10]	0.10 [0.08;0.12]	0.72 [0.50;1.04] p=0.080	0.59 [0.40;0.86] p=0.006	0.81 [0.63;1.06] p=0.123
2009	0.07 [0.05;0.10]	0.08 [0.07;0.09]	0.10 [0.09;0.12]	0.91 [0.67;1.23] p=0.539	0.72 [0.52;0.98] p=0.036	0.78 [0.65;0.96] p=0.017
RR	1.19 [0.78;1.82] p=0.415	0.93[0.73;1.24] p=0.688	0.98 [0.79;1.22] p=0.882	1.26 [0.76;2.08] p=0.366	1.21 [0.75;1.95] p=0.427	0.96 [0.68;1.35] p=0.826

VIII.3 Sub-group analysis for the EI population – As-treated

As treated analysis - Count and incidence rate ratios (IRRs)for specific variables for patients identified by the COPD algorithm

Counts and IRRs for joint homevisits, conventional consultations, contacts to out-of-hours services, admissions, bed days and readmissions. The IRR are presented with 95% confidence intervals (95%CI)

N= 2,736	Intervention (N=765)	Control (N=879)		Ext. control (N=1,092)	Intervention vs. control IRR	Intervention vs. ext control IRR	Control vs. ext control IRR
Joint home visits							
2008	0.002 [0.000;0.014]	0 visits		0.003 [0.001;0.007]	#	0.69 [0.11;4.27] p=0.692	#
2009	0.005 [0.001;0.024]	2 visits		0.003 [0.001;0.007]	#	1.68 [0.37;7.74] p=0.505	#
IRR	2.39 [1.68;3.42] p<0.001	#		0.99 [0.55;1.76] p=0.963	#	2.43 [1.21;4.85] p=0.012	#
Consultations with GP (daytime)							
2008	7.21 [6.33;8.20]	7.16 [6.15;8.20]		6.61 [6.10;7.16]	1.01 [0.83;1.23] p=0.950	1.01 [0.94;1.27] p=0.263	1.08 [0.91;1.29] p=0.356
2009	6.89 [6.21;7.65]	7.67 [6.35;9.27]		6.80 [6.28;7.35]	0.90 [0.73;1.11] p=0.326	1.01 [0.89;1.15] p=0.833	1.13 [0.92;1.39] p=0.248
IRR	0.96 [0.90;1.02] p=0.149	1.07 [1.02;1.13] p=0.010		1.03 [0.98;1.08] p=0.275	0.89 [0.82;0.97] p=0.005	0.93 [0.86;1.01] p=0.069	1.04 [0.97;1.12] p=0.276
Contacts to out-of-hours services							
2008	0.68 [0.51;0.92]	0.61 [0.51;0.75]		0.63 [0.54;0.73]	1.11 [0.79;1.58] p=0.543	1.09 [0.78;1.51] p=0.611	0.98 [0.77;1.25] p=0.855
2009	0.68 [0.53;0.86]	0.70 [0.59;0.83]		0.61 [0.53;0.71]	0.97 [0.73;1.29] p=0.838	1.11 [0.84;1.48] p=0.466	1.14 [0.92;1.43] p=0.232
IRR	0.99 [0.86;1.14] p=0.896	1.14 [1.03;1.25] p=0.010		0.97 [0.83;1.14] p=0.722	0.87 [0.73;1.04] p=0.123	1.02 [0.82;1.27] p=0.854	1.17 [0.97;1.42] p=0.105
Admissions with a lung-related diagnosis							
2008	0.10 [0.07;0.13]	0.10 [0.08;0.14]		0.13 [0.08;0.21]	0.92 [0.63;1.33] p=0.654	0.73 [0.44;1.23] p=0.236	0.80 [0.48;1.31] p=0.372
2009	0.09 [0.07;0.11]	0.12 [0.08;0.16]		0.15 [0.12;0.18]	0.75 [0.51;1.11] p=0.149	0.57 [0.42;0.79] p=0.001	0.76 [0.54;1.09] p=0.132
IRR	0.90 [0.66;1.21] p=0.482	1.10 [0.85;1.42] p=0.464		1.15 [0.81;1.63] p=0.446	0.82 [0.55;1.21] p=0.308	0.78 [0.49;1.25] p=0.306	0.96 [0.63;1.46] p=0.848
Admissions with another diagnosis							
2008	0.43[0.34;0.56]	0.42 [0.37;0.47]		0.42 [0.37;0.48]	1.04 [0.79;1.38] p=0.769	1.04 [0.78;1.38] p=0.812	0.99 [0.83;1.18] p=0.933
2009	0.42 [0.35;0.52]	0.51 [0.46;0.56]		0.49 [0.44;0.55]	0.83 [0.67;1.04] p=0.103	0.86 [0.69;1.07] p=0.187	1.03 [0.89;1.20] p=0.658
IRR	0.98 [0.77;1.24] p=0.842	1.22 [1.03;1.45] p=0.021		1.17 [1.00;1.37] p=0.047	0.80 [0.59;1.07] p=0.137	0.83 [0.62;1.11] p=0.212	1.04 [0.83;1.31] p=0.726
Bed days							
2008	1.85 [1.36;2.53]	1.81 [1.55;2.10]		1.91 [1.46;2.51]	1.03 [0.73;1.45] p=0.884	0.97 [0.64;1.46] p=0.880	0.94 [0.69;1.29] p=0.718
2009	2.12 [1.72;2.63]	2.53 [2.05;3.13]		2.39 [1.94;2.95]	0.84 [0.62;1.13] p=0.250	0.89 [0.66;1.19] p=0.436	1.06 [0.79;1.43] p=0.709
IRR	1.15 [0.84;1.57] p=0.394	1.40 [1.05;1.87] p=0.022		1.25 [0.93;1.68] p=0.143	0.82 [0.53;1.25] p=0.358	0.92 [0.59;1.42] p=0.702	1.12 [0.74;1.70] p=0.591
Readmissions*							
2008	0.09 [0.05;0.13]	0.10 [0.08;0.12]		0.08 [0.05;0.14]	0.87 [0.54;1.41] p=0.585	1.05 [0.54;2.03] p=0.895	1.20 [0.72;1.98] p=0.489
2009	0.09 [0.06;0.13]	0.12 [0.09;0.16]		0.14 [0.11;0.17]	0.74 [0.48;1.14] p=0.174	0.66 [0.45;0.96] p=0.030	0.89 [0.63;1.26] p=0.521
IRR	1.05 [0.65;1.68] p=0.844	1.24 [0.95;1.62] p=0.115		1.66 [1.12;2.49] p=0.014	0.84 [0.49;1.45] p=0.543	0.63 [0.34;1.18] p=0.147	0.75 [0.47;1.20] p=0.227
Contact to outpatient services with a lung-related diagnosis							
2008	0.16 [0.12;0.23]	0.16 [0.11;0.23]		0.18 [0.12;0.27]	1.02 [0.64;1.62] p=0.929	0.93 [0.56;1.54] p=0.770	0.90 [0.54;1.53] p=0.741
2009	0.19 [0.10;0.36]	0.22 [0.15;0.30]		0.23 [0.16;0.34]	0.90 [0.45;1.80] p=0.771	0.84 [0.41;1.73] p=0.639	0.93 [0.57;1.53] p=0.784
IRR	1.18 [0.66;2.13] p=0.572	1.34[0.93;1.94] p=0.118		1.30 [1.17;1.45] p<0.001	0.88 [0.44;1.78] p=0.730	0.91 [0.50;1.67] p=0.757	1.03 [0.70;1.52] p=0.888

* A readmission was defined as an acute admission within 30 days of the last admission.
\# Too few visits undertaken to do any analysis.

APPENDIX IX

IX.1 Analysis for the CD population – per-protocol

Per protocol analysis - Rates and rate ratios for specific variables for patients who confirmed their diagnosis of COPD

Rates and rate ratios (RRs) for planned preventive consultations, additional preventive consultations and spirometries performed at GP practices as well as for patients who were admitted. The RRs are presented with 95% confidence intervals (95% CI)

N= 1,320	Intervention (N=406)	Control (N=376)	Ext. control (N=538)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
Number of patients who had a planned preventive consultation						
2008	0.34 [0.26;0.45]	0.24 [0.18;0.33]	0.25 [0.14;0.45]	1.44 [0.94;2.18] p=0.091	1.36 [0.72;2.55] p=0.347	0.94 [0.49;1.81] p=0.863
2009	0.56 [0.44;0.70]	0.21 [0.15;0.30]	0.29 [0.17;0.48]	2.65 [1.71;4.11] p<0.001	1.93 [1.10;3.38] p=0.022	0.73 [0.39;1.36] p=0.319
RR	1.62 [1.29;2.04] p<0.001	0.88 [0.69;1.12] p=0.249	1.14 [0.91;1.42] p=0.248	1.85 [1.32;2.58] p<0.001	1.42 [1.03;1.96] p=0.030	0.77 [0.55;1.07] p=0.120
Number of patients who had an additional preventive consultation						
2008	0.10 [0.04;0.25]	0.06 [0.03;0.14]	0.10 [0.06;0.18]	1.27 [0.37;4.37] p=0.699	0.97 [0.30;3.15] p=0.962	0.76 [0.33;1.79] p=0.532
2009	0.23 [0.10;0.52]	0.08 [0.03;0.21]	0.12 [0.07;0.24]	2.43 [0.77;7.98] p=0.127	1.87 [0.57;6.23] p=0.234	0.75 [0.26;2.17] p=0.599
RR	2.30 [1.32;4.00] p=0.003	1.18 [0.82;1.70] p=0.377	1.19 [0.84;1.71] p=0.330	1.95 [1.00;3.79] p=0.049	1.92 [0.99;3.72] p=0.052	0.99 [0.59;1.64] p=0.959
Number of patients who had a spirometry performed at the GP						
2008	0.34 [0.27;0.43]	0.23 [0.16;0.33]	0.22 [0.17;0.28]	1.49 [0.96;2.33] p=0.075	1.55 [1.10;2.17] p=0.012	1.03 [0.66;1.63] p=0.885
2009	0.48 [0.38;0.60]	0.24 [0.16;0.36]	0.22 [0.15;0.34]	1.95 [1.23;3.10] p=0.004	2.16 [1.34;3.48] p=0.002	1.11 [0.62;1.95] p=0.731
RR	1.40 [1.12;1.75] p=0.003	1.07 [0.85;1.34] p=0.551	1.00 [0.70;1.44] p=0.998	1.30 [0.95;1.80] p=0.100	1.40 [0.91;2.14] p=0.125	1.07 [0.70;1.64] p=0.750

Proportion who used out-of-hours services – no noteworthy change – data not reported

N= 1,320	Intervention (N=406)	Control (N=376)	Ext. control (N=536)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
Number of patients who were admitted with a lung-related diagnosis						
2008	0.08 [0.05;0.10]	0.07 [0.05;0.10]	0.09 [0.06;0.12]	1.66 [0.76;1.79] p=0.483	0.94 [0.65;1.37] p=0.766	0.81 [0.50;1.32] p=0.398
2009	0.06 [0.05;0.07]	0.06 [0.03;0.09]	0.09 [0.07;0.13]	1.07 [0.63;1.83] p=0.798	0.64 [0.44;0.93] p=0.018	0.60 [0.34;1.06] p=0.076
RR	0.73 [0.54;0.99] p=0.041	0.79 [0.42;1.49] p=0.473	1.08 [0.85;1.35] p=0.550	0.92 [0.46;1.85] p=0.814	0.68 [0.46;1.00] p=0.048	0.74 [0.38;1.45] p=0.375
Number of patients who were admitted to hospital with another diagnosis						
2008	0.23 [0.19;0.28]	0.21 [0.17;0.26]	0.24 [0.21;0.28]	1.10 [0.82;1.48] p=0.509	0.97 [0.76;1.24] p=0.791	0.88[0.67;1.15] p=0.339
2009	0.21 [0.17;0.26]	0.26 [0.23;0.30]	0.26 [0.22;0.31]	0.80 [0.63;1.01] p=0.065	0.81 [0.61;1.06] p=0.130	1.01 [0.81;1.26] p=0.928
RR	0.90 [0.75;1.08] p=0.273	1.24 [0.99;1.56] p=0.059	1.08 [0.92;1.27] p=0.349	0.72 [0.54;0.97] p=0.031	0.84 [0.66;1.07] p=0.150	1.15 [0.87;1.52] p=0.312

Patients who visited the emergency department - no noteworthy change - data not reported

Too few planned joint homevisits undertaken to do any analysis

IX.1 Analysis for the CD population – per-protocol

Per protocol analysis -Count and incidence rate ratios for specific variables for patients who confirmed their diagnosis of COPD

Counts and incidence rate ratios (IRRs) for conventional consultations, contacts to out-of-hours services, admissions, beddays, readmissions and contact to outpatient services. The IRRs are presented with 95% confidence intervals (95% CI)

N= 1,320	Intervention (N=506)	Control (N=376)	Ext. control (N=538)	Intervention vs. control IRR	Intervention vs. ext control IRR	Control vs. ext control IRR
Consultations with GP (daytime)						
2008	7.36 [6.78;9.11]	7.57 [6.44;8.91]	6.76 [6.25;7.30]	1.04 [0.84;1.29] p=0.737	1.16 [0.98;1.37] p=0.076	1.12 [0.94;1.34] p=0.213
2009	7.44 [6.61;8.39]	8.49 [7.14;10.11]	7.29 [6.73;7.89]	0.88 [0.71;1.08] p=0.210	1.02 [0.89;1.18] p=0.773	1.17 [0.96;1.41] p=0.117
IRR	0.94 [0.88;1.02] p=0.166	1.12 [1.07;1.17] p<0.001	1.08 [1.02;1.14] p=0.011	0.84 [0.77;0.92] p<0.001	0.88 [0.80;0.97] p=0.008	1.04 [0.97;1.12] p=0.301
Contacts to out-of-hours services						
2008	0.70 [0.46;1.05]	0.60 [0.42;0.86]	0.61 [0.51;0.74]	1.16 [0.66;2.02] p=0.609	1.14 [0.73;1.79] p=0.566	0.98 [0.66;1.47] p=0.940
2009	0.71 [0.48;1.07]	0.74 [0.56;0.98]	0.56 [0.46;0.68]	0.97 [0.61;1.54] p=0.884	1.27 [0.84;1.94] p=0.258	1.32 [0.94;1.85] p=0.108
IRR	1.02 [0.84;1.24] p=0.812	1.23 [1.02;1.48] p=0.032	0.92 [0.78;1.08] p=0.287	0.83 [0.63;1.10] p=0.197	1.12 [0.87;1.44] p=0.390	1.34 [1.05;1.71] p=0.019
Admissions with lung-related diagnosis						
2008	0.13 [0.10;0.19]	0.15 [0.10;0.21]	0.13 [0.09;0.19]	0.91 [0.57;1.47] p=0.702	1.02 [0.62;1.69] p=0.923	1.12 [0.69;1.89] p=0.657
2009	0.11 [0.08;0.14]	0.13 [0.07;0.24]	0.16 [0.11;0.24]	0.82 [0.44;1.54] p=0.544	0.65 [0.42;1.00] p=0.051	0.78 [0.39;1.59] p=0.506
IRR	0.80 [0.51;1.25] p=0.330	0.88 [0.67;1.16] p=0.379	1.26 [0.95;1.67] p=0.104	0.90 [0.54;1.53] p=0.708	0.63 [0.37;1.08] p=0.092	0.70 [0.47;1.04] p=0.079
Admissions with another diagnosis						
2008	0.36 [0.27;0.48]	0.42 [0.34;0.51]	0.37 [0.32;0.43]	0.87 [0.61;1.23] p=0.429	0.97 [0.71;1.31] p=0.823	1.11 [0.87;1.42] p=0.404
2009	0.38 [0.30;0.47]	0.55 [0.44;0.68]	0.50 [0.40;0.63]	0.69 [0.51;0.95] p=0.021	0.75 [0.55;1.02] p=0.070	1.08 [0.79;1.48] p=0.617
IRR	1.05 [0.78;1.41] p=0.763	1.33 [0.91;1.89] p=0.143	1.35 [1.05;1.73] p=0.018	0.78 [0.50;1.28] p=0.346	0.77 [0.53;1.13] p=0.188	0.97 [0.63;1.51] p=0.906
Acute admissions with another diagnosis						
2008	0.23 [0.18;0.29]	0.22 [0.10;0.50]	0.21 [0.14;0.31]	1.06 [0.46;2.46] p=0.889	1.13 [0.70;1.81] p=0.621	1.06 [0.43;2.63] p=0.897
2009	0.10 [0.06;0.16]	0.20 [0.14;0.29]	0.18 [0.14;0.24]	0.49 [0.27;0.89] p=0.018	0.55 [0.32;0.94] p=0.029	1.12 [0.71;1.75] p=0.634
IRR	0.43 [0.25;0.73] p=0.002	0.93 [0.31;2.81] p=0.898	0.89 [0.79;1.11] p=0.284	0.46 [0.14;1.56] p=0.214	0.49 [0.27;0.86] p=0.014	1.05 [0.34;3.24] p=0.932
Bed days						
2008	1.69 [1.13;2.51]	2.29 [1.79;2.92]	1.71 [1.30;2.26]	0.74 [0.46;1.18] p=0.205	0.98 [0.62;1.56] p=0.948	1.34 [0.90;1.99] p=0.154
2009	1.83 [1.49;2.25]	1.95 [1.45;2.63]	2.29 [1.82;2.89]	0.94 [0.65;1.35] p=0.728	0.80 [0.60;1.07] p=0.138	0.85 [0.59;1.24] p=0.409
IRR	1.09 [0.72;1.65] p=0.693	0.85 [0.65;1.12] p=0.259	1.34 [1.06;1.69] p=0.013	1.27 [0.77;2.10] p=0.349	0.81 [0.51;1.30] p=0.385	0.63 [0.44;0.93] p=0.018
Readmissions*						
2008	0.07 [0.04;0.12]	0.13 [0.10;0.17]	0.05 [0.04;0.08]	0.55 [0.31;1.00] p=0.052	1.36 [0.74;2.52] p=0.325	2.43 [1.51;3.91] p<0.001
2009	0.07 [0.06;0.10]	0.12 [0.06;0.22]	0.14 [0.11;0.19]	0.63 [0.33;1.22] p=0.174	0.51 [0.35;0.76] p=0.001	0.81 [0.42;1.59] p=0.552
IRR	1.03 [0.59;1.79] p=0.918	0.90 [0.50;1.65] p=0.752	2.71 [1.91;3.85] p<0.001	1.13 [0.50;2.58] p=0.767	0.38 [0.20;0.73] p=0.004	0.33 [0.16;0.68] p=0.003
Contact to outpatient services with a lung-related diagnosis						
2008	0.21 [0.14;0.31]	0.32 [0.22;0.45]	0.21 [0.13;0.34]	0.75 [0.43;1.32] p=0.323	0.97 [0.54;1.75] p=0.932	1.29 [0.70;2.40] p=0.415
2009	0.25 [0.15;0.43]	0.32 [0.21;0.51]	0.30 [0.21;0.42]	0.83 [0.41;1.67] p=0.604	0.85 [0.45;1.61] p=0.619	1.02 [0.58;1.80] p=0.939
IRR	1.21 [0.70;2.08] p=0.491	1.03 [0.69;1.53] p=0.895	1.40 [1.12;1.75] p=0.003	1.10 [0.55;2.21] p=0.786	0.87 [0.47;1.68] p=0.660	0.79 [0.49;1.28] p=0.340

*A readmission was defined as an acute admission within 30 days of the last admission.

IX.2 Analysis for the CD population – As-treated

As treated analysis - Rates and rate ratios for specific variables for patients who confirmed their diagnosis of COPD

Rates and rate ratios (RRs) for planned preventive consultations, additional preventive consultations and spirometries performed at GP practices as well as for patients who were admitted. The RRs are presented with 95% confidence intervals (95% CI)

N=1,372	Intervention (N=406)	Control (N=428)	Ext. control (N=538)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
Number of patients who had a planned preventive consultation						
2008	0.34 [0.26;0.45]	0.25 [0.19;0.33]	0.25 [0.14;0.45]	1.37 [0.93;2.02] p=0.112	1.36 [0.72;2.55] p=0.347	0.99 [0.53;1.86] p=0.974
2009	0.56 [0.44;0.70]	0.22 [0.16;0.31]	0.29 [0.17;0.48]	2.50 [1.68;3.72] p<0.001	1.93 [1.10;3.38] p=0.022	0.77 [0.42;1.40] p=0.396
RR	1.62 [1.29;2.04] p<0.001	0.89 [0.72;1.10] p=0.282	1.14 [0.91;1.42] p=0.248	1.82 [1.33;2.50] p<0.001	1.42 [1.03;1.96] p=0.030	0.78 [0.57;1.06] p=0.155
Number of patients who had an additional preventive consultation						
2008	0.10 [0.04;0.29]	0.08 [0.04;0.15]	0.10 [0.06;0.18]	1.66 [0.44;6.23] p=0.453	0.97 [0.30;3.15] p=0.962	0.58 [0.22;1.56] p=0.283
2009	0.23 [0.10;0.52]	0.09 [0.04;0.22]	0.12 [0.07;0.24]	3.03 [0.84;10.96] p=0.092	1.87 [0.67;5.24] p=0.234	0.62 [0.19;2.03] p=0.428
RR	2.30 [1.32;4.00] p=0.003	1.26 [0.84;1.89] p=0.260	1.19 [0.84;1.71] p=0.330	1.82 [0.92;3.63] p=0.088	1.92 [0.99;3.73] p=0.053	1.06 [0.62;1.81] p=0.843
Number of patients who had a spirometry performed at the GP						
2008	0.34 [0.27;0.43]	0.23 [0.16;0.32]	0.22 [0.17;0.28]	1.51 [1.00;2.28] p=0.052	1.55 [1.10;2.17] p=0.012	1.02 [0.67;1.57] p=0.910
2009	0.48 [0.38;0.60]	0.24[0.16;0.35]	0.22 [0.15;0.34]	1.02 [1.29;3.11] p=0.002	2.16 [1.34;3.48] p=0.002	1.08 [0.62;1.88] p=0.794
RR	1.40 [1.12;1.75] p=0.003	1.05 [0.85;1.29] p=0.636	1.00 [0.70;1.44] p=0.998	1.33 [0.98;1.80] p=0.067	1.40 [0.91;2.14] p=0.125	1.05 [0.69;1.60] p=0.816

Proportion who used out-of-hours services – no noteworthy change – data not reported

N=1,372	Intervention (N=406)	Control (N=428)	Ext. control (N=538)	Intervention vs. control RR	Intervention vs. ext control RR	Control vs. ext control RR
Number of patients who were admitted with a lung-related diagnosis						
2008	0.08 [0.06;0.10]	0.07 [0.05;0.10]	0.09 [0.06;0.12]	1.15 [0.75;1.78] p=0.523	0.94 [0.65;1.37] p=0.762	0.82 [0.50;1.34] p=0.428
2009	0.06 [0.04;0.07]	0.06 [0.04;0.10]	0.09 [0.07;0.12]	0.92 [0.57;1.48] p=0.729	0.63 [0.44;0.93] p=0.018	0.70 [0.41;1.17] p=0.172
RR	0.73 [0.54;0.99] p=0.049	0.91 [0.50;1.66] p=0.765	1.07 [0.85;1.36] p=0.550	0.80 [0.41;1.55] p=0.507	0.68 [0.46;1.00] p=0.047	0.85 [0.45;1.61] p=0.618
Number of patients who were admitted to hospital with another diagnosis						
2008	0.23 [0.19;0.28]	0.22 [0.18;0.27]	0.24 [0.21;0.28]	1.03 [0.78;1.36] p=0.817	0.97 [0.76;1.24] p=0.789	0.94 [0.73;1.21] p=0.608
2009	0.21 [0.17;0.26]	0.26 [0.23;0.29]	0.26 [0.21;0.31]	0.80 [0.64;1.01] p=0.062	0.81 [0.61;1.06] p=0.129	1.01 [0.81;1.25] p=0.946
RR	0.90 [0.75;1.08] p=0.269	1.16 [0.93;1.44] p=0.180	1.08 [1.00;1.26] p=0.351	0.78 [0.58;1.03] p=0.082	0.84 [0.66;1.07] p=0.149	1.08 [0.82;1.41] p=0.592

Patients who visited the emergency department - no noteworthy change - data not reported

Too few planned joint homevisits undertaken to do any analysis

IX.2 Analysis for the CD population – As-treated

As treated analysis - Count and incidence rate ratios for specific variables for patients who confirmed their diagnosis of COPD

Counts and incidence rate ratios (IRRs) for conventional consultations, contacts to out-of-hours services, admissions, beddays, readmissions and contact to outpatient services. The IRRs are presented with 95% confidence intervals (95% CI)

N= 1,372	Intervention (N=406)	Control (N=428)	Ext. control (N=538)	Intervention vs. control IRR	Intervention vs. ext control IRR	Control vs. ext control IRR
Consultations with GP (daytime)						
2008	7.84 [6.77;9.08]	7.50 [6.45;8.72]	6.74 [6.24;7.29]	1.05 [0.85;1.29] p=0.673	1.16 [0.98;1.37] p=0.077	1.11 [0.94;1.32] p=0.223
2009	7.42 [6.59;8.37]	8.28 [6.98;9.81]	7.28 [6.73;7.87]	0.90 [0.73;1.10] p=0.294	1.02 [0.89;1.18] p=0.783	1.14 [0.94;1.37] p=0.179
IRR	0.95 [0.88;1.02] p=0.166	1.10 [1.05;1.16] p<0.001	1.08 [1.02;1.14] p=0.012	0.86 [0.78;0.94] p=0.001	0.88 [0.80;0.97] p=0.009	1.02 [0.95;1.11] p=0.565
Contacts to out-of-hours services						
2008	0.70 [0.46;1.06]	0.59 [0.42;0.82]	0.61 [0.51;0.74]	1.18 [0.68;2.05] p=0.548	1.14 [0.73;1.79] p=0.564	0.96 [0.66;1.41] p=0.853
2009	0.72 [0.48;1.07]	0.71 [0.54;0.93]	0.56 [0.46;0.68]	1.01 [0.63;1.61] p=0.975	1.28 [0.84;1.95] p=0.258	1.27 [0.91;1.76] p=0.162
IRR	1.02 [0.84;1.24] p=0.818	1.20 [1.02;1.42] p=0.029	0.92 [0.78;1.08] p=0.281	0.85 [0.66;1.10] p=0.223	1.12 [0.87;1.44] p=0.389	1.31 [1.05;1.65] p=0.019
Admissions with lung-related diagnosis						
2008	0.12 [0.08;0.16]	0.13 [0.09;0.19]	0.11 [0.08;0.17]	0.94 [0.58;1.52] p=0.790	1.04 [0.62;1.73] p=0.884	1.11 [0.65;1.89] p=0.704
2009	0.09 [0.07;0.12]	0.12 [0.07;0.20]	0.14 [0.10;0.21]	0.82 [0.47;1.45] p=0.496	0.66 [0.42;1.03] p=0.069	0.80 [0.42;1.53] p=0.494
IRR	0.80 [0.51;1.26] p=0.336	0.91 [0.67;1.23] p=0.547	1.27 [0.95;1.68] p=0.101	0.88 [0.51;1.51] p=0.638	0.63 [0.37;1.08] p=0.094	0.72 [0.47;1.09] p=0.120
Admissions with another diagnosis						
2008	0.32 [0.25;0.42]	0.38 [0.31;0.47]	0.33 [0.28;0.38]	0.84 [0.60;1.17] p=0.296	0.98 [0.73;1.33] p=0.899	1.17 [0.91;1.51] p=0.224
2009	0.34 [0.27;0.42]	0.45 [0.37;0.55]	0.45 [0.36;0.56]	0.76 [0.56;1.02] p=0.071	0.76 [0.55;1.04] p=0.084	1.00 [0.74;1.36] p=0.978
IRR	1.05 [0.78;1.42] p=0.747	1.16 [0.83;1.63] p=0.373	1.36 [1.06;1.74] p=0.016	0.90 [0.57;1.41] p=0.655	0.77 [0.53;1.13] p=0.187	0.86 [0.57;1.30] p=0.469
Bed days						
2008	1.49 [1.01;2.20]	2.02 [1.58;2.58]	1.48 [1.11;1.98]	0.74 [0.47;1.17] p=0.199	1.01 [0.66;1.60] p=0.978	1.36 [0.92;2.03] p=0.127
2009	1.64 [1.33;2.01]	1.67 [1.27;2.19]	2.02 [1.59;2.56]	0.98 [0.70;1.37] p=0.906	0.81 [0.60;1.09] p=0.063	0.83 [0.58;1.18] p=0.297
IRR	1.10 [0.72;1.67] p=0.674	0.83 [0.62;1.09] p=0.178	1.36 [1.09;1.70] p=0.008	1.33 [0.80;2.21] p=0.278	0.81 [0.50;1.29] p=0.368	0.61 [0.42;0.88] p=0.008
Readmissions*						
2008	0.07 [0.04;0.12]	0.12 [0.09;0.16]	0.05 [0.04;0.08]	0.58 [0.32;1.04] p=0.066	1.35 [0.73;2.52] p=0.338	2.34 [1.46;3.73] p<0.001
2009	0.07 [0.06;0.10]	0.11 [0.06;0.19]	0.14 [0.11;0.19]	0.69 [0.37;1.30] p=0.251	0.51 [0.35;0.76] p=0.001	0.74 [0.39;1.42] p=0.371
IRR	1.03 [0.59;1.80] p=0.921	0.86 [0.49;1.51] p=0.607	2.71 [1.90;3.85] p<0.001	1.92 [0.53;2.66] p=0.667	0.38 [0.20;0.73] p=0.004	0.32 [0.16;0.63] p=0.001
Contact to outpatient services with a lung-related diagnosis						
2008	0.18 [0.13;0.26]	0.24 [0.16;0.37]	0.19 [0.12;0.30]	0.75 [0.43;1.32] p=0.323	0.97 [0.54;1.75] p=0.932	1.29 [0.70;2.40] p=0.415
2009	0.22 [0.13;0.38]	0.27 [0.17;0.43]	0.26 [0.19;0.38]	0.83 [0.41;1.67] p=0.604	0.85 [0.45;1.61] p=0.619	1.02 [0.58;1.80] p=0.939
IRR	1.22 [0.79;2.13] p=0.249	1.11 [0.72;1.71] p=0.638	1.40 [1.13;1.74] p=0.002	1.10 [0.55;2.21] p=0.786	0.87 [0.47;1.68] p=0.660	0.79 [0.49;1.28] p=0.340

*A readmission was defined as an acute admission within 30 days of the last admission